Neos Therapeutics, Inc.
Form 10-Q
November 13, 2015
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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 SEPTEMBER 30, 2015

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 November 13, 2015: 15,942,546 shares.

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NEOS THERAPEUTICS, INC.

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Special note regarding forward-looking statements

This Quarterly Report on Form 10Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, and these statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. 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 potential or continue or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- 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, to develop and commercialize NT-0102, NT-0202, NT-0201, or any other future product or 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 NT-0102 and whether we will be able to address the issues that may relate to those deficiencies;

- the Prescription Drug User Fee Act goal dates for NT-0102 and NT-0202, and the New Drug Application submission date for NT-0201;

- the timing, cost or other aspects of the commercial launch and future sales of NT-0102, NT-0202, NT-0201, or any other future product or product candidate;

- our ability to increase our manufacturing and distribution capabilities for NT-0102, NT-0202, NT-0201, or any other future product or product candidate;

- our estimates regarding anticipated expenses, capital requirements and our needs for additional financing;

- the attention deficit hyperactivity disorder patient market size and market adoption of NT-0102, NT-0202, or NT-0201 by physicians and patients;

- the therapeutic benefits, effectiveness and safety of NT-0102, NT-0202, NT-0201, or any other future product or product candidate;

- our expectations regarding the commercial supply of our NT-0102, NT-0202 or NT-0201 product candidates or our generic Tussionex;

- 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.

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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)

	September 30, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 102,896	$ 13,343
Short term investments		3,000
Accounts receivable, net of allowances of $1 and $204, respectively	50	367
Inventories	2,661	2,031
Other current assets	819	264
Total current assets	106,426	19,005
Property and equipment, net	5,210	5,831
Intangible assets, net	17,046	18,167
Other assets	2,427	2,227
Total assets	$ 131,109	$ 45,230
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 2,376	$ 1,257
Accrued expenses	5,086	2,715
Current portion of long-term debt	5,775	1,653
Total current liabilities	13,237	5,625
Long-Term Liabilities:		
Long-term debt, net of current portion	28,579	23,121
Earnout liability	353	756
Deferred gain on leaseback	760	1,383
Deferred rent	1,163	1,189
Warrant liabilities		1,789
Total long-term liabilities	30,855	28,238

Redeemable Preferred Stock, $0.001 par value				
Series A - 1,170,000 authorized; issued and outstanding; liquidation preference of $5,850 at December 31, 2014; no shares authorized, issued or outstanding as of September 30, 2015				1,068
Series B - 4,000,000 authorized; 3,113,099 issued and outstanding; liquidation preference of $15,565 at December 31, 2014; no shares authorized, issued or outstanding as of September 30, 2015				14,559
Series B-1 - 8,830,000 authorized; 5,461,802 issued and outstanding; liquidation preference of $61,647 at December 31, 2014; no shares authorized, issued or outstanding as of September 30, 2015				32,391
Series C - 13,500,000 authorized; 8,753,547 issued and outstanding at December 31, 2014 ; liquidation preference of $43,768 at December 31, 2014; no shares authorized, issued or outstanding as of September 30, 2015				42,131
				90,149
Stockholders Equity (Deficit):				
Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at September 30, 2015; no shares authorized, issued or outstanding as of December 31, 2014				
Common stock, $0.001 par value, 100,000,000 authorized; 15,839,064 issued and outstanding as of September 30, 2015 and 35,000,000, 938,859 and 882,954 authorized, issued and outstanding at December 31, 2014, respectively		16		1
Additional paid-in capital		194,682		4,831
Accumulated deficit		(107,681)		(83,614)
Total stockholders equity (deficit)		87,017		(78,782)
Total liabilities, redeemable preferred stock and stockholders equity (deficit)	$	131,109	$	45,230

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 September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Product	$ 221	$ (120)	$ 2,133	$ (120)
Manufacturing				113
Development		67		160
Profit sharing		28		169
	221	(25)	2,133	322
Cost of goods sold	1,079	782	3,833	2,225
Gross loss	(858)	(807)	(1,700)	(1,903)
Research and development	2,701	2,727	9,123	8,195
Selling and marketing expenses	1,343	106	2,271	117
General and administrative expenses	2,073	1,245	5,069	4,196
Loss from operations	(6,975)	(4,885)	(18,163)	(14,411)
Interest expense, net	(1,044)	(562)	(2,685)	(2,199)
Other income, net	518	208	623	618
Change in fair value of earnout and warrant liabilities	(1,867)		(1,452)	
Net loss	$ (9,368)	$ (5,239)	$ (21,677)	$ (15,992)
Net loss	(9,368)	(5,239)	(21,677)	(15,992)
Preferred stock accretion to redemption value	(99)	(268)	(1,169)	(850)
Preferred stock dividends	(138)	(551)	(1,221)	(1,634)
Net loss attributable to common stock	$ (9,605)	$ (6,058)	$ (24,067)	$ (18,476)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	12,403,182	878,929	4,767,479	874,480
Net loss per share attributable to common stock, basic and diluted	$ (0.77)	$ (6.89)	$ (5.05)	$ (21.13)

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

Nine months Ended September 30, 2015

(In thousands, except shares)

(unaudited)

	Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2014		**$**	**938,859**	**$ 1**	**(55,905)**	**$**	**$ 4,831**	**$ (83,614)**	**$ (78,782)**
Proceeds from exercise of options and warrants			139,201				72		72
Share-based compensation expense							552		552
Cancellation of treasury stock			(55,905)		55,905				
Series B Preferred Stock accretion to redemption value								(192)	(192)
Series B-1 Preferred Stock accretion to redemption value								(370)	(370)
Series B-1 accrued dividend								(1,221)	(1,221)
Series C Preferred Stock accretion to redemption value								(607)	(607)
Conversion of Redeemable Preferred Stock			9,217,983	9			110,767		110,776
Cashless exercise of Series C warrants issued with Series C financing			78,926				2,842		2,842
Reclassification of Series C warrants issued with senior debt							611		611
Net proceeds from issuance of common stock in IPO			5,520,000	6			75,007		75,013
Net loss								(21,677)	(21,677)
Balance, September 30, 2015		**$**	**15,839,064**	**$ 16**		**$**	**$ 194,682**	**$ (107,681)**	**$ 87,017**

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)

