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 JUNE 30, 2016

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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 August 10, 2016: 16,070,705 shares.

NEOS THERAPEUTICS, INC.

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Special note regarding forward-looking statements

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

- our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing;
- our ability to develop and commercialize Adzenys XR-ODT and, if approved, Cotempla XR-ODT, NT-0201, or any other future product or product candidate;
- the timing, cost or other aspects of the commercial launch and future sales of Adzenys XR-ODT and, if approved, Cotempla XR-ODT, NT-0201, or any other future product or product candidate;
- our ability to increase our manufacturing and distribution capabilities for Adzenys XR-ODT and, if approved, Cotempla XR-ODT, NT-0201, or any other future product or product candidate;
- the attention deficit hyperactivity disorder patient market size and market adoption of Adzenys XR-ODT and, if approved, Cotempla XR-ODT or NT-0201, by physicians and patients;
- the therapeutic benefits, effectiveness and safety of Adzenys XR-ODT and, if approved, Cotempla XR-ODT, NT-0201, or any other future product or product candidate;
- our expectations regarding the commercial supply of our Adzenys XR-ODT and, if approved, Cotempla XR-ODT, NT-0201, or any other future products, and our generic Tussionex;
- our ability to receive, and the timing of any receipt of the U.S. Food and Drug Administration, or FDA, approvals, or other regulatory action in the United States and elsewhere, for Cotempla XR-ODT, NT-0201, and any other future product candidate;
- our expectations regarding federal, state and foreign regulatory requirements;
- deficiencies the FDA has identified in its Complete Response Letter and may identify with respect to Cotempla XR-ODT and whether we will be able to address the issues that may relate to those deficiencies;
- the New Drug Application resubmission date for Cotempla XR-ODT and submission date for NT-0201;
- our estimates regarding anticipated expenses, capital requirements and our needs for additional financing;
- 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; and
- our staffing needs.

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

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and

uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

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

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

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS.

Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(unaudited)

	June 30, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 41,886	$ 90,763
Short-term investments	38,232	—
Accounts receivable, net of allowances of $1,138 and $1,039, respectively	5,659	3,903
Inventories	4,427	2,520
Deferred contract sales organization fees	525	—
Other current assets	1,207	1,058
Total current assets	91,936	98,244
Property and equipment, net	6,848	5,124
Intangible assets, net	16,360	16,672
Other assets	2,564	2,470
Total assets	$ 117,708	$ 122,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,299	$ 4,824
Accrued expenses	9,189	3,141
Deferred revenue	2,614	—
Current portion of long-term debt	1,745	7,973
Total current liabilities	16,847	15,938
Long-Term Liabilities:		
Long-term debt, net of current portion	58,576	26,271
Earnout liability	257	214
Deferred gain on leaseback	132	547
Deferred rent	1,194	1,166
Total long-term liabilities	60,159	28,198

Stockholders' Equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at June 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value, 100,000,000 authorized at June 30, 2016 and December 31, 2015; 16,079,902 and 16,070,705 issued and outstanding at June 30, 2016, respectively; 16,025,155 and 16,015,958 issued and outstanding at December 31, 2015, respectively	16	16
Treasury stock, at cost, 9,197 shares at June 30, 2016 and December 31, 2015	(171)	(171)
Additional paid-in capital	196,757	195,314
Accumulated deficit	(155,938)	(116,785)
Accumulated other comprehensive income	38	—
Total stockholders' equity	40,702	78,374
Total liabilities and stockholders' equity	$ 117,708	$ 122,510

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Net product sales	$ 1,485	$ 1,484	$ 4,068	$ 1,912
Cost of goods sold	1,682	1,659	3,954	2,754
Gross (loss) profit	(197)	(175)	114	(842)
Research and development	4,253	2,102	6,594	6,422
Selling and marketing expenses	16,046	602	22,330	928
General and administrative expenses	3,508	1,659	7,058	2,996
Loss from operations	(24,004)	(4,538)	(35,868)	(11,188)
Interest expense, net	(1,508)	(884)	(2,469)	(1,641)
Loss on debt extinguishment	(1,187)	—	(1,187)	—
Other income, net	207	208	414	415
Change in fair value of earnout and warrant liabilities	(47)	(539)	(43)	105
Net loss	(26,539)	(5,753)	(39,153)	(12,309)
Preferred stock accretion to redemption value	—	(586)	—	(1,070)
Preferred stock dividends	—	(544)	—	(1,083)
Net loss attributable to common stock	$ (26,539)	$ (6,883)	$ (39,153)	$ (14,462)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	16,050,138	887,397	16,037,728	886,323
Net loss per share of common stock, basic and diluted	$ (1.65)	$ (7.76)	$ (2.44)	$ (16.32)

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$ (26,539)	$ (5,753)	$ (39,153)	$ (12,309)
Other comprehensive (loss) income:				
Net unrealized (loss) gain on short-term investments	(21)	—	38	—

Total other comprehensive (loss) income	$ (21)	$ —	$ 38	$ —
Comprehensive loss	$ (26,560)	$ (5,753)	$ (39,115)	$ (12,309)

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Six months Ended June 30, 2016
(In thousands, except shares)
(unaudited)

	Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2015	**—**	**$ —**	**16,025,155**	**$ 16**	**(9,197)**	**$ (171)**	**$195,314**	**$ (116,785)**	**$ —**	**$ 78,374**
Proceeds from exercise of options and warrants	**—**	**—**	**54,747**	**—**	**—**	**—**	**13**	**—**	**—**	**13**
Share-based compensation expense	**—**	**—**	**—**	**—**	**—**	**—**	**1,430**	**—**	**—**	**1,430**
Net unrealized gain on investments	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**38**	**38**
Net loss	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**(39,153)**	**—**	**(39,153)**
Balance, June 30, 2016	**—**	**$ —**	**16,079,902**	**$ 16**	**(9,197)**	**$ (171)**	**$196,757**	**$ (155,938)**	**$ 38**	**$ 40,702**

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)

	Six Months Ended June 30,	
	2016	2015
Cash Flows From Operating Activities:		
Net loss	$ (39,153)	$ (12,309)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,430	234
Depreciation and amortization of property and equipment	929	843
Amortization of intangible assets	812	747
Changes in fair value of earnout and warrant liabilities	43	(105)
Amortization of patents	23	12
Amortization of senior debt fees	261	280
Deferred interest on debt	668	198
Loss on debt extinguishment	942	—
Gain on sale of equipment	(415)	(416)
Change in deferred rent	28	(17)
Net unrealized gain on short-term investment	38	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,756)	(1,729)
Inventories	(1,907)	328
Deferred contract sales organization fees	(525)	—
Other current assets	(149)	29
Other assets	(117)	(124)
Accounts payable	(1,525)	(211)
Accrued expenses	6,048	(556)
Deferred revenue	2,614	—
Net cash used in operating activities	(31,711)	(12,796)
Cash Flows From Investing Activities:		
Net change in short-term investments	(38,232)	3,000
Capital expenditures	(2,653)	(346)

Intangible asset license	(500)	—
Net cash (used in) provided by investing activities	(41,385)	2,654
Cash Flows From Financing Activities:		
Proceeds from Deerfield debt note, net of fees	58,420	—
Proceeds from senior debt note	—	10,000
Payment of senior debt and fee	(26,063)	—
Net proceeds from issuance of stock	13	13,801
Payments made on borrowings	(8,151)	(797)
Payments of initial public offering costs	—	(574)
Net cash provided by financing activities	24,219	22,430
(Decrease) increase in cash and cash equivalents	(48,877)	12,288
Cash and Cash Equivalents:		
Beginning	90,763	13,343
Ending	$ 41,886	$ 25,631
Supplemental Disclosure of Noncash Transactions:		
Initial public offering costs included in accounts payable and accrued expenses	$ —	$ 558
Issuance of stock warrants	$ —	$ 2,131
Preferred stock dividend	$ —	$ 485
Supplemental Cash Flow Information:		
Interest paid	$ 2,787	$ 1,106

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 one approved product and two proprietary product candidates in late stage development 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. 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 and six months ended June 30, 2016 are not necessarily indicative of the results for the year ending December 31, 2016 or any period thereafter. The audited consolidated financial statements as of and for the year ended December 31, 2015 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 18, 2016. 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, 2015.

Principles of consolidation: At June 30, 2016, the consolidated financial statements include the accounts of the Company and its four wholly-owned subsidiaries. At December 31, 2014, Neos Therapeutics, Inc. owned, directly or indirectly, 100% of two of its subsidiaries and 99.9% of the third subsidiary, Neostx, Inc. ("NTX"). The remaining 0.1% ownership of NTX was held by a third party and all such remaining capital stock was acquired by the Company on June 29, 2015, and NTX was merged with and into the Company. The amounts attributable to the noncontrolling interest were not material to the consolidated financial statements. On September 16, 2015, the Company established two new wholly-owned subsidiaries, Neos Therapeutics Brands, LLC and Neos Therapeutics Commercial, LLC. All significant intercompany transactions have been eliminated.

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

Short-term investments: Short-term investments 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 any tax effects reported, as accumulated other comprehensive income, 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 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 is 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.

Fair value of financial instruments: The carrying value of the Company's financial instruments, including cash and cash equivalents, accounts receivable, other current assets, accounts payable, accrued expenses, and debt, approximates fair value due to the short-term nature of the instruments and/or the current interest rates payable in relation to current market conditions. The fair value of the Company's short-term investments and its earnout and warrant liabilities are disclosed in Note 4.

Inventories: Inventories are stated at the lower of actual cost including labor and manufacturing overhead (which approximates first-in, first-out) or market, net of a reserve for obsolete inventory. Increases in the reserve are recorded as charges to cost of goods sold.

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Inventories consist of raw materials, work in process, finished goods and deferred cost of goods. Cost of sales includes the cost of inventory sold or reserved, which includes manufacturing and supply chain costs, product shipping and handling costs, and product royalties. The cost of sales associated with the deferred product revenues are recorded as deferred costs, which are included in inventory until such time as the deferred revenue is recognized. As the Company has little experience of obtaining approval for and launching its drug products, the Company treats any pre-launch inventory that is manufactured for clinical trials or other purposes as research and development expense until objective and persuasive evidence exists that regulatory approval has been received and future economic benefit is probable. Therefore, all manufacturing costs for the production of Adzenys XR-ODT incurred after the January 27, 2016 FDA approval date are being capitalized into inventory.

Deferred contract sales organization fees: The Company records fees billed in accordance with its commercial sales organization contract for services not yet performed as deferred contract sales organization fees. Such fees are recorded as selling and marketing expenses when the services are provided.

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

Revenue recognition: Revenue is generated from product sales, recorded on a net sales basis. Product revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) price to the buyer is fixed and determinable; and (4) collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (1) the price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid for the product, or the buyer is obligated to pay for the product and the obligation is not contingent on resale of the product, (3) the buyer's obligation to pay would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the Company, (5) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated.

The Company sells its generic Tussionex and Adzenys XR-ODT to 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 has no sales history for Adzenys XR-ODT and has determined that at this time it cannot reliably estimate expected returns of the product at the time of shipment to wholesalers. Accordingly, the Company defers recognition of revenue on product shipments of Adzenys XR-ODT until the right of return no longer exists, which occurs at the earlier of the time Adzenys XR-ODT units are dispensed through patient prescriptions or expiration of the right of return. The Company calculates patient prescriptions of Adzenys XR-ODT dispensed using an analysis of third-party information.

Net product sales

Net product sales for the Company's 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 and estimated allowances for product returns, rebates and chargebacks to be incurred on the selling price of the respective product sales. Wholesale distribution fees based on definitive contractual agreements are incurred on the management of these products by wholesalers and are recorded within net sales for generic Tussionex and as deferred wholesale distribution fees in other current assets for Adzenys XR-ODT. The deferred wholesale distribution fees for Adzenys XR-ODT are later recorded within net product sales when revenue associated with those fees is recognized. The Company estimates and records gross to net sales adjustments for product returns, rebates and chargebacks based upon analysis of third-party information, including information obtained from the Company's third party logistics providers ("3PLs"), with respect to its inventory levels and sell-through to the wholesalers' customers, for savings offers from data available from third parties regarding savings offers processed for prescriptions written for the Company's products, and, for generic Tussionex, experience reported by the Company's previous commercialization partners. 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 all other allowances and accruals are recorded in the same period that the related revenue is recognized.

Savings offers

The Company offers savings offers programs for Adzenys XR-ODT to patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. The Company records the amount redeemed based on information from third-party providers and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Product returns

Wholesalers' contractual return rights are limited to defective product, product that was shipped in error, product ordered by customer in error, product returned due to overstock, product returned due to dating or product returned due to recall or other changes in regulatory guidelines. The return policy for expired product allows the wholesaler to return such product starting six months prior to expiry date to twelve months post expiry date.

Generic Tussionex product returns are estimated based upon data available from sales of the Company's product by its former commercialization partner and from actual experience as reported by retailers. Historical trend of returns will be continually monitored and may result in future adjustments to such estimates. On August 26, 2014, the U.S. Drug Enforcement Agency ("DEA") reclassified the Company's generic Tussionex from a Schedule III controlled substance to a Schedule II controlled substance which had the effect of requiring unsold product at the wholesalers and the 3PL to either be relabeled or returned. This new ruling was effective October 6, 2014. As such, the Company established reserves for the estimated returns of such product outstanding at the wholesalers as of October 6, 2014. The Company had no inventory labeled as Schedule III at the 3PL as of the effective date.

Rebates

The Company's products are subject to government-managed Medicare and Medicaid programs whereby discounts and rebates are provided to participating federal and/or state governments. Estimated rebates payable under governmental programs are recorded as a reduction of revenue at the time revenues are recorded. Calculations related to these rebate accruals are estimated based on information from third-party providers. Historical trend of governmental rebates will be continually monitored and may result in future adjustments to such estimates.

Wholesaler Chargebacks

The Company's 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. Chargebacks are accounted for by establishing an accrual in an amount equal to the Company's estimate of chargeback claims at the time of product sale based on information provided by third parties. Due to estimates and assumptions inherent in determining the amount of chargebacks, the actual amount of claims for chargebacks may be different from estimates, which may result in adjustments to such reserves.

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.

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

Management evaluates the Company's tax positions in accordance with guidance on accounting for uncertainty in income taxes. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not that the position will be sustained upon examination. As of June 30, 2016 and December 31, 2015, the Company had no uncertain tax positions that qualify for either recognition or disclosure in the consolidated financial statements. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized. At June 30, 2016 and December 31, 2015, based on the level of historical operating results and projections for the taxable income for the future, the Company has 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.

Warrants: The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on the Company's balance sheet at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense) in the statements of operations. The Company estimates the fair value of its derivative liabilities using third party valuation analysis that utilizes option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for expected volatility, expected life, yield, and risk-free interest rate. Prior to the closing of the initial public offering ("IPO"), the Company's warrants for the

Company's Series C redeemable convertible preferred stock ("Series C warrants") were determined to be derivative liabilities and they were revalued at each subsequent balance sheet date. Upon closing the IPO, the Series C warrants issued in conjunction with the Series C redeemable convertible preferred stock ("Series C preferred stock") financing were exchanged in a cashless exercise for 947,185 shares of Series C preferred stock which converted into 78,926 shares of the Company's common stock. The remaining Series C warrants issued with the senior debt to purchase 170,000 pre-split shares of Series C preferred stock ("Hercules Warrants") were converted into warrants with a term of five years to purchase 70,833 shares of the Company's common stock and the warrant liability was reclassified to Additional Paid in Capital within Stockholders' Equity.

Share-based compensation: 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 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 has, 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. Forfeitures are estimated at the time of grant and revised, if necessary, 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.

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.

Segment information: Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the development, manufacturing and commercialization of pharmaceuticals.

Liquidity: During 2015 and the three and six months ended June 30, 2016, 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 launch of Adzenys XR-ODT or, if approved, one or more of its ADHD product candidates. Management believes the Company presently has sufficient liquidity to continue to operate for at least the next 12 months.

Recent accounting pronouncements: In March 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Compensation — Stock Compensation — Improvements to Employee Share-Based Payment Accounting (Topic 718)*. For public companies, areas of accounting for share-based payment that this ASU was designed to simplify include: the income tax consequences, the accounting policy for forfeitures, the classification of awards as either equity or liabilities and the classification on the statement of cash flows. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2016, including interim periods within those years. The Company is evaluating this ASU and has not determined the effect of this standard on its ongoing financial reporting.

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. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019, including interim periods within those years. The Company is evaluating this ASU and has not determined the effect of this standard on its ongoing financial reporting.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606).* ASU 2014-09 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard will become effective for the Company on January 1, 2018. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. Also, in March 2016 the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers — Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* to clarify the implementation guidance on principal versus agent considerations. This ASU states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Also, in April 2016 the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers — Identifying Performance Obligations and Licensing* to assist preparers with identifying performance obligations and implementing licensing guidance under the new revenue standard. In April 2016 the FASB issued ASU No. 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards*

Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting. This ASU rescinds certain SEC Staff Observer comments in the following areas that are codified in Topic 605, Revenue Recognition, and Topic 932, Extractive Activities—Oil and Gas, effective upon adoption of Topic 606: revenue and expense recognition for freight services in process; accounting for shipping and handling fees and costs c) accounting for consideration given by a vendor to a customer (including reseller of the vendor's products) and d) accounting for gas-balancing arrangements. In May 2016 the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients.* This ASU provides clarifying guidance in certain narrow areas and adds some practical expedients relative to assessing collectability, presentation of taxes collected form customers, noncash consideration, contract modifications at transition, completed contracts at transition and technical corrections. The amendments in ASU 2016-08, 2016-10, 2016-11 and 2016-12 have the same effective date and transition requirements as ASU 2014-09. The Company is evaluating the effect that ASU 2014-09, ASU 2016-08, 2016-10, 2016-11 and 2016-12 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of these standards on its ongoing financial reporting.

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 either are not applicable or 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 redeemable convertible preferred stock, warrants and outstanding stock options under the stock option plan 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.

The following potentially dilutive securities outstanding as of June 30, 2016 and 2015 were excluded from consideration in the computation of diluted net loss per share of common stock for the six months ended June 30, 2016 and 2015, respectively, because including them would have been anti-dilutive:

	June 30, 2016 (unaudited)	June 30, 2015 (unaudited)
Series A Redeemable Convertible Preferred Stock (as converted)	—	487,494
Series B Redeemable Convertible Preferred Stock (as converted)	—	1,297,100
Series B-1 Redeemable Convertible Preferred Stock (as converted)	—	2,275,733
Series C Redeemable Convertible Preferred Stock (as converted)	—	4,803,492
Series C Redeemable Convertible Preferred Stock Warrants (as converted)	70,833	819,650
Common Stock Warrants	—	337,133
Stock options	1,909,460	776,910

Note 4. Fair value of financial instruments

Financial instruments are categorized into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (“Level 1”) and the lowest priority to unobservable inputs (“Level 3”). If the inputs used to measure fair value fall within different levels of the hierarchy, the categorization of the financial instrument is based on the lowest priority level input that is significant to the fair value measurement of the instrument.

Financial assets recorded at fair value on the Company’s consolidated balance sheets are categorized 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 2 inputs include the following:

- Quoted prices for similar assets in active markets.
- Quoted prices for identical or similar assets in nonactive markets.
- Inputs other than quoted market prices that are observable.

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- Inputs that are derived principally from or corroborated by observable market data through correlation or other means.

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

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

Fair Value as of June 30, 2016 (unaudited) (in thousands)	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 41,886	$ —	$ —	$ 41,886
Short term investments	—	38,232	—	38,232
Earnout liability	—	—	257	257
	$ 41,886	$ 38,232	$ 257	$ 80,375

Fair Value as of December 31, 2015 (in thousands)	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 90,763	$ —	$ —	$ 90,763
Earnout liability	—	—	214	214
	$ 90,763	$ —	$ 214	$ 90,977

The Company’s Level 1 assets include cash and cash equivalents. Cash and cash equivalents include bank deposits, certificates of deposit, money market funds and corporate debt securities with a maturity of 90 days or less whose values are considered to approximate fair value at June 30, 2016 and December 31, 2015 due to the short-term nature of the instruments and/or the current interest rates payable in relation to current market conditions.

The Company’s Level 2 assets include short term investments which are classified as available-for-sale securities and have a maturity greater than 90 days, but less than 1 year, with quoted prices in active markets. Level 2 securities primarily consisted of commercial paper and bonds issued by domestic and foreign corporations. The estimated fair values of these securities are determined by third parties using various calculations and valuation techniques that incorporate standard observable inputs and assumptions such as quoted prices for similar assets, benchmark yields, reported trades, broker/dealer quotes, issuer spreads, benchmark securities, bids/offers and other pertinent reference data.

The Company’s cash and cash equivalents and short term investments had quoted prices at June 30, 2016 as shown below:

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June 30, 2016	Amortized Cost	Unrealized Gain / (Loss)	Market Value

		(unaudited) (in thousands)	
Bank deposits and money market funds	$ 38,887	$ —	$ 38,887
Financial and corporate debt securities	41,193	38	41,231
	$ 80,080	$ 38	$ 80,118

Level 3 liabilities included the fair value of the earnout liability at June 30, 2016 and December 31, 2015. The fair value of the earnout liability was determined using the Monte Carlo method as done previously.

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

	Earnout Liability (in thousands)
Balance at December 31, 2015	$ 214
Change in fair value (unaudited)	(4)
Balance at March 31, 2016 (unaudited)	$ 210
Change in fair value (unaudited)	$ 47
Balance at June 30, 2016 (unaudited)	$ 257

Note 5. Inventories

Inventories at the indicated dates consist of the following:

	June 30, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Raw materials	$ 1,437	$ 1,211
Work in progress	2,076	175
Finished goods	1,011	1,189
Deferred cost of goods sold	175	—
Inventory at cost	4,699	2,575
Inventory reserve	(272)	(55)
	$ 4,427	$ 2,520

Note 6. Sale-leaseback transaction

In the aggregate, the Company sold groups of assets for $5.5 million and $795,000 in five separate tranches that occurred in February, July and November 2013, and March 2014, which resulted in a net gains of approximately $2.7 million and $116,000, in the years ended December 31, 2013 and 2014, respectively, and executed capital leases for these assets with repurchase options at the end of each respective lease term. Gains on the transactions are recognized on a straight-line basis over each respective 42-month lease term. For the three months ended June 30, 2016 and 2015, approximately $206,000 and $208,000, respectively, and for the six months ended June 30, 2016 and 2015 approximately $415,000 and $416,000, respectively, of the net gain was recognized in other income on the consolidated statements of operations.

Note 7. Intangible assets, net

Intangible assets, net at the indicated dates consist of the following:

	June 30, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Proprietary modified-release drug delivery technology	$ 15,600	$ 15,600
Tussionex ANDA	4,829	4,829
CPI profit sharing	2,043	2,043
Other	784	284
	23,256	22,756
Accumulated amortization	(6,896)	(6,084)
	$ 16,360	$ 16,672

The $15.6 million of proprietary modified-release drug delivery technology is being amortized over 20 years. Amortization expense of $195,000 was recorded in both the three months ended June 30, 2016 and 2015 and amortization expense of $390,000 was recorded for both the six months ended June 30, 2016 and 2015.

