Neos Therapeutics, Inc.
Form 10-Q
May 16, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended MARCH 31, 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 May 13, 2016: 16,045,891 shares.

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NEOS THERAPEUTICS, INC.

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Special note regarding forward-looking statements

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

- our anticipated cash needs and our estimates regarding our 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, or 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.

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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.

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PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS.

Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	March 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 42,392	$ 90,763
Short-term investments	33,730	
Accounts receivable, net of allowances of $1,382 and $1,039, respectively	6,669	3,903
Inventories	2,501	2,520
Deferred contract sales organization fees	4,772	
Other current assets	3,070	1,058
Total current assets	93,134	98,244
Property and equipment, net	5,403	5,124
Intangible assets, net	16,772	16,672
Other assets	2,545	2,470
Total assets	$ 117,854	$ 122,510
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 3,469	$ 4,824
Contract sales organization payable	5,874	
Accrued expenses	6,205	3,141
Current portion of long-term debt	2,336	7,973
Total current liabilities	17,884	15,938
Long-Term Liabilities:		
Long-term debt, net of current portion	31,786	26,271
Earnout liability	210	214
Deferred gain on leaseback	339	547

Deferred rent		1,192		1,166
Total long-term liabilities		33,527		28,198
Stockholders Equity:				
Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at March 31, 2016 and December 31, 2015				
Common stock, $0.001 par value, 100,000,000 authorized at March 31, 2016 and December 31, 2015; 16,047,578 and 16,038,381 issued and outstanding at March 31, 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 March 31, 2016 and December 31, 2015		(171)		(171)
Additional paid-in capital		195,938		195,314
Accumulated deficit		(129,399)		(116,785)
Accumulated other comprehensive income		59		
Total stockholders equity		66,443		78,374
Total liabilities and stockholders equity	$	117,854	$	122,510

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Revenues:		
Net product sales	$ 2,583	$ 428
Cost of goods sold	2,272	1,095
Gross profit (loss)	311	(667)
Research and development	2,341	4,320
Selling and marketing expenses	6,284	326
General and administrative expenses	3,550	1,337
Loss from operations	(11,864)	(6,650)
Interest expense, net	(961)	(757)
Other income, net	207	207
Change in fair value of earnout and warrant liabilities	4	644
Net loss	(12,614)	(6,556)
Preferred stock accretion to redemption value		(484)
Preferred stock dividends		(539)
Net loss attributable to common stock	$ (12,614)	$ (7,579)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	16,025,318	885,237
Net loss per share of common stock, basic and diluted	$ (0.79)	$ (8.56)

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Net loss	$ (12,614)	$ (6,556)
Other comprehensive income:		
Net unrealized gain on short-term investments	59	
Total other comprehensive income :	$ 59	$
Comprehensive loss	$ (12,555)	$ (6,556)

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

Three months Ended March 31, 2016

(In thousands, except shares)

(unaudited)

	Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Income	Equity
Balance, December 31, 2015		$	16,025,155	$ 16	(9,197)	$ (171)	$ 195,314	$ (116,785)	$	$ 78,374
Proceeds from exercise of options and warrants			22,423				1			1
Share-based compensation expense							623			623
Net unrealized gain on investments									59	59
Net loss								(12,614)		(12,614)
Balance, March 31, 2016		$	16,047,578	$ 16	(9,197)	$ (171)	$ 195,938	$ (129,399)	$ 59	$ 66,443

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Cash Flows From Operating Activities:		
Net loss	$ (12,614)	$ (6,556)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	439	415
Amortization of intangible assets	400	374
Changes in fair value of warrant and earnout liabilities	(4)	(644)
Amortization of patents	10	6
Amortization of senior debt fees	154	138
Gain on sale of equipment	(208)	(208)
Share-based compensation expense	623	97
Interest accrued on note payable	176	98
Change in deferred rent	26	(8)
Net unrealized gain on short-term investment	59	
Changes in operating assets and liabilities:		
Accounts receivable	(2,766)	36
Inventories	19	80
Other current assets	(2,012)	7
Other assets	(85)	(265)
Accounts payable	(1,355)	(688)
Contract sales organization payable	1,102	
Accrued expenses	3,064	(496)
Net cash used in operating activities	(12,972)	(7,614)
Cash Flows From Investing Activities:		
Net change in short-term investments	(33,730)	3,000
Capital expenditures	(718)	(220)
Intangible asset license	(500)	
Net cash (used in) provided by investing activities	(34,948)	2,780
Cash Flows From Financing Activities:		
Proceeds from senior debt note		5,000
Net proceeds from issuance of stock	1	13,051
Payments made on borrowings	(452)	(391)
Net cash (used in) provided by financing activities	(451)	17,660
(Decrease) increase in cash and cash equivalents	(48,371)	12,826
Cash and Cash Equivalents:		
Beginning	90,763	13,343