	Nine Months Ended Sept 30,	
	2015	**2014**
Cash Flows From Operating Activities:		
Net loss	$ (21,677)	$ (15,992)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	1,277	1,228
Amortization of intangible assets	1,121	664
Changes in fair value of warrant and earnout liabilities	1,452	
Amortization of patents	17	
Amortization and write-off of senior debt fees	426	487
Gain on sale of equipment	(623)	(616)
Provision for bad debts		(204)
Share-based compensation expense	552	136
Interest accrued on note payable	372	414
Change in deferred rent	(26)	49
Changes in operating assets and liabilities:		
Accounts receivable	317	558
Inventories	(630)	(1,174)
Other current assets	(555)	(1)
Other assets	(217)	(136)
Accounts payable	919	35
Accrued expenses	2,356	1,087
Net cash used in operating activities	(14,919)	(13,465)
Cash Flows From Investing Activities:		
Net proceeds from sale (purchase) of short-term investments	3,000	4,499
Capital expenditures	(656)	(105)
Intangible asset acquisition		(6,283)
Net cash provided by (used in) investing activities	2,344	(1,889)
Cash Flows From Financing Activities:		
Proceeds from senior debt note	10,000	15,000
Proceeds from sale of equipment		795
Net proceeds from issuance of common and preferred stock	18,119	9,906
Net proceeds from initial public offering, net of underwriting discounts and commissions	77,004	
Payments of initial public offering costs	(1,778)	
Payments made on borrowings	(1,217)	(11,293)
Deferred financing costs		(563)
Net cash provided by financing activities	102,128	13,845
Increase (decrease) in cash and cash equivalents	89,553	(1,509)

Cash and Cash Equivalents:				
Beginning		13,343		11,947
Ending	$	102,896	$	10,438
Supplemental Noncash Investing and Financing Activities:				
Earnout liability incurred in connection with intangible asset acquistion	$		$	589
Initial public offering costs included in accounts payable and accrued expenses	$	213	$	
Issuance of stock warrants	$	2,131	$	372
Exercise of Series C warrants for Series C Preferred Stock	$	2,322		
Cashless exercise of Series C warrants from Series C financing in IPO closing	$	2,842	$	
Conversion of redeemable preferred stocks into common stock	$	110,776	$	
Reclassification of Series C warrants issued with senior debt upon IPO closing	$	611	$	
Preferred stock accretion	$	1,169	$	850
Preferred stock dividend	$	1,221	$	1,634
Supplemental Cash Flow Information:				
Interest paid	$	1,820	$	1,314

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 and nine months ended September 30, 2015 are not necessarily indicative of the results for the year ending December 31, 2015 or any period thereafter. The audited consolidated financial statements as of and for the year ended December 31, 2014 included information and footnotes necessary for such presentation and were included in the Neos Therapeutics, Inc. final prospectus dated as of July 22, 2015 and filed with the SEC, on July 24, 2015 (Final Prospectus). 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, 2014.

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 three proprietary product candidates for the treatment of attention deficit hyperactivity disorder (ADHD) which are in late-stage development and/or regulatory review. 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 8). 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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

convertible preferred stock (Series C preferred stock) to several existing investors upon the exercise of warrants to purchase Series C preferred stock (Series C warrants) held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $5.0 million. On 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. 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

With the closing of the Company s IPO, the Company is no longer accruing preferred stock dividends or accreting the redeemable preferred stock to its redemption value as these Preferred Shares were retired and cancelled as stated above. There have been no other material changes to the significant accounting policies previously disclosed in the Company s Final Prospectus for the year ended December 31, 2014.

Principles of consolidation: At September 30, 2015, 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 U.S. Treasury Bills that have original maturities greater than three months but less than or equal to one year and are classified as available-for-sale securities. These investments are recorded at fair value. Realized gains and losses are reported in the consolidated statements of operations. Unrealized gains and losses are immaterial.

Fair value of financial instruments: The carrying value of the Company s financial instruments, including cash and cash equivalents, short-term investments, 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 warrants and earnout liabilities is 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.

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 ranging from 10 to 20 years.

Deferred Offering Costs: The Company capitalizes certain legal, accounting and other third-party fees that are directly

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

associated with in-process equity financings as deferred offering costs (non-current) until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders equity (deficit) as a reduction of additional paid-in capital generated as a result of the financing.

Revenue recognition: Revenue is generated from product sales, recorded on a net sales basis, and historically, manufacturing, development and profit sharing from a development and manufacturing agreement. 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.

The Company expects that manufacturing, profit sharing and development revenue will end as the Company has terminated the Company s development and manufacturing agreement. As a result of the Company s acquisition of the rights to commercialize and derive future profits from the Tussionex ANDA, the Company will utilize its manufacturing capability to derive revenue directly from sales made by the Company, rather than through the Company s former commercial partner.

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,

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

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.

Manufacturing

Manufacturing revenue is derived from product manufactured by the Company and sold by the Company s former commercial partner under a development and manufacturing agreement. Manufacturing revenue is derived from a contractual supply price paid to the Company by the Company s commercial partners.

Profit sharing

Profit sharing revenue is recorded as the product is sold by the Company s former commercial partner. The profit share is the Company s share of the net profits after taking into account net revenue, which is gross product sales by the Company s former commercial partner, net of discounts, returns and allowances incurred by the Company s former commercial partner, less collaboration expenses.

Development revenue

Development revenue from the development and manufacturing agreement has been recognized as the related services are completed. Development revenue in the form of milestone payments is recognized upon achievement of the related milestones and provided that collectability is reasonably assured and other revenue recognition criteria are met. Amounts received under cost reimbursement arrangements for production and research and development are recorded as offsets to the costs incurred and not recognized as revenue.

Research and development costs: Research and development costs are charged to operations when incurred and include salaries and benefits, facilities costs, overhead costs, 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 December 31, 2014 and September 30, 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 December 31, 2014 and September 30, 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.

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At December 31, 2014, the Company had a net operating loss carry-forward of $86,551,000 and research and development credits of $2,029,000, 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 there would not be a material limitation in the utilization of the net operating loss carry-forwards and credits due to any ownership changes.

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 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 (Deficit).

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. 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 2014 and the three and nine months ended September 30, 2015 and 2014, 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 one or more of its ADHD product candidates. With the completion of the Company s IPO in July 2015, 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.