Prior to the August 28, 2014 acquisition of the rights to Tussionex ANDA from Cornerstone Biopharma, Inc. (“Cornerstone”) and Coating Place, Inc. (“CPI”), the Company, Cornerstone and CPI shared profits generated by the sale and manufacture of the product under a development and manufacturing agreement, and Cornerstone had commercialization rights to the product. The Company paid $4.2 million to Cornerstone and $90,000 of legal fees to buy out its rights to commercialize and derive future profits from the product and entered into an asset acquisition agreement whereby Cornerstone transferred certain assets associated with the product to the Company. In addition, the Company paid $2.0 million to CPI and $43,000 of legal fees to buy out its rights to future profits from the collaboration and entered into an agreement whereby CPI will continue to supply a component of the product. Additional estimated earnout costs due to Cornerstone of $589,000, recorded at fair value by the Company based upon a valuation provided by a third party valuation firm, were capitalized as part of the purchase price of this intangible asset. This earnout amount was revalued at June 30, 2016, resulting in a $47,000 and $43,000, respectively, increase in the estimated fair value of the earnout which is recorded as expense in other income (expense), net in the Company’s consolidated statement of operations for the three and six months ended June 30, 2016. This earnout amount was revalued at June 30, 2015, resulting in a $42,000 increase in the estimated fair value of the earnout which is recorded in other income (expense), net in the Company’s consolidated statement of operations for the three months ended June 30, 2015. The net decrease of $400,000 for the six months ended June 30, 2015 resulted from new information regarding the projected impact of the DEA’s reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance. These two intangible assets have an expected life of ten years and are being amortized on a straight-line basis beginning September 2014. Total amortization expense related to these intangible assets was $172,000 and $171,000, respectively, for each of the three months ended June 30, 2016 and 2015, respectively, and $344,000 and $343,000, for the six months ended June 30, 2016 and 2015, respectively.

Note 8. Other assets

Other assets at the indicated dates consist of the following:

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	June 30, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Patents	$ 2,356	$ 2,273
Deposits	208	197
	$ 2,564	$ 2,470

Patents utilized in the manufacturing of the Company’s generic Tussionex product which total $231,000 are being amortized over their expected useful life of 10 years. Patents utilized in the manufacturing of Adzenys XR-ODT which total $459,000 are being amortized over their expected useful life of approximately 16 years, beginning with the PDUFA approval of Adzenys XR-ODT on January 27, 2016. Patent amortization expense of $13,000 and $6,000, was recorded for the three months ended June 30, 2016 and 2015, respectively, and patent amortization expense of $23,000 and $12,000, was recorded for the six months ended June 30, 2016 and 2015, respectively,.

Note 9. Long-term debt

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

	June 30, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Deerfield senior secured credit facility, net of discount of $1,544	$ 58,887	$ —
Senior debt, net of discount of $1,167	—	24,895
10% subordinated note payable to a related party	—	6,994
Capital leases, maturing through August 2017	1,434	2,355
	60,321	34,244
Less current portion	(1,745)	(7,973)
Long-term debt	$ 58,576	$ 26,271

On May 11, 2016, the Company entered into a $60 million senior secured credit facility (“Facility”) with Deerfield Private Design Fund III, L.P. (66 2/3% of loan) and Deerfield Special Situations Fund, L.P. (33 1/3% of Loan) (“Deerfield”), as lenders. Principal on the new 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 has an option to defer payment of each of the first four interest payments until June 1, 2017. The Company exercised the option to defer the first interest payment, adding such amount to the outstanding loan principal until it is paid on June 1, 2017. 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. Borrowings under the Facility are collateralized by substantially all of the Company’s assets, except the Company’s assets under capital lease, and the Company will maintain cash on deposit of not less than $5 million. 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 ("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 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.

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 lender may declare all outstanding obligations accrued under the Facility to be immediately due and payable, and exercise its security interests and other rights. As of June 30, 2016, the Company was in compliance with the covenants under the Facility

Debt discount amortization for the Facility was calculated using the effective interest rate, charged to interest expense and totaled $36,000 for the three and six months ended June 30, 2016.

Senior debt: In March 2014, the Company entered into the LSA with Hercules Technology III, L.P., ("Hercules"), which was subsequently amended in August 2014, September 2014, December 2014 and June 2015. As amended, the LSA provided a total commitment of $25.0 million, available in four draws. Borrowings under the LSA were collateralized by substantially all of the Company's assets, except the Company's intellectual property and assets under capital lease. The first draw of $10.0 million, ("Tranche 1"), was issued during March 2014 and was used in its entirety to repay outstanding principal under a previous credit facility. The second draw of $5.0 million, ("Tranche 2"), was issued during September 2014. The third draw ("Tranche 3") in the amount of $5.0 million was issued in March 2015. In June 2015, the fourth and final draw of $5.0 million, ("Tranche 4"), was issued prior to meeting the Tranche 4 milestones, which were met in July 2015.

Each draw was to be repaid in monthly installments, comprised of interest-only monthly payments until May 2016, when installments of interest and principal calculated over a thirty-month amortization period commenced. A balloon payment of the entire principal balance outstanding on October 1, 2017 and all accrued but unpaid interest thereunder was due and payable on October 1, 2017. The interest rate was 9% per annum for Tranche 1 and Tranche 4 and 10.5% per annum for Tranche 2 and Tranche 3. An end of term charge of $1.1 million was payable at the earliest to occur of (1) October 1, 2017, (2) the date the Company prepaid its outstanding Secured Obligations, as defined therein, or (3) the date the Secured Obligations became due and payable. As such, the end of term charge of $1.1 million was paid on May 11, 2016 when the Company prepaid its outstanding Secured Obligations, as defined therein.

In connection with the LSA, the Company issued the Hercules Warrants which consisted of 60,000 Series C warrants in March 2014 and 110,000 Series C warrants in September 2014 at the then current price of $5.00 per share. The Hercules Warrants became warrants with a term of five years for the purchase of 70,833 shares of common stock at a price of $12.00 per share upon the closing of the Company's IPO and were therefore reclassified from warrant liability to Additional Paid in Capital within Stockholders' Equity.

The fair value of the 60,000 Hercules Warrants issued March 28, 2014 as part of the initial draw-down described above was $124,000 and the residual proceeds of $9,876,000 were allocated to the $10.0 million interest bearing note. The fair value of the 110,000 Hercules Warrants issued September 25, 2014 as part of the second draw-down described above was $248,000 and the residual proceeds of $4,752,000 were allocated to the $5.0 million interest bearing note. The warrants were recorded as a liability with a related debt discount to be amortized as interest over the term of the LSA.

LSA end of term charge amortization totaled $38,000 and $121,000 for the three and six months ended June 30, 2016, respectively, and $76,000 and $151,000 for the three and six months ended June 30, 2015, respectively. LSA debt discount amortization charged to interest expense totaled $33,000 and $104,000 for the three and six months ended June 30, 2016, and $65,000 and $129,000 for the three and six months ended June 30, 2015, respectively. At the end of the three and six months ended June 30, 2015, the Hercules warrant fair values were remeasured and the changes in fair value of approximately $87,000 and $119,000, respectively, were recorded in other income (expense), net in the Company's consolidated statements of operations.

The early prepayment of the LSA resulted in a $1,187,000 loss on debt extinguishment (due to recording the $243,000 LSA prepayment charge, writing off $503,000 of unamortized LSA end of term charge and the $439,000 of unamortized LSA loan cost and expensing the $2,500 of legal fees paid on behalf of Hercules) which is separately shown in the statement of operations for the three and six months ended June 30, 2016.

10% subordinated related party note: The Company had a Note in the aggregate principal amount of $5.9 million that was issued by the Company to Essex which was to mature in March 2017. Interest was to be accrued and added to the principal balance until such time as the Company achieved positive EBITDA for three consecutive months. On July 19, 2014, the interest rate on the Note was reduced to 6% for the period from July 19, 2014 through June 28, 2015 pursuant to an amendment to the Note entered into as consideration for the $128,000 payment made by the Company to Essex as part of the Settlement and Release of Claims Agreement with Essex and a third party (see Note 15). The Company recorded this amendment as a loan modification. On May 11, 2016, the Company prepaid the $5.9 million outstanding aggregate principal and $1,317,000 in accrued and unpaid interest. At December 31,

2015, the aggregate principal amount of the Note was $5.9 million and $1,059,000 in interest had been accrued through December 31, 2015.

Capital lease obligations to related party: As described in Notes 6 and 15, during the years ended December 31, 2013 and 2014, the Company entered into agreements with a related party for the sale-leaseback of existing and newly acquired assets with a total capitalized cost of $5.5 million and $795,000, respectively, which are classified as capital leases. The approximate imputed interest rate on these leases is 14.5% and interest expense on these leases was $61,000 and $123,000 for the three months ended June 30, 2016 and 2015, respectively, and $139,000 and $261,000 for the six months ended June 30, 2016 and 2015, respectively.

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

Period ending:	**June 30, 2016**
	(unaudited)
	(in thousands)

2017	$	1,745
2018		120
2019		15,000
2020		15,000
2021		15,000
Thereafter		15,000
Future principal payments	$	61,865
Less unamortized debt discount		(1,544)
Less current portion of long-term debt		(1,745)
Total long-term debt	$	58,576

Note 10. Common stock and redeemable convertible preferred stock

Reverse Stock Split

On July 10, 2015, the Company filed an amendment to its amended and restated certificate of incorporation, effecting a 1-for-2.4 reverse stock split of the Company's issued and outstanding shares of common stock as approved by the Company's board of directors on July 9, 2015. All issued and outstanding common stock and per share amounts contained in the Company's financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

Authorized Shares

In connection with the closing of the Company's IPO on July 28, 2015, the Company amended and restated its certificate of incorporation to authorize 5,000,000 shares of preferred stock, par value $0.001 per share, and 100,000,000 shares of common stock, par value $0.001 per share.

Public Offerings and Related Transactions

On July 28, 2015, the Company closed its IPO whereby the Company sold 5,520,000 shares of common stock, at a public offering price of $15.00 per share, which includes 720,000 shares of common stock resulting from the underwriters' exercise of their over-allotment option at the IPO price on July 23, 2015. Proceeds from the Company's IPO, net of underwriting discounts and commissions and other offering costs, were $75.0 million. Upon the closing of the Company's IPO, all of the Company's Preferred Shares converted into shares of the Company's Common Stock, all such Preferred Shares were retired and cancelled and shall not be reissued as shares of such series, and all rights and preferences of those Preferred Shares were cancelled including the right to receive undeclared accumulated dividends. Each of the following occurred in connection with the closing of the Company's IPO on July 28, 2015:

- Following the 1-for-2.4 reverse stock split of the Company's common stock effected on July 10, 2015 each share of Series C preferred stock converted into 0.41667 shares of common stock resulting in the conversion of all outstanding shares of convertible preferred stock into 9,217,983 shares of the Company's common stock;

- the conversion of the Hercules Warrants to purchase 170,000 shares of Series C preferred stock into warrants to purchase 70,833 shares of the Company's common stock and the resultant reclassification of the warrant liability to Additional Paid in Capital within Stockholders' Equity; and

- the net exercise of outstanding Series C warrants issued in conjunction with the Series C preferred stock financing to purchase 947,185 shares of Series C preferred stock for 78,926 shares of the Company's common stock.

The Company had classified its classes of redeemable convertible preferred stock as mezzanine equity based upon the terms and conditions which contain various redemption and conversion features.

In connection with the sale of shares of the Company's Series B-1 Redeemable Convertible Preferred Stock ("Series B-1 preferred stock"), the Series B-1 investors also received warrants to purchase 389,474 shares of common stock at an exercise price of $0.0024 per share ("Series B-1 warrants"). In 2015, the Company issued a total of 286,968 shares of its common stock upon the exercise of Series B-1 warrants held by several investors at an exercise price of $0.0024 per share. During the six months ended June 30, 2016, the Company issued a total of 43,861 shares of its common stock upon the exercise of Series B-1 warrants held by several investors at an exercise price of $0.0024 per share. The remaining Series B-1 warrants to purchase 6,297 shares of common stock expired on June 10, 2016.

Between December 2014 and February 2015, the Company closed on an additional Series C preferred stock financing raising a total of $20.6 million, including $7.5 million in December 2014 and $13.1 million during the six months ended June 30, 2015. The Company issued 1,499,935 shares in December 2014 and 2,624,936 shares during the three months ended March 31, 2015 of Series C preferred stock. In addition, the Company issued a Series C warrant to purchase one additional share of Series C preferred stock at a purchase price of $5.00 per share for every two purchased shares of Series C preferred stock, provided the investor purchased its pro-rata share of the Series C preferred stock. In the event that the Company's Series C preferred stock converted into common stock or another class of the Company's stock ("Conversion Stock") during the warrant exercise period, then the warrants would become exercisable for the Conversion Stock and the exercise price of those warrants was to be ratably adjusted. The Company issued Series C warrants to purchase 749,967 shares of Series C preferred stock in December 2014 and 1,197,218 shares of Series C preferred stock during the six months ended June 30, 2015 (see warrant liability section below). On June 30, 2015, the Company issued a total of 150,000 shares of its Series C preferred stock to an investor upon the exercise of warrants held by that investor at an exercise price of $5.00 per share, for an aggregate exercise price of $750,000. Between July 6 and July 27, 2015, the Company issued 850,000 shares of its Series C preferred stock to several investors upon the exercise of warrants held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $4.25 million.

On August 1, 2016 the Company filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale by the Company of up to an aggregate of $125,000,000 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 $40,000,000 of its common stock from time to time in "at-the-market" offerings under the Shelf.

Dividends: From and after the date of the issuance of the Company's Series B-1 redeemable convertible preferred stock until the retirement and cancellation of Series B-1 preferred stock in conjunction with the Company's IPO, dividends at the rate per annum of 8% of the Series B-1 preferred stock original issuance price of $5.00 were accrued on such shares of Series B-1 preferred stock. Dividends accrued from day to day, whether or not declared, and were cumulative. The accruing dividends were to be payable in additional shares of Series B-1 preferred stock, valued at the Series B-1 preferred stock original issuance price, unless the board of directors of the Company elected to pay all or any portion of the accruing dividends in cash. In accordance with the conversion provision of the Company's Third Amended and Restated Certificate of Incorporation, as amended, which was triggered upon the Company's IPO, all rights with respect to the Preferred Shares of the Company were terminated, including the right to receive undeclared dividends. The Series B-1 preferred stock cumulative dividends were never declared by the Company's board of directors.

Redemption: Prior to the retirement and cancellation of the Company's Preferred Shares as a result of the IPO, the holders of a majority of the outstanding shares of Series C preferred stock, Series B-1 preferred stock and Series B Redeemable Convertible Preferred Stock ("Series B preferred stock"), voting together as a single class, could require the Company to redeem the Series C preferred stock, Series B-1 preferred stock and Series B preferred stock at their original purchase price of $5.00 per share in three annual installments by giving a sixty-day notice at any time on or after March 31, 2017. On March 25, 2014, the Company amended the initial redemption date, extending it to November 1, 2017. On each redemption date, the Company was to redeem, on a pro rata

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basis in accordance with the number of shares of Series C preferred stock, Series B-1 preferred stock and Series B preferred stock owned by each holder, that number of outstanding shares of Series C preferred stock, Series B-1 preferred stock and Series B preferred stock. If the Company did not have sufficient funds legally available to redeem on any redemption date, the Company was to redeem a pro rata portion of each holder's Series C preferred stock, Series B-1 preferred stock and Series B preferred stock out of funds legally available.

The Series C preferred stock, Series B-1 preferred stock and Series B preferred stock were to be redeemable on November 1, 2017, and their carrying value was being accreted to the minimum redemption value of $5.00 per share or $57,642,000, $27,309,000 and $15,565,000, respectively, over the period from issuance through November 1, 2017 using the effective interest method for issuances through the IPO effective date. The amount of accretion recorded for each of the Series C preferred stock, Series B-1 preferred stock and Series B preferred stock for the three months ended June 30, 2015 was $335,000, $165,000 and $86,000, respectively. The amount of accretion recorded for each of the Series C preferred stock, Series B-1 preferred stock and Series B preferred stock for the six months ended June 30, 2015 was $570,000, $329,000 and $171,000, respectively.

In accordance with the conversion provision of the Company's Third Amended and Restated Certificate of Incorporation, as amended, which was triggered upon the Company's IPO, all rights with respect to the Preferred Shares of the Company were terminated, including redemption rights.

Warrant liability: In connection with the December 2014 $7.5 million additional Series C preferred stock financing (see above), the Company issued warrants to purchase an aggregate 749,967 shares of the Series C preferred stock. The proceeds from the December 2014 additional Series C preferred stock financing with Series C warrants were allocated to the two elements based on the fair value of the Series C warrants at time of issuance. The remainder of the proceeds was allocated to the redeemable convertible preferred instrument portion of the transaction, resulting in a discount. The portion of the proceeds so allocated to the warrants was accounted for as a warrant liability and periodically adjusted to fair value through the statement of operations. The related preferred stock discount was amortized as preferred stock accretion to redemption value over the remaining term until the redemption date using the effective interest method. The fair value of the 749,967 Series C warrants was $1,335,000, with the residual $6,108,000, net of legal fees of $57,000, allocated to the 1,499,935 shares of Series C preferred stock as of December 2014.

The proceeds from the 2015 additional Series C preferred stock financing with stock purchase warrants were allocated to the two elements based on the fair value of the Series C warrants at time of issuance. The remainder of the proceeds was allocated to the redeemable convertible preferred instrument portion of the transaction, resulting in a discount. The portion of the proceeds so allocated to the Series C warrants was accounted for as a warrant liability and periodically adjusted to fair value through the statement of operations. The related preferred stock discount is amortized as preferred stock accretion to redemption value over the remaining term until the redemption date using the effective interest method. The fair value of the 1,197,218 Series C warrants was $2,131,000, with the residual $10,916,000, net of legal fees of $78,000, allocated to the 2,624,936 shares of Series C preferred stock.

At June 30, 2015, the Series C warrant fair values were remeasured and an increase in fair value of approximately $129,000 was recorded in other income (expense), net in the Company's consolidated statements of operations for the second quarter, for a net reduction in the warrant fair value of $105,000 for the six months ended June 30, 2015.

On the IPO effective date of July 22, 2015, the Series C warrant fair values were remeasured for a final time and an increase in fair value of approximately $1,698,000 for the year-to-date was recorded in other income (expense), net in the Company's consolidated statements of operations. Upon the closing of the Company's IPO, all of the shares of the Company's redeemable convertible preferred stock ("Preferred Shares") were retired and cancelled and shall not be reissued as shares of such series, and all rights and preferences of those Preferred Shares were cancelled including the right to receive undeclared accumulated dividends. On the IPO closing date, all outstanding shares of redeemable preferred stock converted into 9,217,983 shares of common stock and all remaining outstanding Series C warrants issued in conjunction with purchases of Series C preferred stock were net exercised at the IPO price for 78,926 shares of common stock.

Note 11. Stock Based Compensation

In July 2015, the Company adopted the Neos Therapeutics, Inc. 2015 Stock Option and Incentive Plan ("2015 Plan") which became effective immediately prior to the closing of the IPO and initially had 767,330 shares of common stock reserved for issuance. On January 1, 2016 and each January 1 thereafter, the number of shares of common stock reserved and available for issuance under the 2015 Plan shall be cumulatively increased by five percent of the number of shares of stock issued and outstanding on the immediately preceding December 31 or such lesser number of shares determined by the administrator of the 2015 Plan. Accordingly, on January 1, 2016, the Company added 800,797 shares to the option pool. The 2015 Plan superseded the Neos Therapeutics, Inc.

2009 Equity Plan (“2009 Plan”), originally adopted in November 2009 and which had 1,375,037 shares for 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. The exercise price per share for the stock covered by a stock option 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 options 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. 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 vest over a three-year period based on achieving certain operational milestones and the remaining options vest in equal increments over a four-year period. 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, 2015, 1,389 shares related to forfeited 2009 Plan options and 9,197 shares related to the surrender of restricted stock were added to the shares available under the 2015 Plan. During the six months ended June 30, 2016, 5,000 shares related to forfeited 2009 Plan options were added to the shares available under the 2015 Plan. As of June 30, 2016, 398,774 shares of common stock remain available for grant under the 2015 Plan.

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

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

	Six Months Ended June 30, 2016 (unaudited)
Estimated dividend yield	0%
Expected stock price volatility	60%
Weighted-average risk-free interest rate	1.21%
Expected life of option in years	6.25
Weighted-average option fair value at grant	$ 6.05

Total compensation cost that has been charged to general and administrative expense related to stock options was $784,000 and $1,385,000 for the three and six months ended June 30, 2016, respectively, and $115,000 and $189,000 for the three and six months ended June 30, 2015, respectively. At June 30, 2016, there was $9.7 million of unrecognized compensation cost, which is expected to be recognized over a weighted-average period of 3.2 years. For the six months ended June 30, 2016, the Company issued 10,886 shares of the Company’s common stock upon the exercise of outstanding stock options and received proceeds of $13,000 and realized no tax benefit from the exercised stock options.

A summary of outstanding and exercisable options as of June 30, 2016 and December 31, 2015 and the activity from December 31, 2015 through June 30, 2016, is presented below:

	Number of Options	Weighted-Average Exercise Price	Intrinsic Value (in thousands)
Outstanding at December 31, 2015	1,352,283	$ 13.607	$ 964
Exercisable at December 31, 2015	229,000	$ 3.385	$ 2,504
Granted (unaudited)	621,595	$ 10.744	
Exercised (unaudited)	(10,886)	1.231	
Expired, forfeited or cancelled (unaudited)	(53,532)	22.571	
Outstanding at June 30, 2016 (unaudited)	1,909,460	$ 12.494	$ 2,463
Exercisable at June 30, 2016 (unaudited)	333,867	$ 5.464	$ 1,506

The weighted-average remaining contractual life of options outstanding and exercisable on June 30, 2016 was 8.9 and 7.5 years, respectively. The option exercise price for all options granted January 1, 2016 through June 30, 2016 ranged from $10.32 to $10.96 per share. The weighted-average remaining contractual life of options outstanding and exercisable on December 31, 2015 was 8.9 and 7.3 years, respectively. The option exercise price for all options granted in the year ended December 31, 2015 ranged from $9.32 to $25.50 per share.

Restricted stock: Under the 2009 Plan, the Company granted 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.

The Company did not issue any shares of restricted stock for the six months ended June 30, 2016, or for the year ended December 31, 2015. Restricted stock compensation cost of $22,000 and $45,000 for each of the three and six months ended June 30, 2016 and 2015, respectively, has been charged to general and administrative expenses. At June 30, 2016, there was $117,000 of unrecognized compensation cost related to restricted stock, which is expected to be recognized over 15.5 months. No vested restricted stock awards were settled during the six months ended June 30, 2016. On October 16, 2015, the Company settled in cash certain vested restricted stock awards having a value of $658,000 and the Company realized a tax benefit of $224,000. On October 16, 2015, 9,197 shares of restricted stock were surrendered by the holder to the Company to cover taxes associated with vesting of restricted stock. The fair value of such shares was determined to be $18.54 per share, the closing price of the Company's stock on such date.

The Company had 71,025 shares of unvested restricted stock with a weighted average fair value of $2.55 as of June 30, 2016 and December 31, 2015. For the six months ended June 30, 2016, there were no shares of restricted stock granted, vested or forfeited.

Note 12. Treasury stock

The Company has the authority to repurchase common stock from former employees, officers, directors or other persons who performed services for the Company at the lower of the original purchase price or the then-current fair market value. On February 19, 2015, the Company's board of directors approved the cancellation of the Company's 55,905 shares of treasury stock which had been repurchased at the original purchase price of $0.002 in 2013. On October 16, 2015, 9,197 shares 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.

Note 13. Commitments and contingencies

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 $1,194,000 and $1,166,000 at June 30, 2016 and December 31, 2015, 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 $59,000 and $116,000 for the three and six months ended June 30, 2016, respectively, and $60,000 and $119,000 for the three and six months ended June 30, 2015, respectively. Rent expense, excluding the share of operating expenses, for the three and six months ended June 30, 2016 was $252,000 and $505,000, respectively, and $218,000 and $436,000 for the three and six months ended June 30, 2015, 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 $291,000 and $543,000 of bonus expense for the three and six months ended June 30, 2016.