Ending	$	42,392	$	26,169
Supplemental Disclosure of Noncash Transactions:				
Issuance of stock warrants	$		$	2,131
Preferred stock accretion	$		$	485
Preferred stock dividend	$		$	539
Deferred contract sales organization fees	$	4,772	$	
Supplemental Cash Flow Information:				
Interest paid	$	687	$	498

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Basis of presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC) for reporting on Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and footnotes necessary for a complete presentation of financial position, results of operations, and cash flows. In the opinion of management, all adjustments (consisting of normal, recurring adjustments) necessary for a fair presentation of results of operations for and financial condition as of the end of the interim period have been included. Results of operations for the three months ended March 31, 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.

Note 2. 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, or FDA, on January 27, 2016. The Company is currently producing inventory to support the commercial launch of Adzenys XR-ODT announced 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. These products are developed and manufactured using the Company s proprietary and patented modified-release drug delivery technology. The Company s 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, the Company 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 the Company on June 29, 2015. Historically, the Company was primarily engaged in the development and contract manufacturing of unapproved or Drug Efficacy Study Indication (DESI), pharmaceuticals and, to a lesser extent, nutraceuticals for third parties. The unapproved or DESI pharmaceuticals contract business was discontinued in 2007 and the manufacturing of nutraceuticals for third parties was discontinued in March 2013.

On August 28, 2014, the Company completed an acquisition of all of the rights to the Tussionex Abbreviated New Drug Application (Tussionex ANDA), which included the rights to produce, develop, market and sell, as well as all the profits from such selling activities, the Company s generic Tussionex, which the Company 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. (CPI), a supplier of the resins for the product (see Note 9). Prior to the acquisition, the Company, Cornerstone and CPI

shared profits generated by the sale and manufacture of the product under a development and manufacturing agreement with those companies.

On July 28, 2015, the Company closed its initial public offering (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.

In connection with the IPO, the Company s board of directors approved a 1-for-2.4 reverse stock split of the Company s common stock which also resulted in a proportional adjustment to the conversion ratios of the preferred stock and the preferred stock warrants. All references to common stock and per share amounts in these condensed financial statements and accompanying footnotes have been retroactively adjusted for all periods presented to give effect to this reverse stock split.

Between June 30, 2015 and July 27, 2015, the Company issued a total of 1,000,000 shares of its Series C redeemable convertible preferred stock (Series C preferred stock) to several existing investors upon the exercise of warrants to purchase Series C preferred

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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. 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 redeemable preferred stock into 9,217,983 shares of common stock on the IPO closing date. 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 on the IPO closing date. 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. These transactions produced a significant increase in the number of shares outstanding which will impact the year-over-year comparability of the Company s loss per share calculations. Additionally, in connection with the closing of the IPO, the Company amended and restated its certificate of incorporation to increase the number of authorized shares of common stock to 100,000,000 and to authorize 5,000,000 shares of undesignated preferred stock.

Note 3. Summary of significant accounting policies

Principles of consolidation: At March 31, 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 5.

Inventories: Inventories, comprised of raw materials, labor, and manufacturing overhead, as well as finished goods inventory, are stated at the lower of cost (actual, which approximates first-in, first-out) or market, net of an allowance for obsolete inventory. Increases in the reserve are recorded as charges to cost of goods sold. As the Company does not have a history of 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.

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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 ANDA, are recorded at cost and amortized over the estimated lives of the assets, which primarily range from 10 to 20 years.

Contract sales organization payable: The Company records amounts billed in accordance with its commercial sales organization contract, but unpaid as of the balance sheet date, as a contract sales organization payable in current liabilities.

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 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 (freight on board destination). These wholesalers then resell the product to retail customers such as food, drug and mass merchandisers.