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Recent accounting pronouncements: In July 2015, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (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 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 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. The Company is evaluating the effect that ASU 2014-09 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 the standard on its ongoing financial reporting.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period.* This ASU requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. The Company does not expect the adoption of this standard will have a material impact on the Company s financial statements.

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 does not expect the adoption of this standard will have a material impact on the Company s financial statements.

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

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.

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The following potentially dilutive securities outstanding as of September 30, 2015 and 2014 were excluded from consideration in the computation of diluted net loss per share of common stock for the three and nine months ended September 30, 2015 and 2014, respectively, because including them would have been anti-dilutive:

	September 30, 2015	September 30, 2014
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)		3,022,306
Series C Redeemable Convertible Preferred Stock Warrants (as converted)	70,833	70,833
Common Stock Warrants (as converted)	235,695	337,133
Stock options	1,224,227	523,184

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 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:

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	Fair Value as of December 31, 2014			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Cash and cash equivalents	$ 13,343	$	$	$ 13,343
Short term investments	3,000			3,000
Earnout liability			756	756
Series C Redeemable Preferred Stock Warrants			1,789	1,789
	$ 16,343	$	$ 2,545	$ 18,888

	Fair Value as of September 30, 2015			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Cash and cash equivalents	$ 102,896	$	$	$ 102,896
Earnout liability			353	353
	$ 102,896	$	$ 353	$ 103,249

The Company s Level 1 assets include bank deposits, U.S. Treasury bills and money market funds with quoted prices in active markets.

Level 3 liabilities included the fair values of the earnout liability and the outstanding Series C warrants at December 31, 2014. There were no outstanding warrants to purchase preferred stock as of September 30, 2015.

Various methodologies were utilized to value the Level 3 liabilities including Black-Scholes, Probability-Weighted Expected Return (PWERM), Option Pricing and Monte Carlo. The methodologies and significant inputs used in the determination of the fair value of the Hercules Warrants were as follows:

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	Revalue Series C Warrants Issued with Senior Debt at December 31, 2014	Revalue Series C Warrants Issued with Senior Debt at March 31, 2015	Revalue Series C Warrants Issued with Senior Debt at June 30, 2015	Revalue Series C Warrants Issued with Senior Debt at July 22, 2015
	(Dollars in thousands, except $5 and $12 Exercise Prices)			
Date of Valuation	**12/31/2014**	**3/31/2015**	**6/30/2015**	**7/22/2015**
Valuation Method	PWERM and Option Pricing	PWERM and Option Pricing	PWERM and Option Pricing	Black-Scholes-Merton Option-Pricing
Dividend yield (per share)	0	0	0	0
Exercise price	$ 5	$ 5	$ 5	$ 12
Volatility (annual)	60%	60%	60%	60%
Risk-free rate (annual)	.25% - 2.47%	.19% - 2.31%	.14% - 2.83%	1.78%
Contractual term (years)	1 - 5	.75 - 5	.5 - 5	5
Number of warrants	170,000	170,000	170,000	70,833
Fair value of liability at valuation date	$ 454	$ 486	$ 573	$ 611

As the Hercules Warrants converted into warrants for common stock, with a term of five years from the IPO date, it was determined that the Black-Scholes-Merton Option-Pricing model would provide a better indication of the fair value as it was designed to calculate the value of a put or call option over time.

The methodologies and significant inputs used in the determination of the fair value of the Series C warrants issued with the Series C preferred stock were as follows:

	Initial Valuation of December 31, 2014 Warrants Issued With Series C Redeemable Preferred Stock	Initial Valuation of January 2015 Warrants Issued With Series C Redeemable Preferred Stock	Initial Valuation of February 2015 Warrants Issued With Series C Redeemable Preferred Stock	Revalue All Warrants Issued With Series C Redeemable Preferred Stock at March 31, 2015	Revalue All Warrants Issued With Series C Redeemable Preferred Stock at June 30, 2015	Revalue All Warrants Issued With Series C Redeemable Preferred Stock at July 22, 2015
	(Dollars in thousands, except $5 and $12 Exercise Prices)					
Date of Valuation	**12/31/2014**	**1/31/2015**	**2/28/2015**	**3/31/2015**	**6/30/2015**	**7/22/2015**
Valuation Method	PWERM and Option Pricing	PWERM and Option Pricing	PWERM and Option Pricing	PWERM and Option Pricing	PWERM and Option Pricing	
Dividend yield (per share)	0	0	0	0	0	0
Exercise price	$ 5	$ 5	$ 5	$ 5	$ 5	$ 12

Volatility (annual)	60%	60%	60%	60%	60%	
Risk-free rate (annual)	.25% - 2.47%	.25% - 2.47%	.25% - 2.47%	.19% - 2.31%	.14% - 2.83%	
Contractual term (years)	1 - 5	1 - 5	1 - 5	.75 - 5	.5 - 5	
Number of warrants	749,967	590,906	606,312	1,947,185	1,797,185	1,347,185
Fair value of liability at valuation date	$ 1,335	$ 1,052	$ 1,079	$ 3,233	$ 3,361	$ 4,042

Immediately after the July 22, 2015 revaluation, the Series C warrants issued with the Series C preferred stock were exchanged in a post-split net exercise whereby the option to purchase one share of Series C preferred stock plus the adjusted exercise price of $12.00 was exchanged for one share of common stock with an initial price to the public of $15.00; therefore, the value of these Series C warrants was determined to be its intrinsic value of $3.00 per share.