Note 14. License agreements

On July 23, 2015, the Company entered into a Settlement Agreement and an associated License Agreement with Shire LLC for a non-exclusive license to certain patents for certain activities with respect to the Company's New Drug Application No. 204326 for an extended-release orally disintegrating amphetamine polistirex tablet ("Neos NDA"). In accordance with the terms of the Agreement, following the receipt of the approval from the FDA for Adzenys XR-ODT, the Company paid a lump sum, non-refundable license fee of an amount less than $1.0 million on February 26, 2016. This license fee was capitalized as an intangible asset and is being amortized over the life of the longest associated patent. The Company is paying a single digit royalty on net sales of Adzenys XR-ODT during the life of the patents. The royalties are being recorded as cost of goods sold in the same period as the net sales upon which they are calculated.

Note 15. Related party transactions

At December 31, 2015, the Company was obligated under a $5,935,000 long-term subordinated note ("Note") that was issued by the Company to Essex. See Note 9 for further details. On July 21, 2014, the Company, Essex and a third party entered into a Settlement Agreement and Release of Claims Agreement resolving certain issues and disputes whereby Essex paid $256,000 to the third party, the Company paid Essex $128,000 and Essex agreed to reduce the interest rate on the Note from 10% to 6% beginning on July 19, 2014 until such time as the Company recovered the full amount of its payment to Essex, which ended on June 28, 2015, at which time the interest rate on the Note returned to 10%. The third party released both Essex and the Company from any and all claims. The Company repaid this loan and the related accrued interest on May 11, 2016 using proceeds from the new $60 million Facility (see Note 9).

As described in Note 6, in 2012, the Company negotiated financing arrangements with a related party that provided for the sale-leaseback of up to $6.5 million of the Company's property and equipment. In 2013, the Company executed four transactions totaling $5.5 million and in March 2014, the Company completed the final tranche of the sale-leaseback arrangement, raising an additional $795,000.

Note 16. Subsequent events

On July 25, 2016, the Company 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. The certification notice alleges 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. Neos is evaluating the paragraph IV certification and intends to vigorously enforce its intellectual property rights relating to Adzenys XR-ODT. Neos has 45 days from the receipt of the paragraph IV certification to commence a patent infringement lawsuit against Actavis that would automatically stay, or bar, the FDA from approving Actavis's ANDA for 30 months or until a district court decision that is adverse to the asserted patents, whichever is earlier.

On July 28, 2016, the Company exercised the option to defer the second interest payment due September 1, 2016 under the Facility, and will add, when otherwise due, such amount to the outstanding loan principal until it is paid on June 1, 2017.

On August 1, 2016 the Company filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale by the Company of up to an aggregate of $125,000,000 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 $40,000,000 of its common stock from time to time in "at-the-market" offerings under the Shelf.

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, 2015 and 2014 and notes thereto included in our Annual Report on Form 10-K as filed with the SEC on March 18, 2016. 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 and our two product candidates for the treatment of attention deficit hyperactivity disorder ("ADHD"). Our product 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 believe Adzenys XR-ODT is and, if approved, Cotempla XR-ODT will be the first amphetamine XR-ODT and the first methylphenidate XR-ODT, respectively, for the treatment of ADHD on the market. Cotempla XR-ODT is the provisionally accepted trade name of our methylphenidate XR-ODT. 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. We are evaluating the paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to Adzenys XR-ODT. Should we determine that litigation is warranted, we anticipate incurring increasing amounts of legal fees in the enforcement of our intellectual property rights.

On November 10, 2015, we announced that we received a Complete Response Letter from the FDA in its review of our New Drug Application ("NDA") for Cotempla XR-ODT, which requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. We expect to resubmit an NDA for Cotempla XR-ODT in the fourth quarter of 2016. In addition, we plan to submit an NDA for NT-0201, our amphetamine XR liquid suspension, in the fourth quarter of 2016.

We plan to focus on commercialization in the United States using our own commercial infrastructure. We are manufacturing Adzenys XR-ODT, and, if approved, intend to manufacture Cotempla XR-ODT and NT-0201 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.

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 product candidates which consist of 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 recent initial public offering of our common stock, 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 $39.2 million and $30.8 million for the six months ended June 30, 2016 and the year ended December 31, 2015, respectively. As of June 30, 2016 and December 31, 2015, we had an accumulated deficit of approximately $155.9 million and $116.8 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:

- seek regulatory approval for our product candidates;
- build and operate commercial infrastructure to support sales and marketing for Adzenys XR-ODT and, if approved, our product candidates;
- continue research and development activities for new product candidates;
- manufacture supplies for our preclinical studies and clinical trials; and
- operate as a public company.

On July 28, 2015, we closed our initial public offering ("IPO"), whereby we sold 5,520,000 shares of 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. The net proceeds from our IPO, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $75.0 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 a $60 million senior secured credit facility ("Facility") with Deerfield Private Design Fund III, L.P. (66 2/3% of loan) and Deerfield Special Situations Fund, L.P. (33 1/3% of Loan) ("Deerfield"), as lenders. Approximately $33 million of the proceeds was used to prepay 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 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 have an option to defer payment of each of the first four interest payments until June 1, 2017. We exercised the option to defer the first two interest payments, adding such amounts to the outstanding loan principal until they are paid on June 1, 2017.

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 $125,000,000 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 $40,000,000 of our common stock from time to time in "at-the-market" offerings under the Shelf.

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 and, if approved, any of our product candidates.

FINANCIAL OPERATIONS OVERVIEW

Revenue

Our revenue is currently generated primarily from product sales of our generic Tussionex recorded on a net sales basis. We sell our product 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 profits from the Tussionex ANDA, and the commercial launch of Adzenys XR-ODT, we expect our future revenue to increase from historical levels.

We historically had generated revenue from manufacturing, development and profit sharing from a development and manufacturing agreement until we terminated our development and manufacturing agreement in August 2014. As a result of our acquisition of the rights to commercialize and derive future profits from the Tussionex ANDA, we have utilized our manufacturing capability to derive revenue directly from sales made by us, rather than through a commercial partner. Sales of our generic Tussionex are seasonal and correlate with the cough and cold season.

In the future, we will seek to generate additional revenue from product sales of Adzenys XR-ODT and, if approved, our two late-stage branded product candidates. We do not expect to generate any significant revenue unless or until we commercialize our product candidates. We launched Adzenys XR-ODT on May 16, 2016. We have no Adzenys XR-ODT sales history and have determined that at this time we cannot reliably estimate expected returns of the product at the time of shipment to wholesalers. Accordingly, we defer recognition of revenue on product shipments of Adzenys XR-ODT until the right of return no longer exists, which occurs at the earlier of the time Adzenys XR-ODT units are dispensed through patient prescriptions or expiration of the right of return. We calculate patient prescriptions of Adzenys XR-ODT dispensed using an analysis of third-party information. If we fail to successfully market Adzenys XR-ODT or to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, 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 of employees engaged in research and development activities;
- expenses incurred under third party agreements with contract research organizations ("CROs"), and investigative sites that conducted 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.

The largest component of our total operating expenses has historically 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(unaudited) (in thousands)			
NT-0102 Cotempla XR-ODT	$ 966	$ 91	$ 1,222	$ 2,510
NT-0201 Amphetamine Liquid	742	113	817	147
NT-0202 Adzenys XR- ODT	587	33	1,012	81
Other Research and Development Activities (1)	1,958	1,865	3,543	3,684
	$ 4,253	$ 2,102	$ 6,594	$ 6,422

(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 seek regulatory approval of our two ADHD product candidates and explore new product candidates, but will decrease as a percentage of revenue if Adzenys XR-ODT is commercially successful or any of our product candidates are approved and 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 IPO and debt financing and revenues, if any, from Adzenys XR-ODT and, if approved, our product candidates.

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.

On October 16, 2015, we received notification from the FDA stating that, as part of its ongoing review of our NDA for Cotempla XR-ODT, it had identified deficiencies that precluded discussion of labeling and post marketing requirements or commitments at that time. On November 10, 2015, we announced that we received a Complete Response Letter from the FDA, which requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an

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assessment of food effect, and to provide process validation and three months of stability data. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. We expect to resubmit an NDA for Cotempla XR-ODT and submit an NDA for NT-0201, our amphetamine XR liquid suspension, in the fourth quarter of 2016. Any further actions required by the FDA may result in further research and development expenses. For additional information regarding the FDA review process, including the Prescription Drug User Fee Act, see "Government Regulation—NDA and FDA review process" in our Annual Report on Form 10-K as filed with the SEC on March 18, 2016.

Selling and marketing

Selling and marketing expenses consist primarily of salaries and related costs for personnel, commercialization activities for Adzenys XR-ODT and our product candidates, trade sales expenses for our generic Tussionex and commercial sales organization costs incurred in the preparation for and in the launch of Adzenys XR-ODT. Other selling and marketing expenses include market research, brand development, advertising agency and other public relations costs, managed care relations, sales planning and market data and analysis.

We expect that our selling and marketing expenses will increase with the commercialization of Adzenys XR-ODT and, if approved, our product candidates, particularly as we move to a business model in which we commercialize our own products 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 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 Adzenys XR-ODT and, if approved, our product candidates. In addition, 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. We are evaluating the paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to Adzenys XR-ODT. Should we determine that litigation is warranted, we anticipate incurring increasing amounts of legal fees in the enforcement of our intellectual property rights.

Interest expense, net

Interest income consists of interest earned on our cash and cash equivalents and short-term investments. The primary objective of our investment policy is liquidity and capital preservation.

Interest expense to date has consisted primarily of interest expense on senior debt, including the amortization of debt discounts, a subordinated note payable to a related party (“Note”) and the capitalized leases resulting from the sale-leaseback transactions of our 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. An additional element of interest expense is the loss on debt extinguishment incurred upon prepaying the Loan and Security Agreement with Hercules (“LSA”) and the Note, which consisted of a prepayment charge, payment of legal fees on behalf of the lender and writing off unamortized end-of-term fees and unamortized debt discount.

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. These sale-leaseback financings occurred in five separate transactions, each with a 42-month lease term. The gains on the transactions are being recognized on a straight-line basis over the respective 42-month lease term (see Note 6 in the notes to our financial statements above). Other income and expense also included changes resulting from the remeasurement of the fair values of our earnout liability and our warrant liabilities through the effective date of the IPO, July 22, 2015.

RESULTS OF OPERATIONS

Three months ended June 30, 2016 compared to the three months ended June 30, 2015

Revenues

The following table summarizes our revenues for the three months ended June 30, 2016 and 2015:

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	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Product	$ 1,485	$ 1,484	$ 1	0.1%

Total product revenues were unchanged at $1.5 million for the three months ended June 30, 2016 and 2015, most of which were generated from net sales of our generic Tussionex for which we acquired all commercialization and profit rights in August 2014. Also included were the initial $48,000 of net sales based on dispensed patient prescriptions of our Adzenys XR-ODT which was launched May 16, 2016.

We have no sales history for Adzenys XR-ODT and have determined that at this time we cannot reliably estimate expected returns of the product at the time of shipment to wholesalers. Accordingly, we defer recognition of revenue on product shipments of Adzenys XR-ODT until the right of return no longer exists, which occurs at the earlier of the time Adzenys XR-ODT units are dispensed through patient prescriptions or expiration of the right of return. We calculate patient prescriptions of Adzenys XR-ODT dispensed using an analysis of third-party information.

Cost of goods sold

The following table summarizes our cost of goods sold for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Cost of Goods Sold	$ 1,682	$ 1,659	$ 23	1.4%

The total cost of goods sold was essentially unchanged at $1.7 million for the three months ended June 30, 2016 and June 30, 2015. The $23,000 increase was primarily due to a $0.2 million increase in other cost of goods sold, principally due to $0.1 million of increased lab and manufacturing supplies and $0.1

million of raw material scrap expense, partially offset by a $0.1 million decrease in labor costs and a $0.1 million decrease in facility costs due to capitalized costs associated with the Adzenys XR-ODT inventory build.

Research and development expenses

The following table summarizes our research and development expenses for three months ended June 30, 2016 and 2015:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Research and Development Expenses	$ 4,253	$ 2,102	$ 2,151	102.3%

Research and development expenses were $4.3 million for the three months ended June 30, 2016, an increase of $2.2 million or 102.3%, from the $2.1 million for the three months ended June 30, 2015. This increase was primarily due to a $1.2 million increase in clinical studies for our product candidates, $0.5 million for the quarterly regulatory fees for Adzenys XR-ODT, a $0.3 million increase in research and development materials to support our clinical programs, a $0.2 million increase in research and development compensation expense and a $0.1 million increase in medical affairs spending, partially offset by a $0.1 million decrease in services of outside firms.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Selling and Marketing	$ 16,046	$ 602	$ 15,444	2,565.4%

The total selling and marketing expenses were $16.0 million for the three months ended June 30, 2016, an increase of $15.4 million or 2,565.4%, from the $0.6 million for the three months ended June 30, 2015. Commercial sales organization costs increased $6.9 million due to the outsourced field salesforce and sales support organization. Selling and marketing professional services, exclusive of commercial sales organization costs, increased by $6.9 million due to advertising agency costs for Adzenys launch promotions, managed care research and marketing expenses and non-personal promotion and data analysis costs incurred in 2016 for Adzenys XR-ODT. Salary and compensation expense increased $1.3 million for the build out of our sales and marketing management as part of the launch of Adzenys XR-ODT. In addition, selling and marketing travel and entertainment expenses increased $0.3 million related to commercialization activities.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
General and Administrative	$ 3,508	$ 1,659	$ 1,849	111.5%

The total general and administrative expenses were $3.5 million for the three months ended June 30, 2016, an increase of $1.8 million or 111.5%, from the $1.7 million for the three months ended June 30, 2015. Salary and compensation expense increased $1.0 million in the three months ended June 30, 2016 primarily due a $0.7 million increase in compensation related to share-based payments and a $0.3 million increase in 2016 principally due to the addition of personnel to handle the administrative and compliance work associated with being a public and commercial company. Also, professional fees increased $0.5 million in 2016 primarily for legal, public filing, SOX compliance and information technology services. In addition, general and administrative expenses increased by $0.2 million in 2016 for the officers insurance policy premium in 2016 as a result of completing our IPO and $0.1 million for board of directors fees and expenses.

Interest expense

The following table summarizes interest expense for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Interest Expense, Net	$ 2,695	$ 884	$ 1,811	204.9%

The total interest expense was $2.7 million for the three months ended June 30, 2016, an increase of $1.8 million or 204.9%, from the $0.9 million for the three months ended June 30, 2015. Of this increase, the early prepayment of the LSA resulted in a $1.2 million loss on debt extinguishment due to recording the $0.2 million LSA prepayment charge, writing off the $0.5 million of unamortized LSA end of term charge and the $0.5 million of unamortized LSA loan. Additionally, interest on the senior debt was $0.7 million higher due to the increased amount of debt in 2016, which was partially offset by a $0.1 million reduction in capital lease interest due to the reduced capital lease balances resulting from ongoing lease payments and interest income on short term investments.

Other income (expense), net

The following table summarizes our other income (expense) for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Other Income, Net	$ 160	$ (331)	$ 491	148.3%

Other income, net was $0.2 million of net income for the three months ended June 30, 2016, an absolute increase of $0.5 million or 148.3%, from the $0.3 million of net expense for the three months ended June 30, 2015. This decrease reflects the change in 2015 in the fair values of the earnout liability and the warrant liabilities due to the projected impact of the DEA's reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance and a review of the anticipated launch dates of our three ADHD product candidates. In 2016, as a result of our IPO, the warrants are no longer being revalued at each balance sheet date (see Note 2 — W*arrants* in the notes to our financial statements above).

Six months ended June 30, 2016 compared to the six months ended June 30, 2015

Revenues

The following table summarizes our revenues for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Product	$ 4,068	$ 1,912	$ 2,156	112.8%

Total product revenues were $4.1 million for the six months ended June 30, 2016, an increase of $2.2 million or 112.8%, from the $1.9 million for the six months ended June 30, 2015. The $2.2 million increase in product revenues primarily resulted from sales of our generic Tussionex to a large pharmacy chain in 2016, which were initiated in the second fiscal quarter of 2015. Also included in revenues were the initial $48,000 of net sales based on dispensed patient prescriptions of our Adzenys XR-ODT which was launched May 16, 2016.

We have no sales history for Adzenys XR-ODT and have determined that at this time we cannot reliably estimate expected returns of the product at the time of shipment to wholesalers. Accordingly, we defer recognition of revenue on product shipments of Adzenys XR-ODT until the right of return no longer exists, which occurs at the earlier of the time Adzenys XR-ODT units are dispensed through patient prescriptions or expiration of the right of return. We calculate patient prescriptions of Adzenys XR-ODT dispensed using an analysis of third-party information.

Cost of goods sold

The following table summarizes our cost of goods sold for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Cost of Goods Sold	$ 3,954	$ 2,754	$ 1,200	43.6%

The total cost of goods sold was $4.0 million for the six months ended June 30, 2016, an increase of $1.2 million or 43.6%, from the $2.8 million for the six months ended June 30, 2015. This increase was primarily due to a $1.1 million increase in raw material costs

due to the increased sales of Tussionex and initial sales of Adzenys XR-ODT and a $0.3 million increase in other cost of goods sold, principally due to $0.2 million of increased lab and manufacturing supplies and $0.1 million of expenses for services from outside firms, partially offset by a $0.2 million decrease in facility costs due to commercialization of Adzenys XR-ODT.

Research and development expenses

The following table summarizes our research and development expenses for six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Research and Development Expenses	$ 6,594	$ 6,422	$ 172	2.7%

Research and development expenses were $6.6 million for the six months ended June 30, 2016, an increase of $0.2 million or 2.7%, from the $6.4 million for the six months ended June 30, 2015. This increase was primarily due to a $1.2 million increase in clinical studies for our product candidates, a $0.8 million accrual of the regulatory fee for Adzenys XR-ODT, a $0.2 million increase in research and development materials to support our clinical programs, a $0.2

million increase in research and development compensation expense and a $0.2 million increase in medical affairs spending, partially offset by a $2.3 million FDA filing fee for the NDA for Cotempla XR-ODT submitted in January 2015 and a $0.1 million decrease in services of outside firms.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Selling and Marketing	$ 22,330	$ 928	$ 21,402	2,306.3%

The total selling and marketing expenses were $22.3 million for the six months ended June 30, 2016, an increase of $21.4 million or 2,306.4%, from the $0.9 million for the six months ended June 30, 2015. Commercial sales organization cost increased $9.2 million due to the outsourced field salesforce and sales support organization. Selling and marketing professional services, exclusive of commercial sales organization costs, increased by $9.2 million due to advertising agency costs for Adzenys launch promotions, managed care research and marketing costs, non-personal promotion for the launch of Adzenys XR-ODT, purchases of sales data, administrative costs associated with savings offers for Adzenys XR-ODT and public relations costs incurred in 2016 for Adzenys XR-ODT. Additionally, salary and compensation expense increased $2.3 million and recruiting fees increased $0.2 million for the build out of our sales and marketing management. Selling and marketing travel and entertainment expenses increased $0.5 million related to commercialization activities.

General and administrative expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
General and Administrative	$ 7,058	$ 2,996	$ 4,062	135.6%

The total general and administrative expenses were $7.1 million for the six months ended June 30, 2016, an increase of $4.1 million or 135.6%, from the $3.0 million for the six months ended June 30, 2015. Salary and compensation expense increased $2.1 million in the six months ended June 30, 2016 primarily due a $1.2 million increase in compensation related to share-based payments and a $0.9 million increase in 2016, principally due to the addition of personnel to handle the administrative and compliance work

associated with being a public and commercial company. Also, professional fees increased $1.3 million in 2016 primarily for legal, public filing, audit, tax, SOX compliance, information technology and business development services. In addition, general and administrative expenses increased by $0.4 million in 2016 for the officers' insurance policy premium in 2016 as a result of completing our IPO, $0.1 million for board of directors fees and expenses, $0.1 million for state license and permit fees $0.1 million for depreciation.

Interest expense

The following table summarizes interest expense for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Interest Expense, Net	$ 3,656	$ 1,641	$ 2,015	122.8%

The total interest expense was $3.7 million for the six months ended June 30, 2016, an increase of $2.0 million or 122.8%, from the $1.7 million for the six months ended June 30, 2015. Of this increase, the early prepayment of the LSA resulted in a $1.2 million loss on debt extinguishment due to recording the $0.2 million LSA prepayment charge, writing off the $0.5 million of unamortized LSA end of term charge and the $0.5 million of unamortized LSA loan discount. Additionally, interest on senior debt was $1.0 million higher due to the increased amount of debt in 2016 and interest on the subordinated debt was $0.1 million higher due to the temporary reduction in 2015 in the interest rate on the note from 10% to 6% pursuant to the Settlement and Release of Claims Agreement with Essex and a third party (see Note 15 in the notes to our financial statements above). These increases were partially offset by a $0.3 million reduction in capital lease interest due to the reduced capital lease balances resulting from ongoing lease payments and interest income on short term investments.

Other income (expense), net

The following table summarizes our other income (expense) for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Increase (Decrease)
	(unaudited) (in thousands)			
Other Income, Net	$ 371	$ 520	$ (149)	(28.7)%

Other income, net was $0.4 million for the six months ended June 30, 2016, a decrease of $0.1 million or 28.7%, from the $0.5 million for the six months ended June 30, 2015. This decrease reflects the change in 2015 in the fair values of the earnout liability and the warrant liabilities due to the projected impact of the DEA's reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance and a review of the anticipated launch dates of our three ADHD product candidates. In 2016, as a result of our IPO, the warrants are no longer being revalued at each balance sheet date (see Note 2 — W*arrants* in the notes to our financial statements above).

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

Since our reorganization in 2009 until our IPO, we have 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. 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.

On May 11, 2016, we entered into a $60 million senior secured credit facility ("Facility") with Deerfield as lender. Principal on the new 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 have an option to defer payment of each of the first four interest payments until June 1, 2017. We exercised the option to defer the first interest payment, adding such amount to the outstanding loan principal until it is paid on June 1, 2017. 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 million. In connection with the Facility, we paid a $1,350,000 yield enhancement fee to Deerfield, approximately $173,000 of legal costs to our attorneys and $58,000 of legal fees on behalf of Deerfield's attorneys. 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 10% Note, which were otherwise payable in 2016 and 2017.

As of June 30, 2016, we had $41.9 million in cash and cash equivalents and $38.2 million in short-term investments. Between December 2014 and February 2015, we issued and sold 4,124,871 shares of Series C redeemable convertible preferred stock ("Series C preferred stock") for net proceeds of $20.6 million, of which $7.5 million was received in the December 31, 2014 and $13.1 million was received in the first three months of 2015. Between June 30 and July 27, 2015, we issued 1,000,000 shares of our Series C preferred stock to several investors upon the exercise of warrants for Series C preferred stock ("Series C warrants") held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $5.0 million. On March 13, 2015, we received an advance of $5.0 million under our senior debt facility as a result of achievement of a certain regulatory milestone. In addition, on June 10, 2015, we drew down the final $5.0 million tranche under our senior debt facility prior to meeting the milestones associated with that tranche. 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.

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.

Cash flows

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

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)
	(unaudited) (in thousands)		
Net Cash (used in) provided by:			
Net Cash used in operating activities	$ (31,711)	$ (12,796)	$ (18,915)
Net Cash (used in) provided by investing activities	(41,385)	2,654	(44,039)
Net Cash provided by financing activities	24,219	22,430	1,789
Net (decrease) increase in cash and cash equivalents	$ (48,877)	$ 12,288	$ (61,165)

Cash used in operating activities

Net cash used in operating activities during these periods primarily reflected our net losses and changes in working capital, partially offset by non-cash charges including depreciation expense, amortization of intangible assets net of amortized gain on sale of equipment, changes in fair value of warrant and earnout liabilities, and share-based compensation expense.