Net product sales

Net product sales for the Company s generic Tussionex product represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments include wholesaler fees and estimated allowances for product returns, government rebates, chargebacks and prompt-payment discounts to be incurred on the selling price of the respective product sales. Wholesale distribution fees are incurred on the management of these products by wholesalers and are recorded within net product sales based on definitive contractual agreements. The Company estimates gross to net sales adjustments for allowances for product returns, government rebates and chargebacks based upon analysis of third-party information, including information obtained from the Company s third party logistics provider (3PL), with respect to its inventory levels and sell-through to the wholesalers customers, data available from third parties regarding prescriptions written for the Company s products, as well as actual experience as reported by the Company s customers and 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. Allowances and accruals are recorded in the same period that 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.

Medicaid rebates

The Company s products are subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Estimated rebates payable under governmental programs, including Medicaid, are recorded as a reduction of revenue at the time revenues are recorded. Calculations related to these rebate accruals are estimated based on sales of the Company s product by its former commercialization partner. Historical trend of Medicaid rebates will be continually monitored and may result in future adjustments to such estimates.

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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 the distributor. 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 March 31, 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 March 31, 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.

At December 31, 2015, the Company had a federal net operating loss carry-forward of $122,075,000 and research and development credits of $2,010,000, which begin to expire in 2024. The Company analyzed the impact of any ownership change(s) under Section 382 of the Internal Revenue Code and determined that the amount of federal net operating loss that will expire unused due to the Section 382 limitation is $6,089,000. The amount of federal research and development credit that will expire unused is $350,000. The deferred tax assets for both carryforwards have been adjusted downward accordingly.

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 IPO, the Company s Series C warrants were determined to be derivative liabilities and they were revalued at each subsequent balance sheet date. Upon closing the IPO, the warrants issued in conjunction with the 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 our IPO, the Company s board of directors has determined the fair value of each share of underlying common stock

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based on the closing price of our 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 months ended March 31, 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.

Application of revised accounting standards: 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. The Company has irrevocably elected not to avail itself of this extended transition period and, as a result, will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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 July 2015, the FASB issued ASU No. 2015-11, *Inventory Simplifying the Measurement of Inventory (Topic 330).* The amendments in this ASU require an entity to measure inventory that is not measured using the last-in, first-out (LIFO) or retail inventory methods at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The amendments in this ASU are effective 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 August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern.* ASU 2014-15 is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. This ASU is for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company has performed the review required by this ASU and believes the Company presently has sufficient liquidity to continue to operate for the next twelve months.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers.* 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

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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. The amendments in ASU 2016-08 and 2016-10 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 and ASU 2016-10 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.

Reclassifications: Certain reclassifications have been made to the prior year s consolidated financial statements to conform to the current year s presentation.

Subsequent events: The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Note 4. 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 March 31, 2016 and 2015 were excluded from consideration in the computation of diluted net loss per share of common stock for the three months ended March 31, 2016 and 2015, respectively, because including them would have been anti-dilutive:

	March 31,	
	2016	**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)		4,740,992
Series C Redeemable Convertible Preferred Stock Warrants (as converted)	70,833	882,150
Common Stock Warrants	31,068	337,133
Stock options	1,375,418	627,745

Note 5. 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

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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.
- 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 March 31, 2016			
	Level 1	Level 2	Level 3	Total
	(unaudited) (in thousands)			
Cash and cash equivalents	$ 42,392	$	$	$ 42,392
Short term investments	33,730			33,730
Earnout liability			210	210
	$ 76,122	$	$ 210	$ 76,332

	Fair Value as of December 31, 2015			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
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 and short term investments. 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 due to the short-term nature of the instruments and/or the current interest rates payable in relation to current market

conditions. Short term investments 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. The Company s cash and cash equivalents approximated fair market value at December 31, 2015. The Company s cash and cash equivalents and short term investments had quoted prices in active markets at March 31, 2016 as shown below:

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	Amortized Cost	March 31, 2016 Unrealized Gain / (Loss) (unaudited) (in thousands)	Market Value
Bank deposits and money market funds	$ 17,399	$	$ 17,399
Financial and corporate debt securities	58,664	59	58,723
	$ 76,063	$ 59	$ 76,122

Level 3 liabilities included the fair value of the earnout liability at March 31, 2016 and December 31, 2015.