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

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	December 31, 2014 Earnout Liability	March 31, 2015 Earnout Liability	June 30, 2015 Earnout Liability	September 30, 2015 Earnout Liability
	(Dollars in thousands)			
Date of Valuation	**12/31/2014**	**3/31/2015**	**6/30/2015**	**9/30/2015**
Valuation Method	Monte Carlo	Monte Carlo	Monte Carlo	Monte Carlo
Volatility (annual)	50%	50%	50%	50%
Risk-free rate (annual)	.15% - 3.21%	.14% - 3.00%	.09% - 3.51%	.15% - 3.21%
Time period from valuation until end of earnout	.5 - 9.5	.375 - 9.375	.25 - 9.0	.125 - 8.75
Earnout Target 1	$ 13,700	$ 13,700	$ 13,700	$ 13,700
Earnout Target 2	$ 18,200	$ 18,200	$ 18,200	$ 18,200
Discount rate	7.96% - 11.03%	8.18% - 11.04%	7.96% - 11.39%	8.16% - 11.22%
Fair value of liability at valuation date	$ 756	$ 314	$ 356	$ 353

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

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

	Earnout Liability	Series C Warrants Issued With Senior Debt	Series C Warrants Issued With Series C Redeemable Preferred Stock Financing
		(in thousands)	
Balance at December 31, 2014	$ 756	$ 454	$ 1,335
Additions during the period			2,131
Changes in fair value	(403)	157	1,698
Warrants exercised			(2322)
Cashless warrant exercise due to IPO			(2842)
Conversion to common stock warrant		(611)	
Balance at September 30, 2015	$ 353	$	$

The reductions in fair value of the earnout liability shown above resulted from new information regarding the projected impact of the DEA s reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance and a review of the launch dates of the Company s three ADHD product candidates. The increases in the fair value of the Series C warrants were due to the increased weighting of the IPO scenario in the PWERM model.

Note 6. Inventories

Inventories at the indicated dates consist of the following:

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	September 30, 2015	December 31, 2014
	(in thousands)	
Raw materials	$ 1,149	$ 646
Work in progress	86	82
Finished goods	1,506	1,499
Inventory at cost	2,741	2,227
Inventory reserve	(80)	(196)
	$ 2,661	$ 2,031

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 the three months ended September 30, 2015 and 2014, approximately $207,000 and $208,000, respectively, and for the nine months ended September 30, 2015 and 2014 approximately $623,000 and $616,000, respectively, 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:

	September 30, 2015	December 31, 2014
	(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	284	284
	22,756	22,756

Accumulated amortization		(5,710)		(4,589)
	$	17,046	$	18,167

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 September 30, 2015 and 2014 and amortization expense of $585,000 was recorded for both the nine months ended September 30, 2015 and 2014.

On August 28, 2014, the Company completed an acquisition of the rights to Tussionex ANDA from Cornerstone and CPI which was accounted for as an asset acquisition. 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, and Cornerstone

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had commercialization rights to the product. The Company paid $4.2 million to Cornerstone to buy out its rights to commercialize and derive future profits from the product and entered into an agreement whereby Cornerstone transferred certain assets associated with the product to the Company. Legal fees of $90,000 associated with this buyout agreement have been capitalized as part of the purchase price. 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 September 30, 2015, resulting in a $3,000 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 September 30, 2015. The net decrease of $403,000 for the nine months ended September 30, 2015 resulted from new information regarding the projected impact of the DEA s reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance. In addition, the Company paid $2.0 million to CPI 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. Legal fees of $43,000 associated with this buyout agreement have been capitalized as part of the purchase price of this intangible asset. These two intangible assets have an expected life of ten years and are being amortized on a straight-line basis beginning September 2014. Total amortization expense related to these intangible assets was $172,000 and $515,000 for the three and nine months ended September 30, 2015, respectively, and $57,000 and $57,000 for the three and nine months ended September 30, 2014, respectively.

Note 9. Other assets

Other assets at the indicated dates consist of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Patents	$ 2,244	$ 2,051
Deposits	183	176
	$ 2,427	$ 2,227

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. For the three and nine months ended September 30, 2015, $5,000 and $17,000, respectively, of patent amortization expense was recorded. There was no patent amortization expense for the three and nine months ended September 30, 2014. After consummation of the Company s IPO, the $1,991,000 balance of Deferred IPO Offering Costs incurred in 2015 was reclassified to stockholders equity (deficit) as a reduction of additional paid-in capital.

Note 10. Long-term debt

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

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	September 30, 2015	December 31, 2014
	(in thousands)	
Senior debt, net of discount of $1,317 and $1,743	$ 24,745	$ 14,320
10% subordinated note payable to a related party	6,818	6,446
Capital leases, maturing through August 2017	2,791	4,008
	34,354	24,774
Less current portion	(5,775)	(1,653)
Long-term debt	$ 28,579	$ 23,121

Senior debt: In March 2014, the Company entered into a Loan and Security Agreement (LSA) with 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 December 31, 2014 and September 30, 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 for the purchase of 70,833 shares of common stock at a price of $12.00 per shares upon the closing of the Company s IPO and were therefore reclassified from warrant liability to Additional Paid in Capital within Shareholders Equity (Deficit).

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 $79,000 and $230,000 for the three and nine months ended September 30, 2015, respectively. End of term charge amortization totaled $22,000 and $53,000 for the three and nine months ended September 30, 2014, respectively. Debt discount amortization to interest expense for the senior debt totaled $67,000 and $196,000 for the three and nine months ended September 30, 2015, respectively. Debt discount amortization to interest expense for the senior debt totaled $36,000 and $64,000 for the three and nine months ended September 30, 2014, respectively. As of July 22, 2015, the fair values of the Hercules Warrants were remeasured and the change in fair value of approximately $38,000 for the three months ended September 30, 2015 has been recorded in other income (expense), net in the Company s consolidated statements of operations and cumulatively for the nine months ended September 30, 2015, a total of $157,000 has been recorded in other income (expense), net in the Company s consolidated statements of operations.

Credit Agreement: Previously, the Company had a credit agreement entered into on August 20, 2012 (the Credit Agreement) with a financial institution. The Credit Agreement provided for a four-year $10.0 million term loan, with an annual interest rate of 9.5% payable monthly. In addition, a $250,000 fee payable at maturity was being amortized using the effective interest method. The proceeds from the initial $10.0 million draw on the LSA were used to repay the outstanding $10.0 million Credit Agreement balance and $697,000 of interest expense related to the Credit Agreement in March 2014. The early prepayment of the Credit Agreement resulted in a $445,000 loss (due to recording the $98,000 prepayment penalty and writing off the $154,000 unamortized exit fee and the $193,000 of unamortized loan cost) reflected in interest expense for the nine months ended September 30, 2014.

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). 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 December 31, 2014 and September 30, 2015, the aggregate principal amount of the Note was $5.9 million, and $511,000 and $883,000 in interest had been accrued through the year ended December 31, 2014 and through the nine months ended September 30, 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 $110,000 and $371,000 for the three months ended September 30, 2015 and September 30, 2014, respectively, and $169,000 and $507,000 for the nine months ended September 30, 2015 and 2014, respectively.