Net cash used in operating activities was $31.7 million and $12.8 million for the six months ended June 30, 2016 and 2015, respectively. The $18.9 million increase in net cash used from operating activities was due to the $26.8 million increase in our net losses, as discussed above, partially offset by a $4.9 million increase in the provision of cash from working capital changes and a $3.0 million increase in noncash items. The increase in provision of cash from working capital changes primarily resulted from a net $5.3 million increase in accounts payable and accrued expenses due to the timing of vendor invoicing and payments and a $2.6 million increase in deferred revenue related to the launch of Adzenys XR-ODT, partially offset by increased cash usage from a $2.2 million increase in inventories associated with increased sales of our generic Tussionex and initial sales of Adzenys XR-ODT and a $0.5

million increase in deferred contract sales organization fees. The increase in noncash items was principally due to a $1.2 million increase in share-based compensation expense, the $0.9 loss on debt extinguishment related to unamortized debt discount, the $0.5 million of deferred interest on the Facility, the $0.1 million increase in the changes in the fair value of the warrant and earnout liabilities since 2015, a $0.1 million increase in amortization of intangible assets and a $0.1 million increase in depreciation and amortization of property and equipment due to equipment to be used in the production and testing of Adzenys XR-ODT and, if approved, our other product candidates and a new ERP system.

Cash (used in) provided by investing activities

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

Net cash used by investing activities was $41.4 million for the six months ended June 30, 2016 primarily due to the $38.2 million net purchase of short term investments, $2.7 million of capital expenditures principally for equipment to be used in the production and testing of Adzenys XR-ODT and, if approved, our other product candidates and a new ERP system and $0.5 million for fees related to a license associated with the commercialization of Adzenys XR-ODT. Net cash provided by investing activities of $2.7 million for the six months ended June 30, 2015 was primarily due to the net sale of $3.0 million of short term investments, partially offset by a $0.3 million of capital expenditures in 2015 in association with the expansion of our controlled substances vault.

Cash provided by financing activities

Net cash provided by financing activities of $24.2 million in the six months ended June 30, 2016 resulted from proceeds of $60.0 million from the issuance of notes to Deerfield, partially offset by a $1.4 yield enhancement fee paid to Deerfield and $0.2 million of legal fees, the full repayment of the $25.0 million of principal under the LSA and $7.2 million of principal and interest under the related party loan, a $1.1 million end of term charge payment and $0.9 million of principal payments under the sales leasebacks. Net cash provided by financing activities of $22.4 million in the six months ended June 30, 2015 primarily resulted from proceeds of $13.8 million, net of issuance costs, received from the sale of 2,624,936 shares of our Series C preferred stock and the exercise of warrants for 150,000 shares of Series C preferred stock and proceeds of $10.0 million from the remaining drawdowns under the LSA (see "-Credit Facilities" below for details), partially offset by $0.6 million of deferred IPO costs and $0.8 million of principal payments under the sales leasebacks.

Credit facilities

On May 11, 2016, we entered into a $60 million senior secured credit facility ("Facility") with Deerfield Private Design Fund III, L.P. (66 2/3% of loan) and Deerfield Special Situations Fund, L.P. (33 1/3% of Loan) ("Deerfield"), as lenders. 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 10% amended and restated subordinated note (the "Note") that was issued by us to Essex Capital Corporation ("Essex") which was to mature in March 2017, which were otherwise payable in 2016 and 2017. Principal on the new 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 have an option to defer payment of each of the first four interest payments until June 1, 2017. As of June 30, 2016, we had exercised the option to defer the first interest payment, adding such amount to the outstanding loan principal until it is paid on June 1, 2017. 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 million. In connection with the Facility, we paid a $1,350,000 yield enhancement fee to Deerfield, approximately $173,000 of legal costs to our attorneys and $58,000 of legal fees on behalf of Deerfield's attorneys.

The Facility, also contains certain customary nonfinancial covenants, including limitations on our ability to transfer assets, engage in a change of control, merge or acquire with or into another entity, incur additional indebtedness and distribute assets to shareholders. Upon an event of default, the lender may declare all outstanding obligations accrued under the Facility to be immediately due and payable, and exercise its security interests and other rights. As of June 30, 2016, we were in compliance with the covenants under the Facility.

In March 2014, we entered into the LSA with Hercules Technology III, L.P., and ("Hercules"), which was subsequently amended in August 2014, September 2014, December 2014 and June 2015. As amended, the LSA provided a total commitment of $25.0 million, available in four draws. Borrowings under the LSA were collateralized by substantially all of our assets, except our intellectual property and assets under capital lease. The first draw of $10.0 million, ("Tranche 1"), was issued during March 2014 and was used in its entirety to repay outstanding principal under a previous credit facility. The second draw of $5.0 million, ("Tranche 2"), was issued during September 2014. The third draw ("Tranche 3") in the amount of $5.0 million was issued in March 2015. In June 2015, the

fourth and final draw of $5.0 million, ("Tranche 4"), was issued prior to meeting the Tranche 4 milestones, which were met in July 2015.

Each draw was to be repaid in monthly installments, comprised of interest-only monthly payments until May 2016, when installments of interest and principal calculated over a thirty-month amortization period commenced. A balloon payment of the entire principal balance outstanding on October 1, 2017 and all accrued but unpaid interest thereunder was due and payable on October 1, 2017. The interest rate was 9% per annum for Tranche 1 and Tranche 4 and 10.5% per annum for Tranche 2 and Tranche 3. An end of term charge of $1.1 million was paid on May 11, 2016 when we prepaid our outstanding Secured Obligations, as defined therein.

The LSA, as amended, also contained certain financial and 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, repurchase or redeem stock or other equity interest other than pursuant to employee stock repurchase plans or other similar agreements, make investments and engage in transactions with affiliates. Upon an event of default, the lender could declare the unpaid principal amount of all outstanding loans and interest accrued under the loan and security agreement to be immediately due and payable, and exercise its security interests and other rights. As of December 31, 2015, we were in compliance with the covenants under the LSA, as amended.

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. On July 19, 2014, the interest rate on the Note was reduced to 6% for the period from July 19, 2014 through June 28, 2015 pursuant to an amendment to the Note entered into as consideration for the $128,000 payment made by us to Essex as part of the Settlement and Release of Claims Agreement with Essex and a third party. This agreement resolved certain issues and disputes whereby Essex paid $256,000 to the third party, we paid Essex $128,000 and Essex agreed to reduce the interest rate on the Note from 10% to 6% for the July 2015 through June 2015. The third party released both Essex and us from any and all claims. At May 11, 2016 and December 31, 2015, the aggregate principal amount of the Note was $5.9 million and $1,317,000 and $1,059,000 in interest had been accrued through May 11, 2016 and December 31, 2015, respectively.

During the years ended December 31, 2014 and 2013, we entered into five 42-month agreements with Essex for the sale-leaseback of existing and newly acquired assets with a total capitalized cost of $795,000 and $5.5 million, respectively, and a bargain purchase option at the end of the respective lease, all of which are classified as capital leases. The approximate imputed interest rate on these leases is 14.5%. 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 $125,000,000 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 $40,000,000 of our common stock from time to time in “at-the-market” offerings under the Shelf.

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 or, if approved, our product candidates. In addition, we may not be profitable even if we succeed in commercializing Adzenys XR-ODT or, if approved, any of our product candidates. We expect to continue to incur operating losses in the future over the next several years as we seek regulatory approval for our product candidates and build commercial infrastructure to support sales and marketing of Adzenys XR-ODT or, if approved, our product candidates. We believe that our existing cash and cash equivalents and short-term investments will be sufficient to fund our anticipated operating requirements for at least the next twelve months. 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 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 and timing involved in obtaining regulatory approvals for our product candidates;
- the timing and number of product candidates for which we obtain regulatory approval;
- the costs of developing and 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;
- the costs of our manufacturing capabilities to support our commercialization activities, including any costs associated with adding new capabilities;

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- 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 as we evolve into a commercial organization.

We may not generate a sufficient amount of product revenues from sales of Adzenys XR-ODT to finance our cash requirements. Until we obtain regulatory approval to market our 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, 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 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 generated from product sales, recorded on a net sales basis in consideration of product returns, Medicaid rebates and wholesaler chargebacks, each of which is described in more detail below. Product revenue is recognized when all of the following Criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; price to the buyer is fixed and determinable; and collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if the price to the buyer is substantially fixed or determinable at the date of sale, the buyer has paid for the product, or the buyer is obligated to pay for the product and the obligation is not contingent on resale of the product, the buyer's obligation to pay would not be changed in the event of theft or physical destruction or damage of the product, the buyer acquiring the product for resale has economic substance apart from that provided by us, we do not have significant obligations for future performance to directly bring about resale of the product by the buyer and the amount of future returns can be reasonably estimated.

We have no sales history for Adzenys XR-ODT and have determined that at this time we cannot reliably estimate expected returns of the product at the time of shipment to wholesalers. Accordingly, we defer recognition of revenue on product shipments of Adzenys XR-ODT until the right of return no longer exists, which occurs at the earlier of the time Adzenys XR-ODT units are dispensed through patient prescriptions or expiration of the right of return. We calculate patient prescriptions of Adzenys XR-ODT dispensed using an analysis of third-party information.

We sell our generic Tussionex and Adzenys XR-ODT to a limited number of pharmaceutical wholesalers. 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.

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Net product sales

Net product sales for our generic Tussionex and Adzenys XR-ODT products represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments include savings offers, wholesaler fees and, in the case of generic Tussionex, estimated allowances for product returns, rebates and chargebacks and prompt-payment discounts to be incurred on the selling price of the respective product sales. Wholesale distribution fees based on definitive contractual agreements are incurred on the management of these products by wholesalers and are recorded within net sales for generic Tussionex and as deferred wholesale distribution fees in other current assets for Adzenys XR-ODT. The deferred wholesale distribution fees for Adzenys XR-ODT are later recorded within net product sales when revenue associated with those fees is recognized. We estimate and record gross to net sales adjustments for product returns, rebates and chargebacks based upon analysis of third-party information, including information obtained from our third party logistics providers ("3PLs"), with respect to its inventory levels and sell-through to the wholesalers' customers, for savings offers from data available from third parties regarding savings offers processed for prescriptions written for our products, and, for generic Tussionex, experience reported by our previous commercialization partners. 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 all other allowances and accruals are recorded in the same period that the related revenue is recognized.

Savings offers

We offer savings offers programs for Adzenys XR-ODT to patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. We record the amount redeemed based on information from third-party providers and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Product returns

Wholesalers' contractual return rights are limited to defective product, product that was shipped in error, product ordered by customer in error, product returned due to overstock, product returned due to dating or product returned due to recall or other changes in regulatory guidelines. The return policy for expired product allows the wholesaler to return such product starting six months prior to expiry date to twelve months post expiry date.

Generic Tussionex product returns are estimated based upon data available from sales of our product by our former commercialization partner and from actual experience as reported by retailers. Historical trend of returns will be continually monitored and may result in future adjustments to such estimates. On August 26, 2014, the U.S. Drug Enforcement Agency ("DEA") reclassified our generic Tussionex from a Schedule III controlled substance to a Schedule II controlled substance which had the effect of requiring unsold product at the wholesalers and the 3PL to either be relabeled or returned. This new ruling was effective October 6, 2014. As such, we established reserves for the estimated returns of such product outstanding at the wholesalers as of October 6, 2014. We had no inventory labeled as Schedule III at the 3PL as of the effective date.

Rebates

Our products are subject to government-managed Medicare and Medicaid programs whereby discounts and rebates are provided to participating federal and/or state governments. Estimated rebates payable under governmental programs are recorded as a reduction of revenue at the time revenues are recorded. Calculations related to these rebate accruals are estimated based on information from third-party providers. Historical trend of governmental 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. Chargebacks are accounted for by establishing an accrual in an amount equal to our estimate of chargeback claims at the time of product sale based on information provided by third parties. Due to estimates and assumptions inherent in determining the amount of chargebacks, the actual amount of claims for chargebacks may be different from estimates, which may result in adjustments to such reserves.

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 its 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. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest.

We reported share-based compensation expense for stock options granted to employees in our consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(unaudited) (in thousands)			
General and Administrative				
Options	$ 785	$ 115	$ 1,385	$ 189
Restricted Stock	22	22	45	45
	$ 807	$ 137	$ 1,430	$ 234

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 recently 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 the historical volatility of a representative peer group of comparable companies' selected using publicly available industry and market capitalization data. 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 Staff Accounting Bulletin 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 five-year 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. The weighted-average key assumptions used in determining the fair value of options granted during the periods indicated are as follows:

	Six Months Ended June 30, 2016 (unaudited)
Estimated dividend yield	0%
Expected stock price volatility	60%
Weighted-average risk-free interest rate	1.21%
Expected life of option in years	6.25
Weighted-average option fair value at grant	$ 6.05

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

In determining fair value for our common stock, the third party valuation firm determined the fair value of our common stock on the date of grant based on several factors, including:

- our stage of development and business strategy;
- the price per share at which our redeemable convertible preferred stock was issued to investors and the rights, preferences and privileges of the redeemable convertible preferred stock relative to the common stock;
- our financial condition and book value;
- economic and competitive elements affecting us, our industry and our target markets;
- our projected operating results;
- a comparative analysis of our financial condition and operating results with those of publicly-owned companies engaged in similar lines of business;
- the current and historical relationship between the reported stock prices and revenue and earnings levels of selected publicly traded companies engaged in similar lines of business;
- important developments relating to the results of our three branded product candidates; and
- the likelihood of achieving a liquidity event for our outstanding shares of stock.

The valuations we obtained were prepared in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (the "Practice Aid"), which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its common stock. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. Prior to August 2014, we generally used the income approach, utilizing the discounted cash flow method to determine our value and allocating to classes of equity using an option pricing model. Since August 2014, we utilized the Probability-Weighted Expected Return Method ("PWERM"), to determine the value attributable to common stock based on a private company scenario and an initial public offering scenario. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. For each scenario, we utilized the discounted cash flow method to determine our value, allocated to classes of equity using an option pricing model and applied the PWERM approach, weighted based on management's expectations, yielding an estimated marketable, minority fair value of our common stock. A discount for lack of marketability ("DLOM"), based on an option based approach (put option) was then applied, yielding a fair value of our common stock on a non-marketable basis. The material assumptions involved to estimate the fair value of our common stock are the estimated timing of commercial launch dates for our product candidates, the probability weighting

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of the private company scenario and the initial public offering scenario, the timeline to liquidity under each scenario and the DLOM under each scenario.

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.

Intangible assets

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

Warrant liability

We account for our warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on our balance sheet at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense), net, in the statements of operations. Our Series C warrants and Hercules Warrants were classified as liabilities, and we estimated the fair value of these liabilities using option pricing models and assumptions that were based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for expected volatility, contractual term, dividend yield, and risk-free interest rate (see Notes 4, 9 and 10 in the notes to our financial statements above). In connection with the completion of our IPO, all the outstanding Series C warrants and Hercules Warrants automatically converted into warrants to purchase shares of common stock. Upon closing the IPO, the Series C warrants were exchanged in a cashless exercise for 947,185 shares of Series C preferred stock which converted into 78,926 shares of our common stock. The Hercules Warrants to purchase 170,000 pre-split shares of Series C preferred stock were converted into warrants to purchase 70,833 shares of our common stock and the warrant liability was reclassified to Additional Paid in Capital within Stockholders' Equity because the converted warrants met the definition of an equity instrument under derivative accounting guidance.

CONTRACTUAL COMMITMENTS AND OBLIGATIONS

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 $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 10% Note, which were 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 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 have an option to defer payment of each of the first four interest payments until June 1, 2017. As of June 30, 2016, we had exercised the option to defer the first interest payment, and, subsequently in July 2016, we exercised the option to defer the second interest payment due September 1, 2016, adding such amounts to the outstanding loan principal until they are paid on June 1, 2017. Borrowings under the Facility are collateralized by substantially all of our assets, except our assets under capital lease, and we will maintain cash on deposit of not less than $5 million.

The following tables reflect summaries of our estimates of future material contractual obligations as of June 30, 2016, as adjusted to reflect the payments which will be due under the new senior secured credit agreement with Deerfield. Future events could cause actual payments to differ from these estimates.

	Total	< 1 Yr	1-3 Yrs.	3-5 Yrs	Thereafter
			(unaudited) (In thousands)		
Deerfield senior secured facility	95,502	8,366	30,643	39,637	16,856
Capital leases for equipment	1,532	1,407	125	—	—
Earnout liability	257	—	—	—	257
Texas facility operating lease	8,547	931	1,911	1,985	3,720
Pennsylvania office space lease	728	145	299	284	—
	$ 106,566	$ 10,849	$ 32,978	$ 41,906	$ 20,833

We had borrowed all $60.0 million under the Deerfield Facility as of June 30, 2016. The payments above are inclusive of related interest amounts as of June 30, 2016.

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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 with Shire for a non-exclusive license to certain patents for certain activities with respect to our 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. Due to the uncertainty of when these royalty payments will be made and the amount of such royalty payments, they are not presented in the table above. 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 Condensed Consolidated Financial Statements in Item 1 above for further discussion of recent accounting pronouncements.

JOBS ACT

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

ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk

We are exposed to market risk related to changes in interest rates as it impacts our interest income. As of June 30, 2016, we had cash and cash equivalents of $41.9 million and short-term investments of $38.2 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates as our cash equivalents are invested in interest-bearing money market funds. The goals of our investment policy are liquidity and capital preservation to fund our operations. Due to the short-term duration and low risk profile of our cash equivalents and short-term investments portfolios, a 10% change in interest rates would not have a material effect on interest income we recognize or the fair market value of our investments. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates.

Interest risk

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

Effects of Inflation

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

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act of 1934, as amended, (the "Exchange Act"), our management, with the participation of our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period

covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings at this time. 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. 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.

ITEM 1A. RISK FACTORS.

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

RISKS RELATED TO COMMERCIALIZATION

We are heavily dependent on the success of Adzenys XR-ODT and our product candidates, Cotempla XR-ODT and NT-0201. We have not generated substantial revenues from the sales of Adzenys XR-ODT or 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 and, if approved, our product candidates. We have only generated revenues from the sale of our generic Tussionex and contract manufacturing, which contract manufacturing operations were discontinued in 2013. We have only commenced commercializing Adzenys XR-ODT in May 2016 and have not generated substantial revenues from product sales of Adzenys XR-ODT, have not generated any revenues from product sales of our product candidates and 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"), and, if approved, our product candidates, Cotempla XR-ODT, our methylphenidate XR-ODT, and NT-0201, our amphetamine XR liquid suspension, for the treatment of attention deficit hyperactivity disorder, or ADHD, and any other product candidates that we may identify and pursue. Our ability to successfully commercialize Adzenys XR-ODT and our product candidates depends on, among other things, our ability to:

- manufacture commercial quantities of Adzenys XR-ODT and, if approved, our product candidates at acceptable cost levels;
- successfully establish and maintain sales and marketing capabilities to commercialize Adzenys XR-ODT and, if approved, our product candidates; and
- obtain regulatory approvals for Cotempla XR-ODT and NT-0201.

We anticipate incurring significant costs associated with commercialization of Adzenys XR-ODT and, if approved, our product candidates. 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 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, and there is no guarantee that we will be successful in the commercialization of Adzenys XR-ODT, which we only launched in May 2016. We currently have no sales history for Adzenys XR-ODT. Additionally, we may need to build additional sales, marketing and distribution capabilities for Cotempla XR-ODT and NT-0201, if they are approved. We must finish building these capabilities for Cotempla XR-

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ODT and NT-0201, and/or enter into a marketing collaboration with a third party, in order to commercialize Cotempla XR-ODT and NT-0201, if approved. 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 for Adzenys XR-ODT have only been recently established. Establishing and developing our sales force in the United States to market Adzenys XR-ODT was expensive and time-consuming and, if additional such resources are needed for Cotempla XR-ODT and NT-0201, doing so for Cotempla XR-ODT and NT-0201 could similarly be expensive and time consuming and could delay the launch of those products, if approved. We cannot be certain that we will reap the benefits of our commercialization efforts of Adzenys XR-ODT compared to its cost, and there is no guarantee that we will be able to successfully develop this capacity for Cotempla XR-ODT and NT-0201, and even if we do, the cost of establishing and maintaining such an organization may exceed the benefit of doing so.

Our prior experience in the marketing, sale and distribution of pharmaceutical products is limited to our generic Tussionex, and we have 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 and our product candidates outside of the United States and intend to also enter into strategic partnerships with third parties for certain aspects of our commercialization efforts within the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. 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 product 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 U.S. Food and Drug Administration (“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, industry-sponsored scientific and educational activities 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.

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 NT-0201. 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.

Moreover, the facilities used by us to manufacture Cotempla XR-ODT and NT-0201 will be subject to pre-approval inspections after we submit, and, in the case of Cotempla XR-ODT, resubmit our NDAs to the FDA. For example, the FDA conducted a cGMP and

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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. 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 product candidates or if it withdraws any such approval in the future, our ability to develop or market any of our product candidates 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 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 drug product and facility user fees that may be substantial. 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 FDCA;
- impose restrictions on the marketing or manufacturing of any product candidate or product;
- 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; 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 and, if approved, Cotempla XR-ODT and NT-0201, 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 NT-0201, and a substantial majority of our resources are now focused on the commercial launch in the United States of Adzenys XR-ODT, commenced on May 16, 2016, and, if approved, Cotempla XR-ODT by the third quarter of 2017 and NT-0201 in the fourth quarter of 2017. Accordingly, our ability to generate significant product revenue will depend almost entirely on our ability to successfully commercialize Adzenys XR-ODT and to obtain final marketing approval for and successfully commercialize Cotempla XR-ODT and NT-0201. We may not sell Cotempla XR-ODT or NT-0201 in the United States until the FDA grants final marketing approval and, therefore, our planned commercial launch of Cotempla XR-ODT and NT-0201 in the United States could experience unanticipated delays or problems and may be prohibited altogether.

Our ability to successfully commercialize Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201 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 NT-0201;

- manufacture and produce, through a validated process, sufficiently large quantities and inventory of Adzenys XR-ODT, Cotempla XR-ODT and NT-0201 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;
- 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 and, if approved, Cotempla XR-ODT and NT-0201 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 have begun, and 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 commercial launch of Adzenys XR-ODT commenced on May 16, 2016, and, if approved, the planned commercial launch of Cotempla XR-ODT and NT-0201. We have committed and will continue to commit these additional resources prior to obtaining final approval of any of Cotempla XR-ODT or NT-0201 from the FDA. If we are unable to successfully obtain final FDA approval of any of our product candidates or complete these activities, or experience unanticipated delays or problems, our costs could substantially increase and our business, financial condition and results of operations will be adversely affected. In addition, we have certain revenue expectations with respect to the sale of Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201. If we cannot successfully commercialize and achieve those revenue expectations with respect to Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201, our anticipated revenues and liquidity will be materially adversely impacted.

Moreover, even if we are able to timely launch Adzenys XR-ODT and, if approved, Cotempla XR-ODT or NT-0201, 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 name Adderall XR and 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, 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 Shire, Noven, Alcobra, Highland Therapeutics, Sunovian 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

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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 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 product and product candidates that receive regulatory approval, including in comparison to branded or generic competitors;
- the efficacy and safety of our product 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 product 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 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 product, if any, or that reach the market sooner than our products, if any, 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 product 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 product or product candidates, our ability to successfully commercialize such product 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 product and product candidates will be clinically differentiated from branded drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our product and product candidates against other drugs, the opportunity for our product and, if approved, product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

After an NDA, including a 505(b)(2) application, is approved, the covered product becomes a "listed drug" that, in turn, can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, implementing regulations and other applicable laws provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as the listed drugs, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices.

Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product, such as Adzenys XR-ODT, or Cotempla XR-ODT and NT-0201, if approved, 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.

On July 25, 2016, we received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an ANDA with the FDA for a generic version of Adzenys XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Adzenys XR-ODT. While we have the option of bringing a patent infringement suit in federal district court against Actavis within 45 days from the date of receipt of the notice, such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if Actavis is found not to infringe such patents. We are evaluating the paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to Adzenys 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 NT-0201, 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 NT-0201 is a regulated drug product and subject to 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. 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.

We rely on limited sources of supply for Adzenys XR-ODT, Cotempla XR-ODT, NT-0201 and our generic Tussionex, and any disruption in the chain of supply may impact production and sales of Adzenys XR-ODT, Cotempla XR-ODT, NT-0201 and our generic Tussionex, and cause delays in developing and commercializing our product candidates and currently manufactured and commercialized products.

Our approved NDA for Adzenys XR-ODT, and the NDAs we plan to resubmit for Cotempla XR-ODT and submit for NT-0201, 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 and amend any pending 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, NT-0201 or our generic Tussionex to an alternate supplier, and a change of facilities would be a time-consuming and costly endeavor. This would also require us to supplement or amend our NDA filings to include the change of manufacturing site.

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 product 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 product 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, U.S. Drug Enforcement Administration (“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 and NT-0201 and our generic Tussionex that differ from the suppliers used for clinical development of such product candidates.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our products and product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of Adzenys XR-ODT, our generic Tussionex and, if approved, our branded product candidates 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, NT-0201 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 in quantities that meet their demand, and in the future we may enter into agreements with similar penalties for Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201. 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 developments, 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.

If we fail to manufacture Adzenys XR-ODT, or if approved, Cotempla XR-ODT or NT-0201 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 this product or our product candidates 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 and, if approved, Cotempla XR-ODT and NT-0201, we have installed specialized processing equipment in our Grand Prairie, Texas facilities, which we believe will produce sufficient quantities of Adzenys XR-ODT and if approved, Cotempla XR-ODT and NT-0201, for commercialization. We purchase raw materials and components from various suppliers in order to manufacture Adzenys XR-ODT, Cotempla XR-ODT and NT-0201. 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 NT-0201, and may not be able to meet our customers' demands for Adzenys XR-ODT, Cotempla XR-ODT and NT-0201.

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 product. 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 the Company who was, at the time, PharmaFab's president, and Russ McMahen, our 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 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. 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 or, if approved, Cotempla XR-ODT or NT-0201 to meet market demand for Adzenys XR-ODT, Cotempla XR-ODT and NT-0201 on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of Adzenys XR-ODT or, if approved, Cotempla XR-ODT or NT-0201, 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 and, if approved, Cotempla XR-ODT and NT-0201 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 and, if approved, Cotempla XR-ODT and NT-0201. 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, and, if approved, Cotempla XR-ODT and NT-0201, 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, our generic Tussionex and, if approved, our product candidates for commercialization, or future potential product candidates for clinical development, may be jeopardized. Our inability to continue manufacturing adequate supplies of Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201, could adversely affect our ability to generate revenues.

All of our manufacturing capabilities are housed in our sole 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, NT-0201 or our generic Tussionex at our Grand Prairie, Texas facilities could result in a disruption in the supply of Adzenys XR-ODT, and, if approved, Cotempla XR-ODT, and NT-0201, or our generic Tussionex, to physicians and pharmacies, which would adversely affect our ability to generate revenues.

If other patient-friendly forms of extended-release amphetamine or methylphenidate products are approved and successfully commercialized, especially if approved before we can successfully commercialize Adzenys XR-ODT, or, if approved, Cotempla XR-ODT or NT-0201, our business would be materially harmed.

Other third parties may seek approval to manufacture and market their own versions of extended-release amphetamine or methylphenidate in patient-friendly dosage forms for the treatment of ADHD 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 Cotempla XR-ODT and, as a result, we may never achieve significant market share for this product. 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, 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 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.

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 the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate. Additionally, there are legal challenges to the Affordable Care Act in lower courts on other grounds. We will not know the full effects of the Affordable Care Act until applicable federal and state agencies issue regulations or guidance under the law. Although it is too early to determine the effect of 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.

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

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

Additionally, drug prices are under significant scrutiny, and along with other health care costs, continue to be subject to intense political and societal pressures, which we anticipate 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.

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

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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 product or, if approved, product candidates their commercial success may be severely hindered.

Successful sales of our product 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 and, if approved, Cotempla XR-ODT and NT-0201, will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

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

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

Our relationships with customers 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 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. The laws that may affect our ability to operate include:

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

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, which imposes certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to Centers for Medicare and Medicaid Services (“CMS”), information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, 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 criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

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 will 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.

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

We are heavily dependent on the success of our product candidates, Cotempla XR-ODT and NT-0201. We cannot give any assurance that we will receive regulatory approval for such product candidates or any other 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 our product candidates, Cotempla XR-ODT and NT-0201, for the treatment of ADHD, and any other 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. For example, on November 10, 2015, we announced that we received a Complete Response Letter from the FDA for our NDA for Cotempla XR-ODT. We will need to satisfactorily address the deficiencies the FDA identified or may identify in the future in order to obtain the FDA's approval of our NDA. 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.

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 Cotempla XR-ODT, NT-0201 or any other product candidate that we may identify and develop;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate safety and effectiveness of any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the safety risks outweigh clinical and other benefits of our product candidates;
- may require us to conduct additional bioequivalence studies to demonstrate that the proposed commercial product is bioequivalent to the batch used in clinical trials;
- may disagree with our trial design or our interpretation of data from nonclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we inappropriately relied on a certain listed drug or drugs for our 505(b)(2) NDA or that approval of our applications for Cotempla XR-ODT, NT-0201 or any other 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.

For example, on October 16, 2015, we received notification from the FDA stating that, as part of its ongoing review of our NDA for Cotempla XR-ODT, it had identified deficiencies that precluded discussion of labeling and post marketing requirements or commitments at that time. On November 10, 2015, we announced that we received a Complete Response Letter from the FDA, which requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. We expect to resubmit an NDA for Cotempla XR-ODT in the fourth quarter of 2016, but if we are unable to satisfactorily address the agency's concerns, the FDA could deny approval of our NDA for Cotempla XR-ODT.

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.

The FDA may determine that our NDA for NT-0201 for the treatment of attention deficit hyperactivity disorder is not sufficiently complete to permit a substantive review.

We intend to submit to the FDA an NDA for NT-0201, which will be indicated for the treatment of ADHD, in the fourth quarter of 2016. Within 60 days of the agency's receipt of an NDA, the FDA will make a threshold determination of whether the NDA is sufficiently complete to permit a substantive review. This 60-day review is referred to as the filing review. If the NDA is sufficiently

complete, the FDA will file the NDA. If the agency refuses to file the NDA, it will notify us and state the reason(s) for the refusal. The FDA may refuse to file an NDA for various reasons, including, but not limited to, if:

- the NDA is incomplete because it does not on its face contain the information required under the Federal Food, Drug, and Cosmetic Act, or FDCA, or the FDA's regulations;

- the NDA does not contain a statement that each nonclinical laboratory study was conducted in compliance with the GLP, requirements, or for each study not so conducted, a brief statement of the reason for the noncompliance;

- the NDA does not contain a statement that each clinical trial was conducted in compliance with the FDA's institutional review board ("IRB"), regulations or was not subject to those regulations, and the agency's informed consent regulations or a brief statement of the reason for noncompliance; and

- the drug is a duplicate of a listed drug approved before receipt of the NDA and is eligible for approval under an ANDA, for generic drugs.

In its procedures, the FDA has stated that it could find a 505(b)(2) NDA incomplete and refuse to file it if the NDA:

- fails to include appropriate literature or a listed drug citation to support the safety or efficacy of the drug product;

- fails to include data necessary to support any aspects of the proposed drug that represent modifications to the listed drug(s) relied upon;

- fails to provide a bridge, e.g., via comparative bioavailability data, between the proposed drug product and the listed drug product to demonstrate that such reliance is scientifically justified;

- uses an unapproved drug as a reference product for a bioequivalence study; and

- fails to provide a patent certification or statement as required by the FDA's regulations where the 505(b)(2) NDA relies on one or more listed drugs.

Additionally, the FDA will refuse to file an NDA if an approved drug with the same active moiety is entitled to five years of exclusivity, unless the exclusivity period has elapsed or unless four years of the five-year period have elapsed and the NDA contains a certification of patent invalidity or non-infringement.

If the FDA refuses to file our NDA for NT-0201, we may amend the NDA and resubmit it. In such a case, the FDA will again review the NDA and determine whether it is a complete response or may be filed. There can be no assurance that the FDA will file the NDA for NT-0201. If the agency refuses to file the NDA for NT-0201, we will need to address the deficiencies cited by the FDA, which could substantially delay the review process.

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 product candidates described in this Quarterly Report on Form 10-Q. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, 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 Act apply. Accordingly, we may be required to include certifications, known as Paragraph IV certifications, that certify that any patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book"), with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, 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 product 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 product or product candidates may produce undesirable side effects or adverse reactions or events. Although our product 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 product 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 product or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, 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.

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.

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

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

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. 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.

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

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

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

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

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

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

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

Positive results in nonclinical studies and clinical trials of any of our product candidates may not be predictive of similar results in future clinical trials. Also, interim results during a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from any completed nonclinical studies and clinical trials for any of our product candidates may not be predictive of the results we may obtain in later stage trials. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products. For example, On November 10, 2015, we announced that we received a Complete Response Letter from the FDA, which

requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. Although results in this study confirmed results from earlier studies, results from our previous clinical trials may not be predictive of similar results in any future bridging studies.

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. To date, we have focused primarily on developing Adzenys XR-ODT and our product candidates, Cotempla XR-ODT and NT-0201. Adzenys XR-ODT requires substantial additional resources as we implement commercialization strategies and begin generating 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 revenue. We do not anticipate generating substantial revenue from sales of Adzenys XR-ODT, or any revenue from sales of Cotempla XR-ODT, NT-0201 or any of our other product candidates in the near term, if ever. We have incurred significant net losses of $39.2 million for the six months ended June 30, 2016, and $30.8 million and $20.8 million for the years ended December 31, 2015 and 2014, respectively. As of June 30, 2016, we had an accumulated deficit of $155.9 million. We have devoted most of our financial resources to 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 build 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.

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, 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 and, if approved, Cotempla XR-ODT, NT-0201 and any other potential product candidates;

- our ability to successfully launch Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201, and to continue to increase the level of sales in the marketplace;

- the timing of any regulatory approvals of Cotempla XR-ODT and NT-0201;

- 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.

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 June 30, 2016, we had an accumulated deficit of $155.9. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we 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:

- any delays in regulatory review and approval of our product candidates;
- our ability to establish 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 intellectual property infringement lawsuit in which we may become involved; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carry-forwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. We 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.

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. Our independent registered public accounting firm considered our internal controls over financial reporting as of December 31, 2015 for purposes of expressing an opinion on our financial statements but not for purposes of expressing an opinion on the effectiveness of our internal controls, and one significant deficiency in internal controls was identified in connection with the preparation of our financial statements. The significant deficiency was due to inadequate design and implementation of general controls surrounding our information technology, or IT. We are taking steps to remedy the significant deficiency including implementing a new enterprise resource planning software to support financial reporting processes in our efforts to prepare for compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. We are in the very early stages of the costly and challenging process of compiling our system of internal controls over financial reporting and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may discover additional deficiencies in our internal controls over financial reporting, including those identified through testing conducted by us in connection with Section 404 of the Sarbanes-Oxley Act or subsequent testing by our independent registered public accounting firm. Such deficiencies may be deemed to be significant deficiencies or material weaknesses and may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior 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.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from 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 incur liability 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 and, if approved, Cotempla XR-ODT or NT-0201 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 and, if approved, Cotempla XR-ODT and NT-0201, 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 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 Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an ANDA with the FDA for a generic version of Adzenys XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Adzenys 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. We are evaluating the paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to Adzenys XR-ODT. While we have the option of bringing a patent infringement suit in federal district court against Actavis within 45 days from the date of receipt of the notice, such litigation is often time-consuming and costly and its outcome would be unpredictable. We would expect to face generic competition for our Adzenys XR-ODT product if such patents are not upheld or if Actavis is found not to infringe such patents. The resulting loss of exclusivity would impact pricing and our sales of Adzenys 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 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 their approved products and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our products and product candidates may give rise to claims of infringement of the patent rights of others. There may, for example, be issued patents of third parties of which we are currently unaware, that may be infringed by our products or product candidates, which could prevent us from being able to commercialize our products or product candidates, respectively. Because patent applications can take many years to issue, there may be currently pending applications which may later result in issued patents that our products or product candidates may infringe.

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

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

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

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

Our drug development strategy relies heavily upon the 505(b)(2) regulatory approval pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of

intellectual property infringement, the defense of which would be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory approval pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay. However, even if the third party does not sue within the 45-day time limit, thereby invoking the 30-month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45-day limit. 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 LLC, or 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 with Shire for certain of Shire's patents with respect to our Adzenys XR-ODT NDA. Under the terms of the 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 to pay a single-digit royalty on net sales of Adzenys XR-ODT during the life of Shire's 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 $6.81 to $28.99, through August 11, 2016. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- 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;
- failure to successfully execute our commercialization strategy with respect to Adzenys XR-ODT and, if approved, Cotempla XR-ODT or NT-0201, or any other approved potential product candidate in the future;
- 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 product candidates;
- inability to manufacture adequate amounts of product supply or obtain adequate amounts of components of our product supply for our product candidates, 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, NT-0201 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;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

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

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

As of June 30, 2016, our executive officers, directors, 5% or greater stockholders and their affiliates, including shares purchased in the IPO by members of that group and their affiliated entities, beneficially own approximately 55% 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.

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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. Approximately 10,471,356 of our shares became eligible for sale upon expiration of the lock-up period on January 18, 2016, although a portion of such shares held by our affiliates will be subject to volume limitations and other conditions pursuant to Rule 144 of the Securities Act. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period also became eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

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 Sarbanes-Oxley Act, as well as rules subsequently implemented by 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 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 Sarbanes-Oxley 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 billion, 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 Sarbanes-Oxley 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.

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

During the three months ended June 30, 2016, we issued a total of 24,771 shares of its common stock to several investors upon the exercise of Series B-1 warrants held by those investors at an exercise price of $0.0024 per share.

The issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that each issuance of securities was to an accredited investor under Rule 501 of Regulation D and did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. There were no underwriters employed in connection with any of the transactions set forth above.

Use of Proceeds

On July 13, 2015, we commenced our initial public offering, or IPO, pursuant to a registration statement on Form S-1 (File No. 333-205106) that was declared effective by the SEC on July 22, 2015. On July 28, 2015, we closed our IPO whereby we sold 5,520,000 shares of common stock, at a public offering price of $15.00 per share for an aggregate offering price of $82.8 million, which includes 720,000 shares of common stock resulting from the underwriters’ exercise of their over-allotment option at the IPO price on July 23, 2015. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were $75.0 million. The managing underwriters of the IPO were UBS Securities, LLC, BMO Capital Markets Corp., RBC Capital Markets, LLC and JMP

Securities, LLC. No offering expenses were paid or are payable directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

The net proceeds from the offering have been invested in highly-liquid money market funds, government securities or corporate institutions whose debt is rated as investment grade. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 24, 2015.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

		Incorporated by Reference to:			
Exhibit No.	Description	Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-Q	3.1	9/4/15	001-37508
3.2	Amended and Restated By-Laws of the Registrant.	10-Q	3.2	9/4/15	001-37508
4.1	Specimen Common Stock Certificate of the Registrant.	S-1	4.1	7/13/15	333-205106
10.1	Facility Agreement, dated May 11, 2016, among the Registrant, Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P.				
10.2	Employment Agreement, dated as of May 26, 2016, between the Registrant and Juergen A. Martens, Ph.D., EMTM	8-K	10.1	5/31/16	001-37508
31.1	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
31.2	Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.				
101.INS	XBRL Instance Document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Link Document.				

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* 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.

SIGNATURES

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

Neos Therapeutics, Inc.

Date:	August 12, 2016	By:	/s/ Vipin Garg Vipin Garg *President and Chief Executive Officer*
Date:	August 12, 2016	By:	/s/ Richard Eisenstadt Richard Eisenstadt Chief Financial Officer (*Principal Financial and Accounting Officer*)

Exhibit 10.1

FACILITY AGREEMENT

FACILITY AGREEMENT (this "**Agreement**"), dated as of May 11, 2016, between Neos Therapeutics, Inc., a Delaware Corporation (the "**Borrower**"), and the lenders set forth on the signature page of this Agreement (together with their successors and permitted assigns, the "**Lenders**" and, together with the Borrower, the "**Parties**").

W I T N E S S E T H:

WHEREAS, the Borrower wishes to borrow from the Lenders a maximum of Sixty Million Dollars ($60,000,000) for the purpose described in Section 2.1; and

WHEREAS, the Lenders desire to make loans to the Borrower for such purpose,

NOW, THEREFORE, in consideration of the mutual agreements set forth herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

Section 1.1 **General Definitions**. Wherever used in this Agreement, the Exhibits or the Schedules attached hereto, unless the context otherwise requires, the following terms have the following meanings:

"**Affiliate**" means, with respect to any Person, any other Person that directly or indirectly:

(a) owns more than 10% of the beneficial ownership interest of such Person;

(b) controls, or is controlled by, or is under common control with, such Person; or

(c) is a general partner, or managing member of such Person.

A Person shall be deemed to be "**controlled by**" any other Person if such Person possesses, directly or indirectly, power to vote ten percent (10%) or more of the securities (on a fully diluted basis) having ordinary voting power for the election of directors or managers or power to direct or cause the direction of the management and policies of such Person whether by contract or otherwise.

"**Agreement Date**" means the date of this Agreement.

"**Applicable Laws**" means all statutes, rules and regulations of Governmental Authorities in the United States or elsewhere applicable to the Borrower and its Subsidiaries.

"**Authorizations**" has the meaning set forth in Section 3.1(q).

"**Business Day**" means a day on which banks are open for business in The City of New York.

"**Change of Control**" means (a) any "Person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Exchange Act) other than the holders of Borrower's voting stock on the Agreement Date or their Controlled Investment Affiliates, is or shall at any time become the "beneficial owner" (as defined in Rule 13(d)-3 and 13(d)-5 under the Exchange Act), directly or indirectly, of greater than 50% of the voting interest in Borrower's stock, or (b) a sale of substantially all of the assets of Borrower and its Subsidiaries.

"**Code**" means the Internal Revenue Code of 1986, as amended, and any Treasury Regulations promulgated thereunder.

"**Commercial Products**" has the meaning given to it in Section 5.4.

"**Controlled Investment Affiliate**" means as to any Person, any other Person that (a) directly or indirectly, is in Control of, is Controlled by, or is under common Control with, such Person and (b) is organized by such Person primarily for the purpose of making equity or debt investments in one or more companies.

"**Default**" means any event which, at the giving of notice, lapse of time or fulfillment of any other applicable condition (or any combination of the foregoing), would constitute an Event of Default.

"**Disbursement**" and "**Disbursement Request**" have the meaning given to them in Section 2.2.

"**Dollars**" and the "**$**" sign mean the lawful currency of the United States of America.

"**Event of Default**" has the meaning given to it in Section 5.4.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, including the rules and regulations promulgated thereunder.

"**Excluded Taxes**" means with respect to any Lender, (a) Taxes imposed on (or measured by) such Lender's net income, franchise Taxes and branch profit Taxes, in each case (i) imposed by the jurisdiction (or any political subdivision thereof) under the laws of which such Lender is organized or incorporated or in which the applicable lending office of such Lender is located, or (ii) that are Other Connection Taxes, (b) any United States federal withholding Tax imposed on amounts payable to such Lender under the laws in effect at the time such Lender becomes a party to this Agreement or such

Lender changes its lending office, except to the extent such Lender acquired its interest in the Loan from a transferor that was entitled, immediately before such transfer, to receive such Additional Amounts with respect to such withholding Tax pursuant to Section 2.5(a), (c) any United States withholding Tax imposed on amounts payable to such Lender as a result of such Lender's failure to comply with Section 2.5(d) other than as a result of such Lender's legal inability to comply with Section 2.5(d) as a result of a change in law occurring subsequent to the date such Lender became a party to this Agreement, or (d) any

United States withholding Tax imposed on amounts payable to such Lender due to such Lender's non-compliance with FATCA.

"**Excluded Transaction**" means any of the following transactions:

The entering into any collaborative arrangement, licensing, joint venture, partnership, royalty agreement or similar agreements or other research, development manufacturing or other commercial exploitation arrangements relating to Borrower or any Subsidiary's Intellectual Property or other assets (provided, that Borrower has a reasonable basis for believing that the downstream economics potentially to be received by Borrower and its Subsidiaries in connection with such collaborative arrangement, licensing, joint venture, partnership, royalty agreement or similar agreements or other research, development, manufacturing or other commercial exploitation arrangements relating to the IP, when combined with the potential downstream economics of rights in the IP retained by Borrower and its Subsidiaries are adequate to enable Borrower to timely satisfy all obligations of the Borrower and its Subsidiaries under this Agreement), including, without limitation, but subject to the conditions set forth above, (1) any grant to any entity engaged in, or owned by an entity engaged in, the pharmaceutical or biotechnology industry of a license or option to obtain a license to any of Borrower's or any Subsidiary's Intellectual Property or other assets, provided that Borrower or a Subsidiary directly receives from such entity all consideration paid or payable by such entity in consideration of such grant, which consideration may, but need not, include (without limitation) upfront, milestone, royalty and profit-sharing payments, (2) any grant of a license or option to obtain a license to any entity that intends to research, develop, commercialize or manufacture products or services covered by such Intellectual Property or other assets whether directly or through Borrower, any Subsidiary or another entity, and (3) any arrangement or transfers of assets for the manufacture, research, promotion and development of Borrower's or any Subsidiary's products and clinical trial management, and data analysis and similar activities in support of Borrower's or any Subsidiary's development programs.

"**Essex**" means Essex Capital Corporation.

"**Existing Lenders**" means, collectively, Hercules and Essex.

"**Existing Loan Documents**" means that certain Loan and Security Agreement dated March 28, 2014, between Borrower, Pharmafab Texas, LLC and Neos Therapeutics, LP and Hercules and that certain Third Amended and Restated Subordinated Promissory Note dated December 31, 2013, by and between Borrower and Essex, each as amended, amended and restated, supplemented, extended or otherwise modified from time to time.

"**FATCA**" means Sections 1471 through 1474 of the Code as of the date of this Agreement (or any amended or successor version that is substantially comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof and any agreement entered into pursuant to Section 1471(b)(1) of the Code and any intergovernmental agreements entered into in connection with the foregoing.

"**FDA**" means the US Food and Drug Administration.

"**GAAP**" means generally accepted accounting principles consistently applied as set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board (or agencies with similar functions of comparable stature and authority within the accounting profession).

"**Governmental Authority**" means any government, quasi-governmental agency, governmental department, ministry, cabinet, commission, board, bureau, agency, court, tribunal, regulatory authority, instrumentality, judicial, legislative, fiscal, or administrative or public body or entity, whether domestic or foreign, federal, state or local, having jurisdiction over the matter or matters and Person or Persons in question, including, but not limited to the FDA.