The methodologies and significant inputs used in the determination of the fair value of the earnout liability were as follows:

	March 31, 2016 Earnout Liability (unaudited)	December 31, 2015 Earnout Liability
	(Dollars in thousands)	
Date of Valuation	**3/31/2016**	**12/31/2015**
Valuation Method	Monte Carlo	Monte Carlo
Volatility (annual)	50%	50%
Risk-free rate (annual)	.14% - 3.00%	.56% - 3.31%
Time period from valuation until end of earnout	.375 - 9.25	.5 - 9.5
Earnout Target 1	$ 13,700	$ 13,700
Earnout Target 2	$ 18,200	$ 18,200
Discount rate	8.18% - 11.04%	8.11% - 10.86%
Fair value of liability at valuation date	$ 210	$ 214

Significant changes to these assumptions would result in increases/decreases to the fair value of the earnout liability for the periods presented.

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

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Note 6. Inventories

Inventories at the indicated dates consist of the following:

	March 31, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Raw materials	$ 1,209	$ 1,211
Work in progress	485	175
Finished goods	836	1,189
Inventory at cost	2,530	2,575
Inventory reserve	(29)	(55)
	$ 2,501	$ 2,520

Note 7. 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 each of the three months ended March 31, 2016 and 2015, approximately $208,000 of the net gain was recognized in other income on the consolidated statements of operations.

Note 8. Intangible assets, net

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

	March 31, 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	(6,484)	(6,084)

	$	16,772	$	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 for both the three months ended March 31, 2016 and 2015.

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Prior to the August 28, 2014 acquisition of the rights to Tussionex ANDA from Cornerstone and 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 March 31, 2016, resulting in a $4,000 decrease 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 March 31, 2016. This earnout amount was revalued at March 31, 2015, resulting in a $442,000 decrease 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 March 31, 2015. This net decrease resulted primarily 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 for each of the three months ended March 31, 2016 and 2015.

Note 9. Other assets

Other assets at the indicated dates consist of the following:

	March 31, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Patents	$ 2,329	$ 2,273
Deposits	216	197
	$ 2,545	$ 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. For the three months ended March 31, 2016 and 2015, $10,000 and $6,000, respectively, of patent amortization expense was recorded.

Note 10. Long-term debt

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

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	March 31, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Senior debt, net of discount of $1,014 and $1,167	$ 25,049	$ 24,895
10% subordinated note payable to a related party	7,170	6,994
Capital leases, maturing through August 2017	1,903	2,355
	34,122	34,244
Less current portion	(2,336)	(7,973)
Long-term debt	$ 31,786	$ 26,271

On May 11, 2016, the Company entered into a $60 million senior secured credit facility with entities affiliated with Deerfield Private Design Fund III, L.P. (Deerfield) as lenders. 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 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 (see Note 17). As a result, except for a $0.7 million payment made May 2, 2016, the senior debt and the related party subordinated note payable were classified as long-term debt at March 31, 2016.

Senior debt: In March 2014, the Company entered into a Loan and Security Agreement (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 provides a total commitment of $25.0 million, available in four draws. Borrowings under the LSA are 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. The Company met the Tranche 4 Milestones stated in the LSA prior to July 31, 2015.

Each draw is 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 commence. A balloon payment of the entire principal balance outstanding on October 1, 2017 and all accrued but unpaid interest thereunder is due and payable on October 1, 2017. The interest rate is 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 is payable at the earliest to occur of (1) October 1, 2017, (2) the date the Company prepays its outstanding Secured Obligations, as defined therein, or (3) the date the Secured Obligations become due and payable.

The LSA, as amended, also contains certain financial and 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, 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 may 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 March 31, 2016 and December 31, 2015, the Company was in compliance with the covenants under the LSA, as amended.

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.

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End of term charge amortization totaled $83,000 and $75,000 for the three months ended March 31, 2016 and 2015, respectively. Debt discount amortization to interest expense for the senior debt totaled $71,000 and $64,000 for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2015, the fair values of the Hercules Warrants were remeasured and the change in fair value of approximately $32,000 for the three months ended March 31, 2015 was recorded in other income (expense), net in the Company s consolidated statements of operations.