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

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Period ending:		September 30, 2015 (in thousands)
2015	$	436
2016		7,973
2017		27,262
Future principal payments	$	35,671
Less unamortized debt discount		(1,317)
Less current portion of long-term debt		(5,775)
Total long-term debt	$	28,579

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 September 30, 2015 and December 31, 2014. All shares have a par value of $0.001 per share:

	September 30, 2015		December 31, 2014	
	Authorized Shares	Issued and Outstanding Shares	Authorized Shares	Issued and Outstanding Shares
Common Stock	100,000,000	15,839,064	35,000,000	938,859
Preferred Stock	5,000,000			
Series A Preferred Stock			1,170,000	1,170,000
Series B Preferred Stock			4,000,000	3,113,099
Series B-1 Preferred Stock			8,830,000	5,461,802
Series C Preferred Stock			13,500,000	8,753,547
Total Shares Issued		15,839,064		19,437,307
Treasury Stock				(55,905)
Total Outstanding Shares		15,839,064		19,381,402
Total Authorized Shares	105,000,000		62,500,000	

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 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.

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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:

- 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 convertible 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 (Deficit); 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 conjunction with the Company s Series B-1 financing in 2012, the Series B-1 investors also received warrants (Series B-1 warrants) to purchase 389,474 shares of common stock at an exercise price of $0.0024 per share. There were no exercises of Series B-1 warrants in the year ended December 31, 2014. During the nine months ended September 30, 2015, the Company issued a total of 101,431 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 September 30, 2015,

Series B-1 warrants to purchase 235,695 shares of common stock remained outstanding, and expire in 2016. Between October 1 and October 28, 2015, the Company issued 112,402 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 (see Note 17).

In February and March 2014, the Company closed on additional Series C financings totaling 1,986,586 shares, raising $9.9 million. Between December 2014 and February 2015, the Company closed on an additional Series C financing raising a total of $20.6 million, including $7.5 million in December 2014 and $13.1 million during the nine months ended September 30, 2015. The Company issued 1,499,935 shares in December 2014 and 2,624,936 shares during the three months ended March 31, 2015 of Series C preferred stock. In addition, the Company issued a Series C warrant to purchase one additional share of Series C preferred stock at a purchase price of $5.00 per share for every two purchased shares of Series C preferred stock, provided the investor purchased its pro-rata share of the Series C preferred stock. In the event that the Company s Series C preferred stock converted into common stock or another class of the Company s stock (Conversion Stock) during the warrant exercise period, then the warrants would become exercisable for the Conversion Stock and the exercise price of those warrants was to be ratably adjusted. The Company issued Series C warrants to purchase 749,967 shares of Series C preferred stock in December 2014 and 1,197,218 shares of Series C preferred stock during the nine months ended September 30, 2015 (see warrant liability section below). On June 30, 2015, the Company issued a total of 150,000 shares of its Series C preferred stock to an investor upon the exercise of warrants held by that investor at an exercise price of $5.00 per share, for an aggregate exercise price of $750,000. Between July 6 and July 27, 2015, the Company issued 850,000 shares of its Series C preferred stock to several investors upon the exercise of Series C warrants held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $4.25 million.

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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 the three and nine months ended September 30, 2015 and for the three and nine months ended September 30, 2014 for Series C preferred stock amounted to $37,000, $607,000, $21,000 and $66,000, respectively. The amount of accretion recorded for the three and nine months ended September 30, 2015 and for the three and nine months ended September 30, 2014 for Series B-1 preferred stock was $41,000, $370,000, $162,000 and $516,000, respectively. The amount of accretion recorded for the three and nine months ended September 30, 2015 and for the three and nine months ended September 30, 2014 for Series B preferred stock amounted to $21,000, $192,000, $84,000 and $268,000, respectively.

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

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

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

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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.

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 $1,522,000 and $ $1,698,000 has been recorded in other income (expense), net in the Company s consolidated statements of operations for the three and nine months ended September 30, 2015. 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. 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 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.

The Board of Directors approved option grants covering a total of 37,500 shares of common stock to certain non-employee directors on July 9, 2015 under the 2015 Plan. These option grants were effective immediately after the effectiveness of the Company s registration statement. The exercise price of these option grants was equal to the IPO price of $15.00. The Board of Directors approved option grants covering a total of 445,210 shares of common stock to certain non-employee directors and employees on August 20, 2015 under the 2015 Plan. These option grants were effective September 1, 2015. The exercise price of these option grants was equal to the market price of $25.50.

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. Unexercised options 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. During the third quarter of 2015, 2,083 shares related to forfeited 2009 Plan options were transferred into the shares available under the 2015 Plan. As of September 30, 2015, 284,620 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 September 30, 2015	Nine Months Ended September 30, 2015
Estimated dividend yield	0%	0%
Expected stock price volatility	60%	60%
Weighted-average risk-free interest rate	1.57%	1.60%
Expected life of option in years	5	5
Weighted-average option fair value at grant	$ 12.767	$ 10.054

Total compensation cost that has been charged to selling, general and administrative expense related to stock options was $291,000 and $480,000 for the three and nine months ended September 30, 2015, respectively, and $36,000 and $68,000 for the three and nine months ended September 30, 2014, respectively. At September 30, 2015, there was $7.1 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock options compensation which is expected to be recognized over the weighted-average remaining contractual life of options outstanding of approximately 9.1 years. For the nine months ended September 30, 2015, the Company issued 37,753 shares of the Company s common stock upon the exercise of outstanding stock options and received proceeds of $72,000 and realized no tax benefit from the exercised stock options.

A summary of outstanding and exercisable options as of September 30, 2015 and December 31, 2014 and the activity from December 31, 2014 through September 30, 2015, is presented below:

	Number of Options	Weighted-Average Exercise Price	Intrinsic Value (in thousands)
Outstanding at December 31, 2014	511,775	$ 3.684	$ 2,883
Exercisable at December 31, 2014	150,109	$ 1.467	$ 1,179
Granted	754,371	19.431	
Exercised	(37,753)	1.914	
Expired, forfeited or cancelled	(4,166)	2.498	
Outstanding at September 30, 2015	1,224,227	$ 13.446	$ 9,260
Exercisable at September 30, 2015	181,061	2.912	$ 3,277

The weighted-average remaining contractual life of options outstanding and exercisable on December 31, 2014 was 8.7 and 7.3 years, respectively. The option exercise price for all options granted in 2014 ranged from $2.91 to $7.49 per share. The weighted-average remaining contractual life of options outstanding and exercisable on September 30, 2015 was 9.1 and 7.3 years, respectively. The option exercise price for all options granted in the nine months ended September 30, 2015 ranged from $9.32 to $25.50 per share.