"**Health Care Laws**" means all laws relating to the provision and/or administration of, and/or payment for, healthcare products or services, including, without limitation, Applicable Laws with respect to (in each case, to the extent applicable): (a) health care fraud and abuse (including without limitation the following statutes, as amended, modified or supplemented from time to time and any successor statutes thereto and regulations promulgated from time to time thereunder: the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)); the Stark Law (42 U.S.C. § 1395nn); the civil False Claims Act (31 U.S.C. § 3729 et seq.); 42 U.S.C. §§ 1320a-7, 1320a-7b; the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173)); and any state, commonwealth or local laws similar to any of the foregoing; (b) Medicare, Medicaid or other programs which are sponsored or maintained by a governmental payor; (c) quality, safety certification and accreditation standards and requirements; (d) HIPAA; (e) prescription drug, medical device or controlled substances registration, approval, importation, sale, use, distribution, compounding, dispensing, transporting, purchasing, storage, tracking, marketing and security, including state pharmacy and controlled substance laws, the Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act, the Prescription Drug Marketing Act of 1987, and Food and Drug Administration rules and regulation; (l) the provision of free or discounted care or services; and (m) the conditions of participation or enrollment as a provider/supplier in and Laws governing health programs administered by or paid for, in whole or in part by, Governmental Payors.

"**Health Care Permits**" means any and all Permits issued or required under applicable Health Care Laws.

"**Hercules**" means, collectively, Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc.

"**HIPAA**" means the (a) Health Insurance Portability and Accountability Act of 1996; (b) the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009); and (c) any state, commonwealth and local laws regulating the privacy and/or security of individually identifiable health information, including state laws providing for notification of breach of privacy or security of individually identifiable health information, in each case with respect to the laws described in clauses (a), (b) and (c) of this definition, as the same may be amended, modified or supplemented from time to time, any successor statutes thereto, any and all rules or regulations promulgated from time to time thereunder.

"**Indebtedness**" means the following:

(i) all indebtedness for borrowed money;

(ii) the deferred purchase price of assets or services (other than payables) which in accordance with GAAP would be shown to be a liability (or on the liability side of a balance sheet);

(iii) all guarantees of Indebtedness;

(iv) all letters of credit issued or acceptance facilities established for the account of the Borrower and any of its Subsidiaries, including without duplication, all drafts drawn thereunder (except to the extent cash collateralized);

(v) all capitalized lease obligations;

(vi) all indebtedness of another Person secured by any Lien on any property of the Borrower or its Subsidiaries, whether or not such indebtedness has been assumed or is recourse (with the amount thereof, in the case of any such indebtedness that has not been assumed by the Borrower or its Subsidiaries, being measured as the lower of (x) fair market value of such property and (y) the amount of the indebtedness secured); and

(vii) indebtedness created or arising under any conditional sale or title retention agreement.

"**Indemnified Person**" has the meaning given to it in Section 6.11.

"**Indemnified Taxes**" means all Taxes including Other Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of the Borrower under any Loan Document.

"**Indemnity**" has the meaning given to it in Section 6.11.

"**Interest Rate**" means 12.95% per annum.

"**IP**", "**Company IP**" and "**Intellectual Property**" have the meaning given to it in Section 3.1(m).

"**IRS**" means the United States Internal Revenue Service.

"**License**" means any license of Intellectual Property.

"**Lien**" means any lien, pledge, mortgage, security interest, deed of trust, charge, assignment, hypothecation, title retention, or other encumbrance on or with respect to property; provided, however, that any grant or license or option to obtain a license to, or the sale or other transfer of, the Borrower's IP or other assets, whether directly or through the Borrower or another entity shall not constitute a Lien.

"**Loan**" means the loans made by the Lenders to the Borrower pursuant to Section 2.2 in the aggregate principal amount of Sixty Million Dollars ($60,000,000) or, as the context may require, the principal amount thereof from time to time outstanding.

"**Loan Documents**" means this Agreement, the Notes, the Security Agreement and any other document or instrument executed by the Borrower or any Subsidiary and delivered in connection with any of the foregoing and dated the Agreement Date or subsequent thereto, whether or not specifically mentioned herein or therein.

"**Loss**" has the meaning given to it in Section 6.11.

"**Material Adverse Effect**" means a material adverse effect on (a) the business, financial condition or assets of the Borrower and its Subsidiaries (taken as a whole), (b) the validity or enforceability of any Loan Document, (c) the ability of the Borrower and its Subsidiaries (taken as a whole) to timely perform the Obligations when due or (d) the rights and remedies of the Lenders under any Loan Document; provided, however, that any adverse effect that results directly or indirectly from general economic, business, financial or market conditions shall not be deemed to be a Material Adverse Effect.

"**Medicaid**" means, collectively, the health care assistance program established by Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.) and any statutes succeeding thereto, and all Laws pertaining to such program, including (a) all federal statutes affecting such program; (b) all state and commonwealth statutes and plans for medical assistance enacted in connection with such program and federal rules and regulations promulgated in connection with such program; and (c) all applicable provisions of all rules, regulations and legally binding manuals, orders and administrative and reimbursement requirements of all Governmental Authorities promulgated in connection with such program, in each case as the same may be amended, supplemented or otherwise modified from time to time.

"**Medicare**" means, collectively, the health insurance program for the aged and disabled established by Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.) and any statutes succeeding thereto, and all Laws pertaining to such program including (a) all federal statutes (whether set forth in Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.) or elsewhere) affecting such program; and (b) all applicable provisions of all rules, regulations and legally binding manuals, orders, administrative and reimbursement requirements of all Governmental Authorities promulgated in connection with such program, in each case as the same may be amended, supplemented or otherwise modified from time to time.

"**Notes**" means the Notes issued to the Lenders evidencing the Loan in the form attached hereto as Exhibit A.

"**Obligations**" means all obligations (monetary or otherwise) of the Borrower arising under or in connection with this Agreement and the other Loan Documents.

"**Organizational Documents**" means for any Person as of any date, such Person's charter, constitutional or constituent documents, formation documents and/or certificate of incorporation (or equivalent thereof), and each certificate of change of name, and, (a) if such Person is a corporation, its bylaws or memorandum and articles of association (or equivalent

thereof) in current form, (b) if such Person is a limited liability company, its limited liability company agreement or its shareholders agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Other Connection Taxes**" means with respect to any Lender, Taxes imposed as a result of a present or former connection between such Lender and the jurisdiction imposing such Tax (except a connection arising from such Lender having executed, delivered, become a party to, performed its obligations or received a payment under, received or perfected a security interest under, engaged in any transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan Document).

"**Other Taxes**" means any and all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes arising from any payment made hereunder or from the execution, delivery, registration or enforcement of, or otherwise with respect to, any Loan Document except any such Taxes that are Other Connection Taxes imposed with respect to an assignment (other than an assignment made in connection with the exercise of remedies following an Event of Default).

"**Paragraph IV Certification**" means a certification by an applicant filing an ANDA or 505(b)(2) NDA referencing a drug listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* to the FDA that the patent relating to such listed drug is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the ANDA or 505(b)(2) NDA is submitted.

"**Permits**" means all permits, licenses, registrations, certificates, qualifications, accreditations, approvals or similar rights required to be obtained, from any Governmental Authority.

"**Permitted Indebtedness**" means Indebtedness existing as of the Agreement Date and set forth on Exhibit B attached hereto and:

(i) The Obligations;

(ii) Indebtedness in respect of letters of credit;

(iii) Indebtedness to trade creditors in the ordinary course of business;

(iv) Indebtedness in respect of netting services, overdraft protections and other similar and customary services in connection with deposit accounts;

(v) Performance bonds, surety bonds and similar instruments incurred in the ordinary course;

(vi) Guarantees with respect to any Permitted Indebtedness;

(vii) Indebtedness in respect of purchase money financing, capital lease obligations and equipment financing facilities covering existing and

newly-acquired equipment, including for the acquisition, installation, qualification and validation of such equipment up to an aggregate amount outstanding at any time of $8,000,000;

(viii) Indebtedness to employees in respect of benefit plans and employment and severance arrangements;

(ix) a working capital facility ("Working Capital Facility") not to exceed the aggregate sum of $30,000,000 secured by a Lien on Borrower's and its Subsidiaries' accounts receivables, the proceeds thereof and related property (but, in no event inventory), and in which the borrowing base thereunder is limited to not more than the sum of eighty five percent (85%) of the outstanding face amount of eligible accounts receivables and on such other terms reasonably acceptable to Lenders, which is subject to an intercreditor agreement between the provider of such Working Capital Facility and Lenders on terms reasonably acceptable to Lenders, including that Lenders have the option to purchase such Indebtedness at par after the occurrence of an event of default under the Working Capital Facility;

(x) reimbursement obligations with respect to corporate credit cards;

(xi) Subordinated Debt;

(xii) to the extent constituting Indebtedness, Permitted Investments;

(xiii) to the extent constituting Indebtedness, Indebtedness incurred in connection with the financing of insurance premiums;

(xiv) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(xv) (a) Indebtedness owing from any Subsidiary that is a guarantor to Borrower or any other Subsidiary that is a guarantor, (b) Indebtedness owing from a Subsidiary that is not a guarantor of the Obligations to any other Subsidiary that is not a guarantor of the Obligations, and (c) Indebtedness owing from any Subsidiary that is not a guarantor of the Obligations to Borrower or any Subsidiary that is a guarantor of the Obligations not to exceed $250,000 at any time outstanding;

(xvi) other Indebtedness not to exceed $250,000 at any time outstanding; and

(xvii) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (f) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"**Permitted Liens**" means:

(i) Liens existing on the Agreement Date and set forth on Exhibit B;

(ii) Liens in favor of the Lenders;

(iii) carriers', warehousemen's, landlord's, mechanics', construction, materialmen's, repairmen's or other like Liens arising in the ordinary course of business;

(iv) Liens on accounts receivable, the proceeds thereof and property related thereto (but in no event inventory), securing the Indebtedness described in clause (ix) of the definition of Permitted Indebtedness;

(v) Liens for taxes, assessments or governmental charges or levies not past due and payable or that are being contested in good faith by appropriate proceedings;

(vi) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default;

(vii) Liens in favor of financial institutions arising in connection with the Borrower's or its Subsidiaries' accounts maintained in the ordinary course held at such institutions to secure standard fees for services charged by, but not financing made available by, such institutions;

(viii) Liens, pledges or deposits in connection with workers' compensation, unemployment insurance, old-age pensions, social security and other like obligations;

(ix) Easements, rights of way, restrictions and other similar encumbrances affecting real property which, in the aggregate, are not substantial in amount, and which do not in any case materially interfere with the conduct of the business of the applicable Person;

(x) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code (or equivalent in foreign jurisdictions) on items in the course of collection;

(xi) Liens in favor of lessors of equipment;

(xii) Liens securing the Indebtedness permitted by clauses (vii), (x) (but only in cash in a segregated account in an amount not to exceed 110% of the applicable credit card credit limit), (xiii) (but only to the extent attaching to the relevant policies and amounts payable thereunder) and (xvi) (but only with respect to Indebtedness in an aggregate amount of less than $50,000 at any time outstanding) of the definition of Permitted Indebtedness;

(xiii) the filing of precautionary Uniform Commercial Code financing statements (or equivalent in foreign jurisdictions) in connection with operating leases and consignment arrangements;

(xiv) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods;

(xv) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of goods entered into by the Borrower or any Subsidiary in the ordinary course of business; and

(xvi) deposits securing the performance of bids, trade contracts (other than for borrowed money), contracts for the purchase of property, leases, statutory obligations, surety and appeal bonds, performance bonds and other obligations of a like nature, in each case, incurred in the ordinary course of business and not representing an obligation for borrowed money.

"**Person**" means and includes any natural person, individual, partnership, limited partnership, joint venture, corporation, trust, limited liability company, limited company, joint stock company, unincorporated organization, government entity or any political subdivision or agency thereof, or any other entity.

“**Register**” has the meaning set forth in Section 1.4(b).

“**Required Lenders**” means, at any time, Lenders holding Loans representing more than 50% of the sum of the Loans outstanding.

“**SEC**” means the United States Securities and Exchange Commission.

“**Securities Act**” means the Securities Act of 1933, as amended, including the rules and regulations promulgated thereunder.

“**Security Agreement**” means the Guaranty and Security Agreement of even date herewith among Borrower, its Subsidiaries, Deerfield Mgmt, L.P., as collateral agent for Lenders and Lenders.

“**Subordinated Debt**” means unsecured Indebtedness of the Borrower or a Subsidiary of Borrower in an amount approved by Lenders in their sole discretion subordinated to the Obligations, pursuant to subordination terms contained in a written subordination agreement with Lenders acceptable to the Lenders in their sole discretion.

“**Subsidiary or Subsidiaries**” means, as to any Person, any entity of which securities or other ownership interests having ordinary voting power to elect a majority of the board of directors or other persons performing similar functions are at the time directly or indirectly owned by such Person.

“**Tax Affiliate**” means (a) the Borrower and its Subsidiaries and (b) any Affiliate of the Borrower with which the Borrower files or is required to file consolidated, combined or unitary tax returns.

“**Tax Return**” has the meaning set forth in Section 3.1(o).

“**Taxes**” means all present or future taxes, levies, imposts, stamp or other duties, deductions, assessments, fees or other charges or withholdings imposed by any Governmental Authority, together with any interest, additions to tax or penalties applicable thereto.

Section 1.2 **Interpretation**. In this Agreement, unless the context otherwise requires, all words and personal pronouns relating thereto shall be read and construed as the number and gender of the party or parties requires and the verb shall be read and construed as agreeing with the required word and pronoun; the division of this Agreement into Articles and Sections and the use of headings and captions is for convenience of reference only and shall not modify or affect the interpretation or construction of this Agreement or any of its provisions; the words “herein,” “hereof,” “hereunder,” “hereinafter” and “hereto” and words of similar import refer to this Agreement as a whole and not to any particular Article or Section hereof; the words “include,” “including,” and derivations thereof shall be deemed to have the phrase “without limitation” attached thereto unless otherwise expressly stated; references to a specified Article, Exhibit, Section or Schedule shall be construed as a reference to that specified Article, Exhibit, Section or Schedule of this Agreement; and any reference to any of the Loan Documents means such document as the same shall be amended, supplemented or modified and from time to time in effect.

Section 1.3 **Business Day Adjustment**. If the day by which any payment or other performance is due to be made is not a Business Day, that payment or performance shall be made by the next succeeding Business Day.

Section 1.4

(a) The Borrower shall record on its books and records the amount of the Loan, the interest rate applicable, all payments of principal and interest thereon and the principal balance thereof from time to time outstanding.

(b) The Borrower shall establish and maintain at its address referred to in Section 6.1, a record of ownership (the “**Register**”) in which the Borrower agrees to register by book entry the interests (including any rights to receive payment hereunder) of each Lender in the Loan, and any assignment of any such interest, and accounts in the Register in accordance with its usual practice in which it shall record (1) the names and addresses of the Lenders (and any change thereto pursuant to this Agreement), (2) the amount of the Loan and each funding of any participation therein, (3) the amount of any principal or interest due and payable or paid, and (4) any other payment received by the Lenders from the Borrower and its application to the Loan.

(c) Notwithstanding anything to the contrary contained in this Agreement, the Loan (including any Notes evidencing the Loan) is a registered obligation, the right, title and interest of the Lenders and their assignees in and to the Loan shall be transferable

only upon notation of such transfer in the Register and no assignment thereof shall be effective until recorded therein. This Section 1.4 shall be construed so that the Loan is at all times maintained in “registered form” within the meaning of Sections 163(f), 871(h)(2) and 881(c)(2) of the Code and Treasury Regulations Section 5f.103-1(c).

(d) The Borrower and the Lenders shall treat each Person whose name is recorded in the Register as a Lender for all purposes of this Agreement. Information contained in the Register with respect to any Lender shall be available for access by the Borrower or such Lender at any reasonable time and from time to time upon reasonable prior written notice.

ARTICLE 2

AGREEMENT FOR THE LOAN

Section 2.1 **Use of Proceeds**. The proceeds of the Loan will be used for repayment of existing Indebtedness to the Existing Lenders, for working capital and for general corporate purposes.

Section 2.2 **Disbursement**. Subject to the conditions set forth in Article 4 and this Section 2.2, the Lenders shall disburse Loans to the Borrower ("**Disbursement**") on the date of this Agreement upon receipt from the Borrower of a written request ("**Disbursement Request**") for the Disbursement and stating that no Event of Default has occurred and is continuing. The Lenders shall fulfill the Disbursement in accordance with their respective allocations set forth on Schedule 1 hereto.

Section 2.3 **Payment**.

(a) Borrowers shall repay the outstanding principal amount of the Loan in three equal annual installments in the amount of $15,000,000 each, commencing on May , 2019 and continuing on the same day of each year thereafter, together with a final payment of all outstanding principal and interest and all other outstanding Obligations due and payable on May , 2022 (the "**Maturity Date**"). Subject to Sections 2.3(b) and 2.3(c) Borrowers may prepay the Obligations in whole or in part at any time, from time to time.

(b) The Borrower shall, subject to the provisions of this Section 2.3(b), prepay all of the outstanding Obligations upon the occurrence of a Change of Control. Such prepayment shall be accompanied by all accrued and unpaid interest on the principal amount of the Notes prepaid, plus a prepayment fee in the amount of (i) the sum of 9.25% of the amount of principal prepaid plus all interest which, absent such prepayment, would have accrued on the principal amount of the Notes through the first anniversary of the Agreement Date, if such prepayment occurs prior to the first anniversary of the Agreement Date, (ii) 9.25% of the amount of principal prepaid if such prepayment occurs on or after the first anniversary of the Agreement Date, but prior to the second anniversary of the Agreement Date, (iii) 6.0% of the amount of the principal prepaid if such prepayment occurs on or after the second anniversary of the Agreement date but

prior to the third anniversary of the Agreement Date; (iv) 2.75% of the amount of the principal prepaid if such prepayment occurs on or after the third anniversary of the Agreement Date but prior to the fourth anniversary of the Agreement Date and (v) 2.0% of the amount of the principal prepaid on or after the fourth anniversary of the Agreement Date.

(c) Any other prepayment of the Obligations whether voluntary or as a result of acceleration of the Obligations upon the occurrence of an Event of Default shall be accompanied by all accrued and unpaid interest on the principal amount of the Notes prepaid, plus a prepayment fee in the amount of (i) 9.75% of the amount of principal prepaid, plus all interest which, absent such prepayment, would have accrued on the principal amount of the Notes prepaid through the third anniversary of the Agreement Date, if such prepayment occurs prior to the third anniversary of the Agreement Date, (ii) 9.75% of the amount of principal prepaid if such prepayment occurs on or after the third anniversary of the Agreement Date, but prior to the fourth anniversary of the Agreement Date, (iii) 6.5% of the amount of the principal prepaid if such prepayment occurs on or after the fourth anniversary of the Agreement Date but prior to the fifth anniversary of the Agreement Date; and (iv) 3.25% the amount of the principal prepaid if such prepayment occurs on or after the fifth anniversary of the Agreement Date. Borrowers shall provide Lenders thirty days prior written notice of any voluntary prepayment of the Obligations.

(d) Each prepayment by the Borrower shall be applied first, to accrued and unpaid interest and second, to outstanding principal and shall be allocated among the Lenders in accordance with their respective allocations set forth on Schedule 1 hereto.

Section 2.4 **Payments**. All payments by the Borrower hereunder and under any of the Loan Documents shall be made without setoff or counterclaim. Payments of any amounts due to the Lenders under this Agreement shall be made in Dollars in immediately available funds prior to 1:00 p.m. New York City time on such date that any such payment is due, at such bank or places as the Lenders shall from time to time designate in writing at least 5 Business Days prior to the date such payment is due. The Borrower shall pay all and any costs (administrative or otherwise) imposed by banks, clearing houses, or any other financial institution, in connection with making any payments under any of the Loan Documents, except for any costs imposed by the Lenders' banking institutions.

Section 2.5 **Taxes**.

(a) Any and all payments hereunder or under any other Loan Document shall be made, in accordance with this Section 2.5, free and clear of and without deduction for any and all present or future Taxes except as required by Applicable Law. If Borrower shall be required by Applicable Law to deduct any Taxes from or in respect of any sum payable hereunder or under any other Loan Document, (i) Borrower shall make such deductions, (ii) Borrower shall pay the full amount deducted to the relevant Governmental Authority in accordance with Applicable Law, and (iii) to the extent that the deduction is made on account of Indemnified Taxes, the sum payable shall be increased by as much as shall be necessary so that after making all required deductions(including deductions for Taxes applicable to additional sums payable under

this Section 2.5), each Lender shall receive an amount equal to the sum it would have received had no such deductions been made (any and all such additional amounts payable shall hereinafter be referred to as the "**Additional Amounts**"). Within thirty (30) days after the date of any payment of such Taxes, Borrower shall furnish to the applicable Lender the original or a certified copy of a receipt evidencing payment thereof or other evidence of such payment reasonably satisfactory to such Lender.

(b) Borrower agrees to pay and authorizes each Lender to pay in its name (but without duplication), all Other Taxes. If Borrower directly pays such Other Taxes within 30 days after the date of any payment of Other Taxes, Borrower shall furnish to the applicable Lender the original or a certified copy of a receipt evidencing payment thereof or other evidence of such payment reasonably satisfactory to such Lender.

(c) Without duplication with respect to any Additional Amounts, Borrower shall reimburse and indemnify, within 10 days after receipt of demand therefor, each Lender for all Indemnified Taxes (including all Indemnified Taxes imposed on amounts payable under this

Section 2.5(c)) paid by such Lender, whether or not such Indemnified Taxes were correctly or legally asserted. A certificate of the applicable Lender(s) setting forth the amounts to be paid thereunder and delivered to Borrower shall be conclusive, absent manifest error.

(d) Each Lender that is a "United States person" (as such term is defined in Section 7701(a)(30) of the Code) for United States federal income tax purposes shall, on or before the date on which the Lender becomes a party to this Agreement, provide to Borrower a properly completed and executed IRS Form W-9 certifying that such Lender is not subject to backup withholding tax. Each Lender that is not a United States person for United States federal income tax purposes (a "**Foreign Lender**") and is entitled to an exemption from or reduction of United States withholding tax with respect to payments under this Agreement shall, on or before the date on which the Lender becomes a party to this Agreement, provide Borrower with a properly completed and executed IRS Form W-8ECI, W-8BEN, W-BENE, W-8IMY or other applicable forms (together with any required supporting documentation), or any other applicable certificate or document reasonably requested by the Borrower, and, if such Foreign Lender is relying on the portfolio interest exception of Section 871(h) or Section 881(c) of the Code (or any successor provision thereto), shall also provide the Borrower with a certificate (a "**Portfolio Interest Certificate**") representing that such Foreign Lender is not a "bank" for purposes of Section 881(c) of the Code (or any successor provision thereto), is not a 10% holder of the Borrower described in Section 871(h)(3)(B) of the Code (or any successor provision thereto), and is not a controlled foreign corporation receiving interest from a related person (within the meaning of Sections 881(c)(3)(C) and 864(d)(4) of the Code, or any successor provisions thereto). Each Lender shall provide new forms (or successor forms) as reasonably requested by Borrower from time to time and shall notify Borrower in writing within a reasonable time after becoming aware of any event requiring a change in the most recent forms previously delivered by such Lender to Borrower. If the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such

Foreign Lender may provide a Portfolio Interest Certificate on behalf of such direct or indirect Partner.

(e) If a payment to a Lender under this Agreement would be subject to United States withholding tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA, such Lender shall deliver to Borrower, at the times prescribed by law or as reasonably requested by Borrower, such documentation as is required in order for Borrower to comply with its obligations under FATCA, to determine that such Lender has or has not complied with its obligations under FATCA, or to determine the amount to deduct and withhold from such payment.