10% subordinated related party note: The Company has an amended and restated subordinated note (the Note) in the aggregate principal amount of $5.9 million that was issued by the Company to Essex Capital Corporation (Essex) which matures in March 2017. Interest accrues and adds to the principal balance until such time as the Company achieves 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 16). The Company recorded this amendment as a loan modification. At each of March 31, 2016 and December 31, 2015, the aggregate principal amount of the Note was $5.9 million, and $1,235,000 and $1,059,000 in interest had been accrued as of March 31, 2016 and December 31, 2015, respectively.

Capital lease obligations to related party: As described in Notes 7 and 16, 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 $78,000 and $138,000 for the three months ended March 31, 2016 and 2015, respectively.

Future principal payments of long-term debt including capital leases, as adjusted to reflect the payments that will be due under the new debt agreement with Deerfield mentioned above, are as follows:

Period ending:		**March 31, 2016 (unaudited) (in thousands)**
2016	$	2,336
2017		308
2019		15,000
2020		15,000
2021		2,492
Future principal payments	$	35,136
Less unamortized debt discount		(1,014)
Less current portion of long-term debt		(2,336)

Total long-term debt	$	31,786

Note 11. Common stock and redeemable convertible preferred stock

The following table summarizes the authorized, issued and outstanding shares of the Company by class of stock as of March 31, 2016 and December 31, 2015. All shares have a par value of $0.001 per share:

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	March 31, 2016 (unaudited)		December 31, 2015	
	Authorized Shares	Issued and Outstanding Shares	Authorized Shares	Issued and Outstanding Shares
Common Stock	100,000,000	16,047,578	100,000,000	16,025,155
Preferred Stock	5,000,000		5,000,000	
Total Shares Issued		16,047,578		16,025,155
Treasury Stock		(9,197)		(9,197)
Total Outstanding Shares		16,038,381		16,015,958
Total Authorized Shares	105,000,000		105,000,000	

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), 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

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warrants held by several investors at an exercise price of $0.0024 per share. During the three months ended March 31, 2016, the Company issued a total of 19,090 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. As of March 31, 2016, Series B-1 warrants to purchase 31,068 shares of common stock remained outstanding, and expire on May 27, 2016. (See Note 17).

Between December 2014 and March 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 three months ended March 31, 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 first two months of 2015 (see warrant liability section below). From June 30, 2015 through July 27, 2015, the Company issued a total of 1,000,000 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 $5 million.

Dividends: From and after the date of the issuance of the Company s Series B-1 redeemable convertible preferred stock (Series B-1 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 was 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 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 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 March 31, 2015 was $236,000, $164,000 and $85,000, 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.

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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 March 31, 2015, the Series C warrant fair values were remeasured and a reduction in fair value of approximately $234,000 was recorded in other income (expense), net in the Company s consolidated statements of operations.

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 12. Stock options, restricted stock and performance stock options

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 three months ended March 31, 2016, 5,000 shares related to forfeited 2009 Plan options were added to the shares available under the 2015 Plan. As of March 31, 2016, 940,369 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.

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

	Three Months Ended March 31, 2016 (unaudited)
Estimated dividend yield	0%
Expected stock price volatility	60%
Weighted-average risk-free interest rate	1.31%
Expected life of option in years	6.25
Weighted-average option fair value at grant	$ 5.825

Total compensation cost that has been charged to general and administrative expense related to stock options was $600,000 and $74,000 for the three months ended March 31, 2016 and 2015, respectively. At March 31, 2016, there was $7.3 million of unrecognized compensation cost, which is expected to be recognized over a weighted-average period of 2.9 years. For the three months ended March 31, 2016, the Company issued 3,333 shares of the Company s common stock upon the exercise of outstanding stock options and received proceeds of $1,000 and realized no tax benefit from the exercised stock options.

A summary of outstanding and exercisable options as of March 31, 2016 and December 31, 2015 and the activity from December 31, 2015 through March 31, 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)	75,000	$ 10.320	
Exercised (unaudited)	(3,333)	0.320	
Expired, forfeited or cancelled (unaudited)	(48,532)	23.833	
Outstanding at March 31, 2016 (unaudited)	1,375,418	$ 13.099	$
Exercisable at March 31, 2016 (unaudited)	270,207	$ 4.530	$ 1,691

The weighted-average remaining contractual life of options outstanding and exercisable on March 31, 2016 was 8.8 and 7.4 years, respectively. The option exercise price for all options granted January 1, 2016 through March 31, 2016 was $10.32 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.