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Restricted stock: Under the 2009 Plan, the Company granted restricted stock awards to members of its management and selected members of the 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.

For the year ended December 31, 2013, the Company issued 149,244 shares of restricted stock at a grant date fair value of $2.55 per share. Of these shares, 7,195 vested immediately and the remaining 142,049 of these shares vest over 48 months in four equal tranches on the anniversary of the issue date. Restricted stock compensation cost of $27,000 and $72,000 for the three and nine months ended September 30, 2015, respectively, and $23,000 and $68,000 for the three and nine months ended September 30, 2014, respectively, has been charged to selling, general and administrative expenses. At September 30, 2015 and 2014, there was $185,000 and $278,000, respectively, of unrecognized compensation cost related to restricted stock. No vested restricted stock awards were settled during the nine months ended September 30, 2015. On October 16, 2015, the Company settled certain vested restricted stock awards which were settled having a value of $658,000 in cash, 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 106,537 shares of unvested restricted stock with a weighted average fair value of $2.55 as of September 30, 2015 and December 31, 2014. For the nine months ended September 30, 2015, there were no shares 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 office space and manufacturing facility under an operating lease which expires in 2024. 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 $1,163,000 and $1,189,000 at September 30, 2015 and December 31, 2014, respectively. The Company is also liable for a share of operating expenses for the premises as defined in the lease agreement. The Company s share of these operating expenses was $59,000 and $178,000 for the three and nine months ended September 30, 2015, respectively, and $62,000 and $188,000 for the three and nine months ended September 30, 2014, respectively. Rent expense, excluding the share of operating expenses, for the three and nine months ended September 30, 2015 was $218,000 and $654,000, respectively, and $223,000 and $678,000 for the three and nine months ended September 30, 2014, 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 $295,000 and $673,000 of bonus expense for the three and nine months ended September 30, 2015.

Note 15. License agreements

On July 23, 2014, 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). Under the terms of the agreement, the Company is required to pay a lump sum, non-refundable license fee of an amount less than $1.0 million no later than 30 days after receiving regulatory approval by the FDA of the Neos NDA. The Company will also pay a single digit royalty on net sales of the subject product during the life of the patents. Upon receiving such approval by the FDA, the

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license fee will be capitalized and amortized over 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 December 31, 2014 and September 30, 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.

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 October 1 and October 28, 2015, the Company issued 112,402 shares of its common stock to several investors upon the exercise of Series B-1 warrants held by those investors at an exercise price of $0.0024 per share (see Note 11).

On October 16, 2015, the Company settled certain vested restricted stock awards which were settled having a value of $658,000 in cash, and the company realized a tax benefit of $224,000. In October 2015, 9,197 shares of restricted stock were surrendered by the holder to the Company to cover taxes associated with vesting of restricted stock.

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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, 2014 and 2013 and notes thereto included in our final prospectus dated as of July 22, 2015. 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 our three branded product candidates for the treatment of attention deficit hyperactivity disorder, or ADHD. Our 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. If approved, we believe our most advanced product candidates, NT-0102 and NT-0202, will be the first methylphenidate XR-ODT and the first amphetamine XR-ODT, respectively, for the treatment of ADHD on the market. NT-0102 is our methylphenidate XR-ODT, which has a provisionally accepted trade name of Cotempla 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 NT-0102, it has identified deficiencies that preclude discussion of labeling and post marketing requirements/commitments at this time. The FDA stated that this notification does not reflect a final decision on the information under review. 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 to-be-marketed drug product, including an assessment of food effect, and to provide validation and three months of stability data. On July 30, 2015, we announced that we had resubmitted a NDA to the FDA for NT-0202, our amphetamine XR-ODT and we have a Prescription Drug User Fee Act, or PDUFA, goal date of January 27, 2016. The NT-0202 NDA resubmission provides information to specifically address the FDA-issued Complete Response Letter received in September 2013. This includes the results from an additional pharmacokinetic study which was conducted with NT-0202 that utilized a commercial-scale manufacturing process, and the requisite stability data. This submission is a Class 2 resubmission, with a target six-month PDUFA review period. We expect to submit an NDA for NT-0201, our amphetamine XR liquid suspension, following receipt of written feedback from the FDA to incorporate our understanding of the FDA s expectations for the acceptance and subsequent review of such NDA. The FDA s feedback is expected in the fourth quarter of 2015.

If we are successful in obtaining regulatory approval for any of our three branded product candidates, we plan to focus on commercialization in the United States using our own commercial infrastructure. We intend to manufacture our ADHD products 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

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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.

We have incurred significant losses in each year since our reorganization in 2009. Our net losses were $20.8 million for the year ended December 31, 2014, $9.4 million and $5.2 million for the three months ended September 30, 2015 and 2014, respectively, and $21.7 million and $16.0 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of approximately $107.7 million. 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 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.

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 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; however, we expect that these revenue streams will end since 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 intend to utilize 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.

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In the future, we will seek to generate revenue from product sales of our three late-stage branded product candidates. We do not expect to generate any significant revenue unless or until we commercialize our product candidates. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our inability to generate future revenue from product sales may adversely affect our results of operations and financial position.