(f) If a Lender determines in its sole discretion, exercised in good faith, that it has received a refund from a Governmental Authority relating to Taxes in respect of which the Borrower paid Additional Amounts or made a payment pursuant to Sections 2.5(b) or 2.5(c) then, provided no Event of Default has occurred and is continuing, such Lender shall promptly pay such refund (limited to the amount paid by the Borrower under Section 2.5 with respect to the Taxes refunded) to the Borrower, net of all out-of-pocket expense (including Taxes) of such Lender incurred in obtaining such refund or making such payment, provided that the Borrower, upon the request of such Lender, agrees to repay the amount paid over to the Borrower (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) to such Lender if such Lender is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this Section 2.5(f), in no event shall a Lender be required to pay any amount to the Borrower pursuant to this Section 2.5(f), the payments of which would place the Lender in a less favorable net after-Tax position than the Lender would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or Additional Amount with respect to such Tax had never been paid. Nothing in this Section 2.5(f) shall require any Lender to disclose any information it deems confidential (including, without limitation, its tax returns) to any Person, including Borrower.

Section 2.6 **[Reserved]**.

Section 2.7 **Interest**. The outstanding principal amount of the Notes shall bear interest at the Interest Rate (calculated on the basis of a 360 day year for the actual number of days elapsed). Interest shall be paid quarterly in arrears commencing on June 1, 2016 and on the first Business Day of each September, December, March and June thereafter (each, an "**Interest Payment Date**") and on the Maturity Date. Upon thirty days prior written notice from the Borrower to the Lenders prior to any of the first four Interest Payment Dates, Interest otherwise payable on such Interest Payment Date shall not be paid but shall be added to the then outstanding principal amount of the Loans (the aggregate amount of such interest added to principal and all interest accruing thereon, the "**Accrued Interest Amount**"). The Accrued Interest Amount shall be paid on June 1, 2017.

Section 2.8 **Default Interest; Late Payment Fee**. Without limiting the remedies available to the Lenders under the Loan Documents or otherwise, to the maximum extent permitted by applicable law, if an Event of Default occurs and is continuing, at the Lender's

election, the amount outstanding under and in respect of the Notes (which shall include all outstanding principal thereunder, together with any interest and other amounts due and payable with respect to the Notes and not paid when due), shall bear interest at the rate per annum equal to the Interest Rate plus 5.00%. In addition to the foregoing, the Borrower shall pay a late fee on any amount (other than principal) not paid when due (including after giving effect to any grace period provided hereunder) equal to 10% of such overdue amount.

Section 2.9 **Fee**. In consideration of Lenders' agreement to extend the Loan to Borrower, Borrower shall pay to Lenders on the Agreement Date, a yield enhancement payment in the amount of $1,350,000, which yield enhancement payment will be deducted by Lenders from the Disbursement. Borrower agrees to reimburse the Lenders for reasonable, documented out-of-pocket expenses for attorneys, accountants and other professional advisors, and other reasonable documented out-of-pocket expenses incurred by Lenders (i) in connection with their due diligence, negotiation and documentation of the transactions contemplated by the Loan Documents (including their review, negotiation and documentation of any post-closing obligations of the Borrower) and (ii) in connection with all amendments and modifications thereto, whether or not consummated. At Lender's election such reimbursable amounts may be deducted from the Disbursement. The provisions of this Section 2.9 supersede and replace in its entirety that certain Expense Reimbursement Agreement, dated as of April 7, 2016, Neos Therapeutics, Inc. and Deerfield Management Company, L.P. (Series C).

ARTICLE 3

REPRESENTATIONS AND WARRANTIES

Section 3.1 Representations and Warranties of the Borrower. The Borrower represents and warrants to the Lenders that, except as set forth in a Schedule to this Agreement:

(a) The Borrower and its Subsidiaries are conducting their business in compliance with their Organizational Documents, which are in full force and effect.

(b) No Default or Event of Default has occurred and is continuing.

(c) The Borrower and its Subsidiaries (i) are (taken as a whole), on a consolidated basis, capable of paying their debts as they fall due in the ordinary course of business, (ii) have not admitted their inability in writing to pay their debts as they fall due in the ordinary course of business, and (iii) have not taken action, and no such action has been taken by a third party, for the Borrower's or any Subsidiary's winding up, dissolution, or liquidation or similar executory or judicial proceeding or for the appointment of a liquidator, custodian, receiver, trustee, administrator or other similar officer for the Borrower, any Subsidiary or any material portion of or all of their assets or revenues.

(d) No Lien exists on the Borrower's or any Subsidiary's assets, except for Permitted Liens.

(e) The obligation of the Borrower to make any payment under this Agreement (together with all charges in connection therewith) is absolute and unconditional.

(f) No Indebtedness of the Borrower or any Subsidiary exists other than Permitted Indebtedness.

(g) The Borrower is validly existing as a corporation in good standing under the laws of the state of Delaware. The Borrower and its Subsidiaries have full power and authority to own their properties, conduct their business and enter into the Loan Documents and to consummate the transactions contemplated under the Loan Documents, and are duly qualified to do business as a foreign entity and are in good standing in each jurisdiction where the failure to be so qualified could reasonably be expected to result in a Material Adverse Effect.

(h) There is not pending or, to the knowledge of the Borrower, threatened in writing, any action, suit, hearings or other proceeding before any Governmental Authority (a) to which the Borrower or any of its Subsidiaries is a party or (b) which has as the subject thereof any assets owned by the Borrower or any of its Subsidiaries, except, in each case, as would not reasonably be expected to result in a Material Adverse Effect. Except as set forth on Schedule 3.1(h), there are no current or, to the knowledge of the Borrower, pending, legal, governmental or regulatory enforcement actions, suits or other proceedings to which the Borrower or any of its Subsidiaries or any of their assets is subject, except as would not reasonably be expected to result in a Material Adverse Effect.

(i) The Loan Documents have been duly authorized, executed and delivered by the Borrower and each Subsidiary a party thereto, and constitute the valid, legal and binding obligation of the Borrower and its Subsidiaries party thereto, enforceable in accordance with their terms, except as such enforceability may be limited by applicable insolvency, bankruptcy, reorganization, moratorium or other similar laws affecting creditors' rights generally (whether enforcement is sought by proceedings in equity or at law). The execution, delivery and performance of the Loan Documents by the Borrower and its Subsidiaries and the consummation of the transactions therein contemplated will not (A) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute an event of default under, or result in the creation or imposition of any Lien (other than pursuant to the Loan Documents) upon any assets of the Borrower or any of its Subsidiaries pursuant to, any material agreement to which the Borrower or any Subsidiary is a party or by which the Borrower or any of its Subsidiaries are bound or to which any of the assets of the Borrower or any Subsidiary is subject, except to the extent that no Material Adverse Effect would reasonably be expected to result therefrom, (B) result in any violation of or conflict with the provisions of the Organizational Documents, (C) result in the violation of any material Applicable Law or (D) result in the violation of any judgment, order, rule, regulation or decree of any Governmental Authority. No consent, approval, authorization or order of, or registration or filing with any Governmental Authority or other party is required for the execution, delivery and performance of any of the Loan Documents or for the consummation by the Borrower

and its Subsidiaries of the transactions contemplated hereby except for (a) such registrations and filings contemplated by the Security Agreement, (b) as have been obtained or made prior to the date hereof or (c) the failure of which to obtain or make would not reasonably be expected to result in a Material Adverse Effect and the Borrower has the power and authority to enter into the Loan Documents and to consummate the transactions contemplated under the Loan Documents.

(j) [Reserved].

(k) The Borrower and each of its Subsidiaries holds or has applied for, and is operating in good standing and in compliance in all material respects with, all franchises, grants, authorizations, licenses, permits, easements, consents, certificates and orders of any Governmental Authority required for the conduct of its business the failure of which to obtain would reasonably be expected to result in a Material Adverse Effect (collectively, "**Necessary Documents**") and all Necessary Documents are valid and in full force and effect; and neither the Borrower not any Subsidiary has received written notice of any revocation or modification of any of the Necessary Documents and neither the Borrower nor any Subsidiary has any reason to believe that any of the Necessary Documents will not be renewed in the ordinary course of business, and each of the Borrower and its Subsidiaries are in compliance in all material respects with all applicable federal, state, local and foreign laws, regulations, orders and decrees applicable to the conduct of its business.

(l) The Borrower and its Subsidiaries have good and marketable title to all of their assets free and clear of all Liens except Permitted Liens. To Borrower's knowledge, except as could not reasonably be expected to have a Material Adverse Effect, the property held under lease by the

Borrower or any Subsidiary is held under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Borrower or any Subsidiary.

(m) Other than as disclosed in any Paragraph IV Certification made in connection with a new drug application, the Borrower and its Subsidiaries own or, where a license is required, have the right to use pursuant to a valid and enforceable written license, implied license or other legally enforceable right, all of the Intellectual Property (as defined below) that they have publicly described as being owned or licensed by them (the "**Company IP**") or, to the knowledge of the Borrower, that is necessary for the conduct of their business as currently conducted (the "**IP**"). To the knowledge of the Borrower, other than as disclosed in any Paragraph IV Certification made in connection with a new drug application, the Company IP that is registered with or issued by a Governmental Authority is enforceable; there is no outstanding, pending or, to the knowledge of the Borrower, threatened in writing action, suit, other proceeding or claim by any third person challenging or contesting the validity, scope, use, ownership, enforceability, or other rights of the Borrower or any Subsidiary in or to any Company IP and neither the Borrower nor any Subsidiary has received any written notice regarding, any such action, suit, or other proceeding. To the knowledge of the Borrower, other than as disclosed in any Paragraph IV Certification made in connection with a new drug

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application, neither the Borrower nor any Subsidiary has infringed or misappropriated any material rights of others. There is no pending or, to the knowledge of Borrower, threatened in writing action, suit, other proceeding or claim by others that the Borrower or any Subsidiary infringes upon, violates or uses the Intellectual Property rights of others without authorization, and neither the Borrower nor any Subsidiary has received any written notice regarding, any such action, suit, other proceeding or claim. Except as set forth on Schedule 3.1(m), neither the Borrower nor any Subsidiary is a party to or bound by any material licenses with respect to IP other than licenses for computer software acquired in the ordinary course of business. The term "**Intellectual Property**" as used herein means (i) all patents, patent applications, patent disclosures and inventions (whether patentable or unpatentable and whether or not reduced to practice), (ii) all trademarks, service marks, trade dress, trade names, slogans, logos, and corporate names and Internet domain names, together with all of the goodwill associated with each of the foregoing, (iii) copyrights, copyrightable works, and licenses, (iv) registrations and applications for registration for any of the foregoing, (v) computer software (including but not limited to source code and object code), data, databases, and documentation thereof, (vi) trade secrets and other confidential information, (vii) other intellectual property, and (viii) copies and tangible embodiments of the foregoing (in whatever form and medium).

(n) Neither the Borrower nor any of its Subsidiaries is in violation of the Organizational Documents, or, except as could not reasonably be expected to have a Material Adverse Effect, in breach of or otherwise in default under any material agreement under which it may be bound, or to which any of its assets is subject.

(o) All federal and state income and franchise and all other material Tax returns, reports and statements (collectively, the "**Tax Returns**") required to be filed by any Tax Affiliates or extensions have been filed with the appropriate Governmental Authorities, all such Tax Returns are true and correct in all material respects, and all Taxes, assessments and other governmental charges and impositions reflected therein and all other material Taxes, assessments and other governmental charges otherwise due and payable have been paid prior to the date on which any liability may be added thereto for non-payment thereof except for those contested in good faith by appropriate proceedings diligently conducted and for which adequate reserves are maintained on the books of the appropriate Tax Affiliate in accordance with GAAP. As of the Agreement Date, no income or franchise Tax Return or other material Tax Return of the Borrower or any other Tax Affiliate is under audit by any Governmental Authority, and no Tax Affiliate has received written notice from any Governmental Authority of any audit or examination or any assertion of any material claim for Taxes. No Tax Affiliate has participated in a "listed transaction" within the meaning of Treasury Regulation Section 1.6011-4(b) or has been a member of an affiliated, combined or unitary group other than the group of which a Tax Affiliate is the common parent.

(p) Other than as set forth in Schedule 3.1(p), neither the Borrower nor any Subsidiary has granted rights to market or sell its services to any other Person, and are not bound by any agreement that affects the exclusive right of the Borrower or any Subsidiary to develop, license, market or sell its services.

(q) Other than as set forth in Schedule 3.1(q), each of the Borrower and its Subsidiaries: (A) are, as of the date hereof, in compliance with all Applicable Laws in all material respects; (B) has not received any warning letter or other correspondence or notice from any Governmental Authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required in connection with the business of the Borrower or its Subsidiaries by any Applicable Laws (together, the "**Authorizations**"); (C) possesses and complies in all material respects with the Authorizations, which are valid and in full force and effect (other than those Authorizations for which applications have been submitted but which have not yet been issued), in each case, except as would not reasonably be expected to result in a Material Adverse Effect; (D) has not received written notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorization; (E) has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations as and when required, except, in each case, as would not reasonably be expected to result in a Material Adverse Effect.

(r) The audited financial statements of the Borrower and its Subsidiaries as of December 31, 2014 and as of December 31, 2015, together with the related notes fairly present in all material respects the financial condition of the Borrower and its Subsidiaries as of the dates indicated and the results of operations and changes in cash flows for the periods therein specified in conformity with GAAP consistently applied throughout the periods involved.

(s) (i) To the knowledge of the Borrower, no "prohibited transaction" as defined under Section 406 of ERISA or Section 4975 of the Code that is not exempt under ERISA Section 408 or Section 4975 of the Code, under any applicable regulations and published interpretations thereunder or under any applicable prohibited transaction, individual or class exemption issued by the Department of Labor, has occurred with respect to any Employee Benefit Plan, except as for such transaction that would not reasonably be expected to have a Material Adverse Effect, (ii) at no time within the last seven (7) years has the Borrower or any ERISA Affiliate maintained, sponsored, participated in, contributed to or has or had any liability or obligation in respect of any Employee Benefit Plan subject to Section 302 of ERISA, Title IV of ERISA, or Section 412 of the Code or any "multiemployer plan" as defined in Section 3(37) of ERISA, (iii) no Employee Benefit Plan represents any current or future liability for retiree health, life insurance, or other retiree welfare benefits except as may be required by the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or similar state law, (iv) each Employee Benefit Plan is and has been operated in compliance with its terms and all Applicable Laws, including but not limited to ERISA and the Code, except for such failures to comply that would not reasonably be expected to have a Material Adverse Effect, (v) no event has occurred (including a "reportable event" as such term is defined in Section 4043 of ERISA) and no condition exists that would subject the Borrower to any tax, fine, lien, penalty or liability imposed by ERISA, the Code or other Applicable Law, except for any such tax, fine, lien, penalty or liability that would not reasonably be

expected to, individually or in the aggregate, have a Material Adverse Effect and (vi) the Borrower does not have any obligations under any collective bargaining agreement. As used in this clause (t), "**Employee Benefit Plan**" means any material "employee benefit plan" within the meaning of Section 3(3) of ERISA, and all stock purchase, stock option, stock-based severance, employment, change-in-control, medical, disability, fringe benefit, bonus, incentive, deferred compensation, employee loan and all other employee benefit plans, agreements, programs, policies or other arrangements, whether or not subject to ERISA, under which (A) any current or former employee, director or independent contractor of the Borrower or any of its Subsidiaries has any present or future right to benefits and which are contributed to, sponsored by or maintained by the Borrower or any of its respective Subsidiaries or (B) the Borrower or any of its Subsidiaries has had or has any present or future obligation or liability on behalf of any such employee, director or independent contractor; "**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended; "**ERISA Affiliate**" means any member of the Borrower's controlled group as defined in Code Section 414 (b), (c), (m) or (o); and "**Foreign Benefit Plan**" means any Employee Benefit Plan mandated by a government other than the United States of America is subject to the laws or a jurisdiction outside of the United States.

(t) The Borrower's Subsidiaries are set forth in Schedule 3.1(t).

(u) Compliance with Health Care Laws. Other than as set forth in Schedule 3.1(u), each of Borrower and its Subsidiaries is in compliance in all material respects with all Health Care Laws applicable to it, its assets, business or operations.

(v) Health Care Permits. Each of Borrower and its Subsidiaries holds all Health Care Permits necessary for it to own, lease, sublease or operate its assets or to conduct its business or operations as presently conducted. All such Health Care Permits are in full force and effect and there is and has been no default under, violation of, or other noncompliance with the terms and conditions of any such Health Care Permit except as would not reasonably be expected to result in a Material Adverse Effect. No Governmental Authority has taken, or to the knowledge of Borrower intends to take, action to suspend, revoke, terminate, place on probation, materially restrict or not renew any material Health Care Permit of Borrower or any of its subsidiaries.

(w) [Reserved].

(x) Proceedings; Audits. Other than as set forth on Schedule 3.1(x), there are no pending (or, to the knowledge of Borrower, threatened in writing) audits, actions, hearings or proceedings (collectively, "**Proceedings**") against or affecting Borrower or any of its Subsidiaries relating to any actual or alleged non-compliance with any Health Care Law. There exist no restrictions, deficiencies, required plans of correction or other such remedial measures with respect to any material Health Care Permit of Borrower or any of its Subsidiaries.

Section 3.2 **Borrower Acknowledgment**. The Borrower acknowledges that it has made the representations and warranties referred to in Section 3.1 with the intention of

persuading the Lenders to enter into the Loan Documents and that the Lenders have entered into the Loan Documents on the basis of, and in full reliance on, each of such representations and warranties and such representations and warranties shall survive the execution of this Agreement until the Obligations are repaid in full.

Section 3.3 **Representations and Warranties of the Lenders**. Each Lender represents and warrants to the Borrower as of the Agreement Date that:

(a) Such Lender is duly organized and validly existing under the laws of the jurisdiction of its formation.

(b) Each Loan Document to which it is a party has been duly authorized, executed and delivered by such Lender and constitutes the valid and legally binding obligation of such Lender, enforceable in accordance with its terms, except as such enforceability may be limited by (i) applicable insolvency, bankruptcy, reorganization, moratorium or other similar laws affecting creditors' rights generally, and (ii) applicable equitable principles (whether considered in a proceeding at law or in equity).

(c) Such Lender has full power and authority to make each Disbursement and to enter into and perform its other obligations under each of the Loan Documents and carry out the other transactions contemplated thereby.

ARTICLE 4

CONDITIONS OF DISBURSEMENT

Section 4.1 **Conditions to the Disbursement**. The obligation of the Lenders to make the Disbursement shall be subject to the fulfillment of the following conditions:

(a) The Lenders shall have received executed counterparts of the Loan Documents from the Borrower and its Subsidiaries, and the other documents and deliveries set forth on the Closing Checklist attached hereto as Exhibit C;

(b) No Event of Default shall have occurred and be continuing;

(c) All of the representations and warranties set forth in Section 3.1 shall be true and correct in all material respects (except for representations or warranties which relate to a specific date, in which case such representations and warranties shall have been true and correct in all material respects as of such date); and

(d) All existing Indebtedness of Borrower to the Existing Lenders pursuant to the Existing Loan Documents shall be satisfied with the proceeds of the Loans on the Agreement Date.

ARTICLE 5

PARTICULAR COVENANTS AND EVENTS OF DEFAULT

Section 5.1 **Affirmative Covenants**. Unless the Required Lenders shall otherwise agree:

(i) The Borrower shall and shall cause its Subsidiaries to maintain its existence and qualify and remain qualified to do its business as currently conducted, except for any merger or dissolution of a Subsidiary in accordance with Section 5.2(i) and except where the failure to so qualify would not reasonably be expected to result in a Material Adverse Effect.

(ii) The Borrower shall and shall cause its Subsidiaries to comply in all material respects with all Applicable Laws, except where the necessity of compliance therewith is contested in good faith by appropriate proceedings diligently pursued or where such noncompliance would not reasonably be expected to have a Material Adverse Effect.

(iii) The Borrower shall obtain and shall cause its Subsidiaries to obtain and keep in full force and effect all Authorizations, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect.

(iv) The Borrower shall promptly notify the Lenders of the occurrence of (i) any Event of Default and (ii) any claims, litigation, arbitration, mediation or administrative or regulatory proceedings that are instituted or threatened in writing against the Borrower or any of its Subsidiaries in which an adverse decision would reasonably be expected to result in a Material Adverse Effect.

(v) If the Borrower is not required to file reports pursuant to Sections 13 or 15(d) of the Exchange Act, the Borrower will provide to the Lenders quarterly financial statements for itself and its Subsidiaries within 45 days after the end of each quarter, and audited annual financial statements within 120 days after the end of each fiscal year prepared in accordance with GAAP with a report thereon by the Borrower's independent certified public accountants. If the Borrower is required to file such reports, the Borrower will timely file with the SEC (subject to appropriate extensions made under Rule 12b-25 of the Exchange Act) any annual reports, quarterly reports and other periodic reports required to be filed by Borrower pursuant to Section 13 or 15(d) of the Exchange Act, and the Borrower and its Subsidiaries will provide to the Lenders copies of all documents, reports, financial data and other information not available on the SEC EDGAR system and not containing any material non-public information generally prepared in the ordinary course of the Borrower's business that the Lenders may reasonably request.

(vi) The Borrower shall reimburse Lenders on the Agreement Date for all reasonable documented out-of-pocket costs, fees and expenses, including

reasonable documented out-of-pocket attorneys' fees and expenses, in connection with the negotiation, documentation and closing of this Agreement and the other Loan Documents.

(vii) The Borrower shall at all times maintain cash on deposit in accounts subject to a Control Agreement (as defined in the Security Agreement) in favor of Lenders of not less than $5,000,000.

Section 5.2 **Negative Covenants**. Unless the Required Lenders shall otherwise agree:

(i) The Borrower shall not and shall not permit any Subsidiary to (a) liquidate, provided that a Subsidiary may merge into the Borrower or any other Subsidiary, or dissolve (unless such Subsidiary ceases to own any operating assets or conduct business), or (b) enter into any merger, consolidation or reorganization, unless the Borrower or a Subsidiary is the surviving corporation. The Borrower shall not establish any Subsidiary unless any such Subsidiary organized under the laws of the United States of America executes and delivers to the Lenders a Security Agreement substantially in the form delivered to the Lenders by the Borrower and its Subsidiaries on the Agreement Date and takes all steps required to grant the Lenders a Lien on all of its assets (other than Excluded Assets).

(ii) The Borrower shall not, and shall not permit any Subsidiary to, (a) except for Excluded Transactions, enter into any partnership, joint venture, syndicate, pool, profit-sharing or royalty agreement or other combination, or engage in any transaction with any stockholder of the Borrower, any Affiliate of the Borrower or any equity holder of such Affiliate, whereby its income or profits are, or might be, shared with another Person other than a wholly owned Subsidiary (other than royalty agreements with owners of IP resulting from the challenge of any Paragraph IV Certification made in connection with a new drug application), (b) enter into any management contract or similar arrangement whereby a substantial part of its business is managed by another Person, or (c) distribute, or permit the distribution of, any of its assets, including its intangibles, to any stockholder of the Borrower, any Affiliate of the Borrower or any equity holder of such Affiliate other than (x) as may be required under an Employee Benefit Plan (as defined in Section 3.1(s)) or (y) any Tax distributions by any Subsidiary to permit Borrower to pay any Tax liabilities with respect to the income of such Subsidiary.

(iii) The Borrower shall not and shall not permit any Subsidiary to (a) create, incur or suffer any Lien upon any of its assets, except Permitted Liens or (b) assign, sell, transfer or otherwise dispose of, any Loan Document, or its rights and obligations thereunder.

(iv) The Borrower shall not and shall not permit any Subsidiary to create, incur, assume, guarantee or be liable with respect to any Indebtedness, other than Permitted Indebtedness.