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The Company did not issue any shares of restricted stock for the year ended December 31, 2015 or for the three months ended March 31, 2016. Restricted stock compensation cost of $23,000 for each of the three months ended March 31, 2016 and 2015, respectively, has been charged to general and administrative expenses. At March 31, 2016 and 2015, there was $139,000 and $233,000, respectively, of unrecognized compensation cost related to restricted stock. No vested restricted stock awards were settled during the three months ended March 31, 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 March 31, 2016 and December 31, 2015. For the three months ended March 31, 2016, there were no shares of restricted stock granted, vested or forfeited.

Note 13. 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 14. 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 $1,192,000 and $1,166,000 at March 31, 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 for the Grand Prairie facility was $57,000 and $59,000 for the three months ended March 31, 2016 and 2015, respectively. Rent expense for these leases, excluding the share of operating expenses, was $253,000 and $218,000 for the three months ended March 31, 2016 and 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 $252,000 of bonus expense for the three months ended March 31, 2016.

Note 15. 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 will also pay a single digit royalty on net sales of Adzenys XR-ODT during the life of the patents. The royalties will be recorded as cost of goods sold in the same period as the net sales upon which they are calculated.

Note 16. Related party transactions

At March 31, 2016 and 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 10 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.

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As described in Note 7, 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 17. Subsequent events

Between April 1 and May 13, 2016, the Company issued 1,205 shares of its common stock to an investor upon the exercise of Series B-1 warrants held by those investors at an exercise price of $0.0024 per share (see Note 11).

In April 2016, the Company s board of directors authorized the grant of options to purchase 391,595 shares of common stock to its employees.

On May 11, 2016, the Company entered into a $60 million senior secured credit facility with entities affiliated with Deerfield Private Design Fund III, L.P. as lenders. 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 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.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements for the years ended December 31, 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, or ADHD. Our product and product candidates are extended-release, or XR, medications in patient-friendly, orally disintegrating tablets, or 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, or FDA, for Adzenys XR-ODT, our amphetamine XR-ODT, on January 27, 2016. We believe Adzenys XR-ODT 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 October 16, 2015, we received notification from the FDA stating that, as part of its ongoing review of our New Drug Application, or 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. We expect to resubmit an NDA for Cotempla XR-ODT in the fourth quarter of 2016, following the completion of the bioequivalence bridging study. 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, or cGMP, and U.S. Drug Enforcement Administration, or DEA-registered manufacturing facilities, thereby obtaining our products at cost without manufacturer s margins and better controlling supply quality and timing. We 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, or 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, or 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., or 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.

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We have incurred significant losses in each year since our reorganization in 2009. Our net losses were $12.6 million and $30.8 million for the three months ended March 31, 2016 and the year ended December 31, 2015, respectively. As of March 31, 2016 and December 31, 2015, we had an accumulated deficit of approximately $129.4 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 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, or 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 with entities affiliated with Deerfield Private Design Fund III, L.P. as lenders. 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 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 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 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 product through wholesalers. As a result of our acquisition of all of the rights to the Tussionex ANDA, we expect our future revenue to increase from historical levels as a result of our efforts directed toward the commercialization of our generic Tussionex.

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 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. The Company is currently producing inventory to support the commercial launch of Adzenys XR-ODT announced on May 16, 2016. If we fail to effectively launch our marketing plans for 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.

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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, or 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 March 31,	
	2016	2015
	(unaudited)	

		(in thousands)		
NT-0102 Cotempla XR-ODT	$	256	$	2,419
NT-0201 Amphetamine Liquid		75		48
NT-0202 Adzenys XR- ODT		425		34
Other Research and Development Activities (1)		1,585		1,819
	$	2,341	$	4,320

(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 assessment of food effect, and to provide process validation and three months of stability data. We expect to resubmit an

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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.

Selling and marketing

Selling and marketing expenses consist primarily of salaries and related costs for personnel, pre-commercialization activities for Adzenys XR-ODT and our product candidates, trade sales expenses for our generic Tussionex and commercial sales organization costs incurred in preparation for 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.

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 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.