Research and development

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

- expenses, including salaries and benefits of employees engaged in research and development activities;
- expenses incurred under third party agreements with contract research organizations, 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
NT-0102 Methylphenidate ODT	$ 260	$ 532	$ 2,771	$ 1,374
NT-0202 Amphetamine ODT	58	497	139	778
NT-0201 Amphetamine Liquid	38	16	185	775
Other Research and Development Activities (1)	2,345	1,682	6,028	5,268
	$ 2,701	$ 2,727	$ 9,123	$ 8,195

(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 three ADHD product candidates and explore new product candidates, but will decrease as a percentage of revenue if any of our product candidates are approved. 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 revenues, if any, from 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 NT-0102, it has identified

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deficiencies that preclude discussion of labeling and post marketing requirements/commitments at this time. The FDA stated that this notification does not reflect a final decision on the information under review. 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 to-be-marketed drug product, including an assessment of food effect, and to provide validation and three months of stability data. On July 30, 2015, we announced that we had resubmitted a NDA to the FDA for NT-0202, our amphetamine XR-ODT. The NT-0202 NDA resubmission provides information to specifically address the FDA-issued Complete Response Letter received in September 2013. This includes the results from an additional pharmacokinetic study which was conducted with NT-0202 that utilized a commercial-scale manufacturing process, and the requisite stability data. This submission is a Class 2 resubmission, and we have a PDUFA goal date of January 27, 2016. We expect to submit an NDA for NT-0201, our amphetamine XR liquid suspension, following receipt of written feedback from the FDA to incorporate our understanding of the FDA s expectations for the acceptance and subsequent review of such NDA. The FDA s feedback is expected in the fourth quarter of 2015. Any further actions required by the FDA may result in further research and development expenses. For additional information regarding the FDA review process, see Government Regulation NDA and FDA review process in the final prospectus dated as of July 22, 2015.

Selling and marketing

Selling and marketing expenses consist primarily of salaries and related costs for personnel pre-commercialization activities for our product candidates and trade sales of our generic Tussionex. Other selling and marketing expenses include market research, brand development, advertising agency and other public relations costs, managed care sales support and market data and analysis.

We expect that our selling and marketing expenses will increase with the potential commercialization of our product candidates particularly as we move to a business model in which we commercialize our own products in the United States. We also anticipate 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.

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.

Interest expense, net

Interest income consists of interest earned on our cash and cash equivalents. 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. Other income and expense also includes 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.

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RESULTS OF OPERATIONS

Three months ended September 30, 2015 compared to the three months ended September 30, 2014

Revenues

The following table summarizes our revenues for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Product	$ 221	$ (120)	$ 341	284.2%
Profit Sharing		28	(28)	not applicable
Development		67	(67)	not applicable
	$ 221	$ (25)	$ 246	984.0%

Total revenues were $0.2 million for the three months ended September 30, 2015, all of which was product revenue generated from net sales of our generic Tussionex for which we acquired all commercialization and profit rights in August 2014. The net negative total revenue of $(0.025) million for the three months ended September 30, 2014 was due to reserves we established for the estimated returns of our generic Tussionex outstanding at the wholesalers as of the October 6, 2014 effective date of the August 26, 2014 DEA reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance. This ruling had the effect of requiring unsold product to either be relabeled or returned. The reserves were offset by profit sharing and development revenue generated from our development and manufacturing agreement which we terminated in August 2014.

Cost of goods sold

The following table summarizes our cost of goods sold for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Cost of Goods Sold	$ 1,079	$ 782	$ 297	38.0%

The total cost of goods sold was $1.1 million for the three months ended September 30, 2015, an increase of $0.3 million or 38.0%, from the $0.8 million for the three months ended September 30, 2014. This increase was primarily due to $0.2 million of amortization of the intangibles

resulting from the acquisition of the rights to commercialize and derive future profits from Tussionex ANDA and a $0.1 million increase in other costs of goods, including audits of suppliers and distribution costs due to sales of our generic Tussionex in 2015.

Research and development expenses

The following table summarizes our research and development expenses for three months ended September 30, 2015 and 2014:

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	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Research and Development Expenses	$ 2,701	$ 2,727	$ (26)	0.9%

Research and development expenses were unchanged at $2.7 million for the three months ended September 30, 2015 from the three months ended September 30, 2014.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Selling and Marketing	$ 1,343	$ 106	$ 1,237	1167.0%

The total selling and marketing expenses were $1.3 million for the three months ended September 30, 2015, an increase of $1.2 million or 1,167.0%, from the $0.1 million for the three months ended September 30, 2014. Selling and marketing professional services increased by $0.8 million due to the increase in pre-commercialization advertising, market research and public relations expenses incurred in 2015 for the NT-0102 and NT-0202 product candidates. Salary and compensation expense increased $0.4 million due to the addition of personnel as part of pre-commercialization efforts for our product candidates and trade sales support for our generic Tussionex.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
General and Administrative	$ 2,073	$ 1,245	$ 828	66.5%

The total general and administrative expenses were $2.1 million for the three months ended September 30, 2015, an increase of $0.8 million or 66.5%, from the $1.3 million for the three months ended September 30, 2014. Salary and compensation expense increased $0.4 million in the three months ended September 30, 2015 primarily due to a $0.3 million increase in compensation related to share-based compensation and a $0.1 million increase in 2015 due to the addition of contract labor in support of our IPO. In addition, Professional Fees increased by $0.2 million related to the engaging of consultants primarily for audit, tax, business development and recruiting. Also, general and administrative expenses increased by $0.1 million for Directors & Officers Insurance Policy premium following the IPO effective date and $0.1 million for board of directors fees and expenses.

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Interest expense

The following table summarizes interest expense for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Interest Expense	$ 1,044	$ 562	$ 482	85.8%

The total interest expense was $1.0 million for the three months ended September 30, 2015, an increase of $0.5 million or 85.6%, from the $0.6 million for the three months ended September 30, 2014. This increase was principally due to higher interest in 2015 due to the increased senior debt balance.

Other income (expense), net

The following table summarizes our other income (expense) for the three months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Other Income, net	$ (1,349)	$ 208	$ (1,557)	-748.6%

Other income (expense), net was $(1.3) million expense for the three months ended September 30, 2015, a decrease of $1.6 million or 748.6%, from the $0.2 million of income for the three months ended September 30, 2014. This decrease resulted primarily from the increase in the fair value of our warrant liabilities as a result of the measurement of their fair values as of July 22, 2015 which gave increased weighting assigned to the IPO scenario in the PWERM model.