(v) The Borrower shall not and shall not permit any Subsidiary to acquire any assets (other than assets acquired in the ordinary course of business), directly or indirectly, in one or more related transactions, for a consideration, in cash or other property (valued at its fair market value) greater than $500,000.

(vi) The Borrower shall not and shall not permit any Subsidiary to sell or otherwise transfer any of their respective assets other than:

(A) in the ordinary course of business, including sales of inventory, and sales, transfers and other dispositions of used, surplus, obsolete or outmoded machinery or equipment;

(B) sales or transfers to the Borrower or any Subsidiary if such Subsidiary is a Grantor and Guarantor (as defined in the Security Agreement) party to the Security Agreement;

(C) the sale or discount of accounts receivable arising in the ordinary course of business, but only in connection with the compromise or collection thereof and not in connection with any financing transaction;

(D) dispositions of assets subject to any casualty or condemnation proceeding (including in lieu thereof);

(E) leases or subleases of real property granted by the Borrower or any Subsidiary to third Persons not interfering in any material respect with the business of the Borrower or any Subsidiary;

(F) Excluded Transactions;

(G) the use or transfer of cash or cash equivalents in a manner not otherwise prohibited under the Loan Documents;

(H) sales, transfers or issuances of equity interests not resulting in a Change of Control; and

(I) Other dispositions or transfers having a fair market value not to exceed $250,000 per fiscal year.

Section 5.3 **[Reserved.]**

Section 5.4 **General Acceleration Provision upon Events of Default**. If one or more of the events specified in this Section 5.4 shall have happened and be continuing beyond the applicable cure period (each, an "**Event of Default**"), the Required Lenders, by written notice to the Borrower, may declare the outstanding principal of, and accrued and unpaid interest on, all of the Notes or any part of any of them (together with any other amounts accrued or payable under the Loan Documents) to be, and the same shall thereupon become, immediately due and payable, without any further notice and without any presentment, demand, or protest of any kind, all of which are hereby expressly waived by the Borrower, and take any further action available at law

or in equity, including, without limitation, the sale of the Loan and all other rights acquired in connection with the Loan:

(a) The Borrower shall have failed to (i) make payment of principal or interest under the Notes when due and payable or (ii) pay any other Obligations under the Loan Documents within five (5) Business Days of the date when due.

(b) The Borrower shall have failed to comply with the due observance or performance of any covenant contained in any Loan Document (other than the covenants described in (a) above), and such failure shall not have been cured by the Borrower within 20 days after receiving written notice of such failure from the Lenders.

(c) Any representation or warranty made by the Borrower in any Loan Document shall have been incorrect, false or misleading in any material respect (except to the extent that such representation or warranty is qualified by reference to materiality or Material Adverse Effect, to which extent it shall have been incorrect, false or misleading in any respect) as of the date it was made.

(d) (i) The Borrower shall generally be unable to pay its debts as such debts become due in the ordinary course of business, or shall admit in writing its inability to pay its debts as they come due or shall make a general assignment for the benefit of creditors; (ii) the Borrower shall declare a moratorium on the payment of its debts; (iii) the commencement by the Borrower of proceedings to be adjudicated bankrupt or insolvent, or the consent by it to the commencement of bankruptcy or insolvency proceedings against it, or the filing by it of a petition or answer or consent seeking reorganization, intervention or other similar relief under any applicable law, or the consent by it to the filing of any such petition or to the appointment of an intervenor, receiver, liquidator, assignee, trustee, sequestrator (or other similar official) of all or substantially all of its assets; (iv) the commencement against the Borrower of a proceeding in any court of competent jurisdiction under any bankruptcy or other applicable law (as now or hereafter in effect) seeking its liquidation, winding up, dissolution, reorganization, arrangement, adjustment, or the appointment of an intervenor, receiver, liquidator, assignee, trustee, sequestrator (or other similar official), and any such proceeding shall continue undismissed, or any order, judgment or decree approving or ordering any of the foregoing shall continue unstayed or otherwise in effect, for a period of sixty (60) days; (v) the making by the Borrower of an assignment for the benefit of creditors.

(e) One or more final uninsured judgments in excess of $500,000 against the Borrower or any Subsidiary or attachments against any of their respective property remain(s) unpaid, unstayed on appeal, undischarged, unbonded or undismissed for a period of 30 days from the date of entry of such judgment.

(f) Any material authorization of a Government Authority necessary for the execution, delivery or performance of any Loan Document or for the validity or enforceability of any of the Obligations under any Loan Document is not given or is withdrawn or ceases to remain in full force or effect.

(g) The validity of any Loan Document shall be contested by the Borrower, or any Applicable Law shall render any Loan Document invalid or unenforceable or shall cause the Obligations to cease to be in full force and effect.

(h) There is a failure to perform in any agreement involving obligations in excess of $500,000 of the Borrower or any Subsidiary to which the Borrower or any Subsidiary is a party with a third party or parties resulting in such third party's or parties acceleration of the maturity of any Indebtedness for borrowed money in an amount in excess of $500,000.

(i) If any Governmental Authority issues any injunction or other order that prohibits Borrower or its Subsidiaries from marketing, selling or manufacturing any of Borrower's products currently approved by the FDA or any future products of Borrower or its Subsidiaries once approved by the FDA (collectively, the "Commercial Products") if sales of such products covered by such injunction or order accounted for more than 50% of total sales revenue of Borrower and its Subsidiaries for the most recently ended four fiscal quarter periods, and such injunction or other prohibition shall continue to be in force or otherwise effective for more than 60 consecutive calendar days; provided, however, that with respect to manufacturing, if there is one or more alternative manufacturers of the Commercial Product manufacturing on Borrower's or its Subsidiaries' behalf that is not enjoined or otherwise prohibited from manufacturing the Commercial Product and are able to deliver product on Borrower's or its Subsidiaries' behalf in a manner that is consistent with prior levels without a commercial distribution delay, it shall not be an Event of Default under this clause (i) if the Borrower or any of its Subsidiaries are enjoined or otherwise prohibited from manufacturing the Commercial Product.

Section 5.5 **Automatic Acceleration on Dissolution or Bankruptcy**. Notwithstanding any other provisions of this Agreement, if an Event of Default under Section 5.4(d) shall occur, the principal of the Notes (together with any other amounts accrued or payable under this Agreement) shall thereupon become immediately due and payable without any presentment, demand, protest or notice of any kind, all of which are hereby expressly waived by the Borrower.

Section 5.6 **Recovery of Amounts Due**. If any amount payable hereunder is not paid as and when due, the Borrower hereby authorizes the Lenders to proceed, to the fullest extent permitted by applicable law, without prior notice, by right of set-off, banker's lien or counterclaim, against any moneys or other assets of the Borrower to the full extent of all amounts payable to the Lenders.

ARTICLE 6

MISCELLANEOUS

Section 6.1 **Notices**. Any notices required or permitted to be given under the terms hereof shall be sent by certified or registered mail (return receipt requested) or delivered personally or by courier (including a recognized overnight delivery service) or by facsimile or by

electronic mail and shall be effective five (5) days after being placed in the mail, if mailed by regular United States mail, or upon receipt, if delivered personally or by courier (including a recognized overnight delivery service) or by facsimile, or when received by electronic mail in each case addressed to a party. The addresses for such communications shall be the following (or such other addresses provided by written notice to the parties hereto from time to time):

If to the Borrower:

Neos Therapeutics, Inc.
2940 N. Hwy 360, Suite 400
Grand Prairie, TX 75050
Fax: (972) 408-1143
E-mail: reisenstadt@neostx.com
Attention: Richard Eisenstadt

With a copy to:

Goodwin Procter LLP
53 State Street
Boston, MA 02109
Fax: (617) 523-1231
Email: adodson@goodwinprocter.com
Attention: Anna E. Dodson, Esq.

If to the Lenders:

Deerfield Management Company, L.P.
780 Third Avenue, 37th Floor

New York, NY 10017
Fax: 212-599-3075
Email: dclark@deerfield.com
Attn: David J. Clark

With a copy to:

Katten Muchin Rosenman LLP
575 Madison Avenue
New York, New York 10022
Fax: (212) 940-8776
Email: mark.fisher@kattenlaw.com
Attn: Mark I. Fisher, Esq.

Section 6.2 **Waiver of Notice**. Whenever any notice is required to be given to the Lenders or the Borrower under any of the Loan Documents, a waiver thereof in writing signed by the Person or Persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice.

Section 6.3 **Reimbursement of Legal and Other Expenses**. If any amount owing to the Lenders under any Loan Document shall be collected through enforcement of this Agreement, any Loan Document or restructuring of the Loan in the nature of a work-out, settlement, negotiation, or any process of law, or shall be placed in the hands of third Persons for collection, the Borrower shall pay (in addition to all monies then due in respect of the Loan or otherwise payable under any Loan Document) all reasonable and documented external attorneys' and other reasonable documented fees and out-of-pocket expenses incurred in respect of such collection.

Section 6.4 **Governing Law**. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York applicable to contracts made and to be performed in such State. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE PARTIES HEREBY WAIVE ALL RIGHTS TO A TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE OTHER LOAN DOCUMENTS.

Section 6.5 **Successors and Assigns**. This Agreement shall bind and inure to the respective successors and permitted assigns of the Parties, except that (a) the Borrower may not assign or otherwise transfer all or any part of its rights under the Loan Documents without the prior written consent of the Lenders; and (b) absent an Event of Default the Lenders may not assign or otherwise transfer all or part of their rights under the Loan Documents to any Person other than an investment fund managed by Deerfield Management, L.P., without the prior written consent of the Borrower (which consent shall not be unreasonably withheld). Before any Lender assigns all or any part of its rights under this Agreement or the Notes to a party other than an investment fund managed by Deerfield Management, L.P., or there are more than five (5) Lenders, the Parties shall negotiate in good faith to amend this Agreement to appoint an administrative agent providing such agent and the Parties with rights and duties customary among syndicated credit facilities. Upon a Lender's assignment of a Note in accordance with the foregoing sentence, such Lender shall provide notice of a permitted transfer to Borrower for recordation in the Register pursuant to Section 1.4. Upon receipt of a notice of a transfer of an interest in a Note, Borrower shall record the identity of the transferee and other relevant

information in the Register and the transferee shall (to the extent of the interests transferred to such transferee) have all the rights and obligations of, and shall be deemed, a Lender hereunder.

Section 6.6 **Entire Agreement**. The Loan Documents contain the entire understanding of the Parties with respect to the matters covered thereby and supersede any and all other written and oral communications, negotiations, commitments and writings with respect thereto (including, without limitation, any agreement on the reimbursement of costs, etc. referenced in Section 2.9). The provisions of this Agreement may be waived, modified, supplemented or amended only by an instrument in writing signed by the authorized officer of each of Borrower and the Required Lenders.

Section 6.7 **Severability**. If any provision of this Agreement shall be invalid, illegal or unenforceable in any respect under any law, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. The Parties shall endeavor in good faith negotiations to replace the invalid, illegal or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the invalid, illegal or unenforceable provision.

Section 6.8 **Counterparts**. This Agreement may be executed in several counterparts, and by each Party on separate counterparts, each of which and any photocopies and facsimile copies thereof shall be deemed an original, but all of which together shall constitute one and the same agreement.

Section 6.9 **Survival**.

(a) This Agreement and all agreements, representations and warranties made in the Loan Documents, and in any document, certificate or statement delivered pursuant thereto or in connection therewith shall be considered to have been relied upon by the other Parties and shall survive the execution and delivery of this Agreement and the making of the Loan hereunder, and shall continue in force until payment in full of the Obligations (other than inchoate indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement), and the Lenders shall not be deemed to have waived, by reason of making the Loan, any Event of Default that may arise by reason of such representation or warranty proving to have been false or misleading, notwithstanding that the Lenders may have had notice or knowledge of any such Event of Default or may have had notice or knowledge that such representation or warranty was false or misleading at the time the Disbursement was made.

(b) The obligations of the Borrower under Sections 1.4 and 2.5 and the obligations of the Borrower and the Lenders under this Article 6 shall survive and remain in full force and effect regardless of the consummation of the transactions contemplated hereby, the repayment of the Loan, or the termination of this Agreement or any provision hereof.

Section 6.10 **No Waiver**. Neither the failure of, nor any delay on the part of, any Party in exercising any right, power or privilege hereunder, or under any agreement, document or

instrument mentioned herein, shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege hereunder, or under any agreement, document or instrument mentioned herein, preclude other or further exercise thereof or the exercise of any other right, power or privilege; nor shall any waiver of any right, power, privilege or default hereunder, or under any agreement, document or instrument mentioned herein, constitute a waiver of any other right, power, privilege or default or constitute a waiver of any default of the same or of any other term or provision. No course of dealing and no delay in exercising, or omission to exercise, any right, power or remedy accruing to the Lenders upon any default under this Agreement, or any other agreement shall impair any such right, power or remedy or be construed to be a waiver thereof or an acquiescence therein; nor shall the action of the Lenders in respect of any such default, or any acquiescence by it therein, affect or impair any right, power or remedy of the Lenders in respect of any other default. All rights and remedies herein provided are cumulative and not exclusive of any rights or remedies otherwise provided by law.

Section 6.11 **Indemnity**.

(a) The Borrower shall, at all times, indemnify and hold each Lender harmless (the "**Indemnity**") and each of their respective directors, partners, officers, employees, agents, counsel and advisors (each, an "**Indemnified Person**") in connection with any losses, claims (including the reasonable documented out-of-pocket attorneys' fees incurred in defending against such claims), damages, liabilities, penalties, or other expenses arising out of, or relating to, the Loan Documents, the extension of credit hereunder or the Loan or the use of the Loan, which an Indemnified Person may incur or to which an Indemnified Person may become subject, but excluding all Taxes (each, a "**Loss**"). The Indemnity shall not apply to the extent that a court or arbitral tribunal of competent jurisdiction issues a final judgment that such Loss resulted from the gross negligence or willful misconduct of any Indemnified Person. The Indemnity is independent of and in addition to any other agreement of Borrower under any Loan Document to pay any amount to the Lenders, and any exclusion of any obligation to pay any amount under this subsection shall not affect the requirement to pay such amount under any other section hereof or under any other agreement.

(b) Promptly after receipt by an Indemnified Person under this Section 6.11 of notice of the commencement of any action (including any governmental action), such Indemnified Person shall, if a Loss in respect thereof is to be made against the indemnifying person under this Section 6.11, deliver to Borrower a written notice of the commencement thereof, and Borrower shall have the right to participate in, and, to the extent Borrower so desires, to assume control of the defense thereof.

(c) An Indemnified Person shall have the right to retain its own counsel with the documented reasonable fees and out-of-pocket expenses to be paid by the indemnifying person, if, in the reasonable opinion of counsel for the Indemnified Person, the representation by such counsel of the Indemnified Person and Borrower would be inappropriate due to actual or potential differing interests between such Indemnified Person and any other party represented by such counsel in such proceeding. The Borrower shall pay for only one separate such legal counsel for all of the Indemnified Persons. The failure of an Indemnified Person to deliver written notice to the Borrower

within a reasonable time of the commencement of any such action shall not relieve the Borrower of any liability to the Indemnified Person under this Section 6.11, except to the extent that Borrower is actually prejudiced in its ability to defend such action. The indemnification required by this Section 6.11 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as such expense, loss, damage or liability is incurred and is due and payable.

Section 6.12 **No Usury**. The Loan Documents are hereby expressly limited so that in no contingency or event whatsoever, whether by reason of acceleration or otherwise, shall the amount paid or agreed to be paid to the Lenders for the Loan exceed the maximum amount permissible under applicable law. If from any circumstance whatsoever fulfillment of any provision hereof, at the time performance of such provision shall be due, shall involve transcending the limit of validity prescribed by law, then, ipso facto, the obligation to be fulfilled shall be reduced to the limit of such validity, and if from any such circumstance the Lenders shall ever receive anything which might be deemed interest under applicable law that would exceed the highest lawful rate, such amount that would be deemed excessive interest shall be applied to the reduction of the principal amount owing on account of the Loan, or if such deemed excessive interest exceeds the unpaid balance of principal of the Loan, such deemed excess shall be refunded to the Borrower. All sums paid or agreed to be paid to the Lenders for the Loan shall, to the extent permitted by applicable law, be deemed to be amortized, prorated, allocated and spread throughout the full term of the Loan until payment in full so that the deemed rate of interest on account of the Loan is uniform throughout the term thereof. The terms and provisions of this Section shall control and supersede every other provision of this Agreement and the Notes.

Section 6.13 **Further Assurances**. From time to time, the Borrower shall perform any and all acts and execute and deliver to the Lenders such additional documents as may be reasonably requested by the Lenders to carry out the purposes of any Loan Document or to preserve and protect the Lenders' rights as contemplated therein.

Section 6.14 **Confidentiality**. Lenders agree that they will hold any confidential information they may receive from Borrower in connection with the Loan Documents in confidence, unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Section 6.14 by Lenders, (b) is or has been independently developed or conceived by Lenders without use of Borrower's confidential information, or (c) is or has been made known or disclosed to Lender by a third party without a breach of any obligation of confidentiality such third party may have to Borrower; provided, however, that Lenders may disclose confidential information (i) to their attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with this Agreement and the other Loan Documents; (ii) to any prospective purchaser of any Loan from Lenders, if a transfer to such prospective purchaser is permitted and such prospective purchaser agrees to be bound by the provisions of this Section 6.14; (iii) to any existing or prospective Affiliate, partner, member, shareholder or wholly owned subsidiary of a Lender in the ordinary course of business, provided that Lenders inform such Person that such information is confidential and direct such Person to maintain the confidentiality of such information; (iv) as may otherwise be required by law, regulation or legal process; or (v) to any Person in connection with any legal proceeding to which it is a party.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Lenders and the Borrower have caused this Agreement to be duly executed as of the date set forth above.

BORROWER:

NEOS THERAPEUTICS

By: /s/Richard Eisenstadt
Name: Richard Eisenstadt
Title: Chief Financial Officer, Secretary and Treasurer

LENDERS:

DEERFIELD PRIVATE DESIGN FUND III, L.P.

By: Deerfield Mgmt III, L.P., General Partner
By: J.E. Flynn Capital III, LLC, General Partner

By: /s/David J. Clark
Name: David J. Clark
Title: Authorized Signatory

DEERFIELD SPECIAL SITUATIONS FUND, L.P.

By: Deerfield Mgmt III, L.P., General Partner
By: J.E. Flynn Capital, LLC, General Partner

By: /s/David J. Clark
Name: David J. Clark
Title: Authorized Signatory

SCHEDULE 1

LENDER	ALLOCATION OF DISBURSEMENTS AND PAYMENTS
Deerfield Private Design Fund III, L.P.	**66 2/3%**
Deerfield Special Situations Fund, L.P.	**33 1/3%**

EXHIBIT A

PROMISSORY NOTE

THIS NOTE IS BEING ISSUED with original issue discount in the amount of $.

May , 2016

FOR VALUE RECEIVED, Neos Therapeutics, Inc., a Delaware corporation (the "**Maker**"), by means of this Promissory Note (this "**Note**"), hereby unconditionally promises to pay **[ ]** (the "**Payee**"), a principal amount equal to the lesser of (a) **[ ]** and (b) the aggregate outstanding amount of Disbursements made to Maker by Payee pursuant to Section 2.2 of the Facility Agreement referenced to below, in lawful money of the United States of America and in immediately available funds, on the dates provided in the Facility Agreement.

This Note is a "Note" referred to in the Facility Agreement dated as of May , 2016 between the Maker, the Payee and the other parties thereto (as amended, modified and supplemented and in effect from time to time, the "**Facility Agreement**"), with respect to the Loan made by the Payee thereunder. Capitalized terms used herein and not expressly defined in this Note shall have the respective meanings assigned to them in the Facility Agreement.

This Note shall bear interest on the outstanding principal amount hereof pursuant to the provisions of the Facility Agreement.

The Maker shall make all payments to the Payee of interest and principal under this Note in the manner provided in and otherwise in accordance with the Facility Agreement.

If an Event of Default has occurred and is continuing, this Note may in accordance with the applicable provisions of the Facility Agreement, become immediately due and payable.

Subject to the terms of the Facility Agreement, all payments will be free and clear of, and without deduction or withholding for, any present or future taxes. The Maker shall pay all and any costs (administrative or otherwise) imposed by the Maker's banks, clearing houses, or any other financial institution, in connection with making any payments hereunder.

The Maker shall pay all reasonable documented out-of-pocket costs of collection, including, without limitation, all reasonable documented out-of-pocket, legal expenses and attorneys' fees, paid or incurred by the Payee in collecting and enforcing this Note.

Other than those notices required to be provided by Payee to Maker under the terms of the Facility Agreement, the Maker and every endorser of this Note, or the obligations represented hereby, expressly waives presentment, protest, demand, notice of dishonor or default, and notice of any kind with respect to this Note and the Facility Agreement or the performance of the obligations under this Note and/or the Facility Agreement. No renewal or extension of this Note or the Facility Agreement, no delay in the enforcement of payment of this Note or the Facility Agreement, and no delay or omission in exercising any right or power under this Note or the Facility Agreement shall affect the liability of the Maker or any endorser of this Note.

No delay or omission by the Payee in exercising any power or right hereunder shall impair such right or power or be construed to be a waiver of any default, nor shall any single or partial exercise of any power or right hereunder preclude the full exercise thereof or the exercise of any other power or right. The provisions of this Note may be waived or amended only in a writing signed by the Maker and the Payee. This Note may be prepaid in whole or in part in accordance with the provisions of the Facility Agreement.

This Note, and any rights of the Payee arising out of or relating to this Note shall be enforced by the Payee in the courts of the United States of America located in the Southern District of the State of New York. For the benefit of the Payee, the Maker hereby irrevocably agrees that any legal action, suit or other proceeding arising out of or relating to this Note shall be brought in the courts of the State of New York or of the United States of America for the Southern District of New York, and hereby consents that personal service of summons or other legal process may be made as set forth in Section 6.1 of the Facility Agreement, which service the Maker agrees shall be sufficient and valid. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE MAKER AND THE PAYEE HEREBY WAIVE ANY AND ALL RIGHTS TO DEMAND A TRIAL BY JURY IN ANY ACTION, SUIT OR OTHER PROCEEDING ARISING OUT OF OR RELATING TO THIS NOTE OR THE TRANSACTIONS CONTEMPLATED BY THIS NOTE.

This Note shall be governed by, and construed in accordance with, the laws of the State of New York applicable to contracts made and to be performed in such State.

[Signature page follows]

IN WITNESS WHEREOF, an authorized representative of the Maker has executed this Note as of the date first written above.

NEOS THERAPEUTICS, INC.

By: ____________________________
Name:
Title

EXHIBIT B

PERMITTED INDEBTEDNESS

None

EXHIBIT B

PERMITTED LIENS

None

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

I, Vipin Garg, certify that:

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

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

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

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

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

b) Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313;

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

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

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

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

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

Date: August 12, 2016

By: /s/ Vipin Garg
Vipin Garg
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Richard Eisenstadt, certify that:

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

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

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

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

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

b) Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313;

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

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

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

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

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

Date: August 12, 2016

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Neos Therapeutics, Inc. for the quarterly period ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Vipin Garg, as President and Chief Executive Officer of Neos Therapeutics, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Neos Therapeutics, Inc.

Date: August 12, 2016	By:	/s/ Vipin Garg
		Vipin Garg President and Chief Executive Officer (Principal Executive Officer)

In connection with the Quarterly Report on Form 10-Q of Neos Therapeutics, Inc. for the quarterly period ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Richard Eisenstadt, as Chief Financial Officer of Neos Therapeutics, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Neos Therapeutics, Inc.

Date: August 12, 2016	By:	/s/ Richard Eisenstadt
		Richard Eisenstadt Chief Financial Officer (Principal Financial Officer)