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 7 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 March 31, 2016 compared to the three months ended March 31, 2015

Revenues

The following table summarizes our revenues for the three months ended March 31, 2016 and 2015:

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	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(unaudited)			
	(in thousands)			
Product	$ 2,583	$ 428	$ 2,155	503.5%

Total product revenues were $2.6 million and $0.4 million for the three months ended March 31, 2016 and 2015, respectively, all of which was generated from net sales of our generic Tussionex for which we acquired all commercialization and profit rights in August 2014. The $2.2 million increase in product revenues primarily resulted from sales to a large pharmacy chain in 2016, which was initiated in the second fiscal quarter of 2015.

Cost of goods sold

The following table summarizes our cost of goods sold for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(unaudited)			
	(in thousands)			
Cost of Goods Sold	$ 2,272	$ 1,095	$ 1,177	107.5%

The total cost of goods sold was $2.3 million for the three months ended March 31, 2016, an increase of $1.2 million or 107.5%, from the $1.1 million for the three months ended March 31, 2015. This increase was primarily due to $1.0 million increase in raw material costs due to the increased sales of Tussionex and 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 expensed tooling.

Research and development expenses

The following table summarizes our research and development expenses for three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(unaudited)			
	(in thousands)			
Research and Development Expenses	$ 2,341	$ 4,320	$ (1,979)	(45.8)%

Research and development expenses were $2.3 million for the three months ended March 31, 2016, a decrease of $2.0 million or 45.8%, from the $4.3 million for the three months ended March 31, 2015. This decrease was primarily due to a $2.3 million FDA filing fee for the NDA for Cotempla XR-ODT submitted in January 2015, partially offset by a $0.3 million accrual of the FDA finished-drug fee for Adzenys XR-ODT subsequent to the PDUFA approval in January 2016.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the three months ended March 31, 2016 and 2015:

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	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
		(unaudited)		
		(in thousands)		
Selling and Marketing	$ 6,284	$ 326	$ 5,958	1,827.6%

The total selling and marketing expenses were $6.3 million for the three months ended March 31, 2016, an increase of $6.0 million or 1,827.6%, from the $0.3 million for the three months ended March 31, 2015. Selling and marketing professional services increased by $4.4 million due to commercial sales organization start-up costs, market research and data analysis and advertising agency costs, marketing professional services, managed care research and marketing and non-personal promotion incurred in 2016 for Adzenys XR-ODT. Salary and compensation expense increased $1.2 million and recruiting fees increased $0.2 million due to the build out of our sales and marketing management as part of pre-commercialization efforts for Adzenys XR-ODT. In addition, selling and marketing travel expenses increased $0.2 million related to these pre-commercialization activities.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
		(unaudited)		
		(in thousands)		
General and Administrative	$ 3,550	$ 1,337	$ 2,213	165.5%

The total general and administrative expenses were $3.5 million for the three months ended March 31, 2016, an increase of $2.2 million or 165.5%, from the $1.3 million for the three months ended March 31, 2015. Salary and compensation expense increased $1.1 million in the three months ended March 31, 2016 primarily due a $0.5 million increase in compensation related to share-based payments and a $0.5 million increase in 2016 principally due to the addition of personnel to handle the administrative and compliance work associated with being a public company. Also, professional fees increased $0.8 million in 2016 primarily for legal, audit, tax, public filing and recruiting services. In addition, general and administrative expenses increased by $0.2 million in 2016 for 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 March 31, 2016 and 2015:

	Three Months Ended March 31,	Increase	% Increase

	2016	2015	(Decrease)	(Decrease)
		(unaudited)		
		(in thousands)		
Interest Expense, Net	$ 961	$ 757	$ 204	26.9%

The total interest expense was $1.0 million for the three months ended March 31, 2016, an increase of $0.2 million or 26.9%, from the $0.8 million for the three months ended March 31, 2015. The $0.2 million increase resulted from $0.2 million higher interest on senior debt due to the increased debt in 2016, $0.1 million increased interest on the subordinated debt 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 16 in the notes to our financial statements above), which were partially offset by a $0.1 million decrease consisting of a reduction in capital lease interest due to the reduced capital lease balances resulting from ongoing lease payments and interest income on short term investments.

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Other income (expense), net

The following table summarizes our other income (expense) for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,			
	2016	2015	Increase (Decrease)	% Increase (Decrease)