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Revenues

The following table summarizes our revenues for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Product	$ 2,133	$ (120)	$ 2,253	1877.5%
Manufacturing		113	(113)	not applicable
Development		160	(160)	not applicable
Profit Sharing		169	(169)	not applicable
	$ 2,133	$ 322	$ 1,811	562.4%

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Total revenues were $2.1 million for the nine months ended September 30, 2015, an increase of $1.8 million or 562.4%, from the $0.3 million for the nine months ended September 30, 2014. All $2.1 million of product revenue in the nine months ended September 30, 2015 was generated from net sales of our generic Tussionex for which we acquired all commercialization and profit rights in August 2014. This was partially offset by decreases in development, profit sharing and manufacturing revenue. The manufacturing and profit sharing revenues decreased by $0.3 million due to the termination of our development and manufacturing agreement in August 2014. In addition, the $0.1 million decrease in development revenues for the nine months ended September 30, 2015 was due to reduced development work related to our generic Tussionex. The $0.1 million of negative product revenue for the nine months ended September 30, 2014 resulted from reserves we established for the estimated returns of our generic Tussionex outstanding at the wholesalers as of the October 6, 2014 effective date of the August 26, 2014 DEA reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance. This ruling had the effect of requiring unsold product to either be relabeled or returned.

Cost of goods sold

The following table summarizes our cost of goods sold for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Cost of Goods Sold	$ 3,833	$ 2,225	$ 1,608	72.3%

The total cost of goods sold was $3.8 million for the nine months ended September 30, 2015, an increase of $1.6 million or 72.3%, from the $2.2 million for the nine months ended September 30, 2014. This increase was primarily due to $0.5 million increase in raw material costs due to the increased sales of Tussionex, $0.5 million of amortization of the intangibles resulting from the acquisition of the rights to commercialize and derive future profits from Tussionex ANDA and a $0.3 million increase in other cost of goods sold, principally due to distribution costs and freight incurred for the shipment of our generic Tussionex and audits of suppliers in 2015.

Research and development expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Research and Development Expenses	$ 9,123	$ 8,195	$ 928	11.3%

Research and development expenses were $9.1 million for the nine months ended September 30, 2015, an increase of $0.9 million, or 11.3%, from the $8.2 million for the nine months ended September 30, 2014. This increase was primarily due to a $2.3 million FDA filing fee for the NDA for NT-0102 submitted in January 2015, a $0.4 million increase in research and development materials and other costs, a $0.3 million increase in medical affairs spending related to the our ADHD product candidates and a $0.2 million amortization of the annual FDA facility fee for 2015 for our generic Tussionex. These increases were offset by a $1.8 million decrease in clinical expense, primarily as a result of the completion of our classroom study of NT-0102 and the wrapping up of clinical trials for NT-0201 and NT-0202 in 2014 and a $0.5 million decrease in consulting firm services related to the filing of our prior NDA applications.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the nine months ended September 30, 2015 and 2014:

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	Nine Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Selling and Marketing	$ 2,271	$ 117	$ 2,154	1841.0%

The total selling and marketing expenses were $2.3 million for the nine months ended September 30, 2015, an increase of $2.2 million or 69.5%, from the $0.1 million for the nine months ended September 30, 2014. Selling and marketing professional services increased by $1.3 million due to the pre-commercialization advertising agency costs, market research, public relations, data analysis, managed care promotion and corporate communications expenses incurred in the first nine months of 2015 for the NT-0102 and NT-0202 product candidates. Salary and compensation expense $0.7 million due to the addition of personnel as part of pre-commercialization efforts for our new product candidates and trade sales support for our generic Tussionex. In addition, selling and marketing travel expenses increased $0.1 million related to these pre-commercialization activities.

General and administrative expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
General and Administrative	5,069	4,196	873	20.8%

The total general and administrative expenses were $5.1 million for the nine months ended September 30, 2015, an increase of $0.9 million or 20.8%, from the $4.2 million for the nine months ended September 30, 2014. Salary and compensation expense increased $0.7 million in the nine months ended September 30, 2015 primarily due a $0.4 million increase in compensation related to share-based payments and a $0.3 million increase in 2015 due to the restructuring of the executive team and the addition of contract labor during 2014 and 2015 to bring on additional industry experience in support of our IPO. In addition, general and administrative expenses increased by $0.1 million for Directors & Officers Insurance Policy premium for the period following the IPO effective date and $0.1 million for board of directors fees and expenses. Also, Professional Fees included the following offsetting variances: an increase of $0.6 million related to the engaging of consultants primarily for audit, tax, business development, recruiting, computer services, compensation review, financial analysis and government pricing, offset by a $0.6 million decrease in legal fees resulting from the termination and settlement of litigation related to the Paragraph IV certification of our NT-0202 product candidate in July 2014.

Interest expense

The following table summarizes interest expense for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Interest Expense	$ 2,685	$ 2,199	$ 486	22.1%

The total interest expense was $2.7 million for the nine months ended September 30, 2015, an increase of $0.5 million from the $2.2 million for the nine months ended September 30, 2014. The interest on senior debt increased by $0.7 million due to

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higher interest in 2015 due to the increased senior debt balance. This increase was offset by a $0.1 million reduction in capital lease interest due the reduced capital lease balances resulting from the lease payments and a $0.1 million decrease in subordinated debt interest due to the reduction 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).

Other income (expense), net

The following table summarizes our other income (expense) for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Other Income, net	$ (829)	$ 618	$ (1,447)	-234.1%

Other expense was $0.8 million for the nine months ended September 30, 2015, a decrease of $1.4 million or 234.1%, from the $0.6 million of other income for the nine months ended September 30, 2014. This change was due to the $1.5 million year-to-date effect of the remeasurements of the fair values which included a second and third quarter increases in fair values of the warrant and earnout liabilities due to the increased weighting assigned to the IPO scenario in the PWERM model which was partially offset by a decrease in the fair value of the earnout liability, principally in the first quarter of 2015, resulting 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 and a review of the launch dates of our three ADHD product candidates.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

Since our reorganization in 2009 until our IPO, we have financed our operations primarily through private placements of common stock and redeemable convertible preferred stock and bank and other lender financing. On July 28, 2015, we closed our IPO whereby we sold 5,520,000 shares of our common stock, at a public offering price of $15.00 per share, which includes 720,000 shares of our common stock resulting from the underwriters exercise of their over-allotment option at the IPO price. We received aggregate net proceeds of $75.0 million from the offering, after deducting underwriting discounts and commissions of $5.8 million and offering expenses of approximately $2.0 million.

As of September 30, 2015, we had $102.9 million in cash and cash equivalents. Between December 2014 and February 2015, we issued and sold 4,124,871 shares of Series C redeemable convertible preferred stock, or Series C preferred stock, for net proceeds of $20.6 million, of which $7.5 million is reflected in the December 31, 2014 cash balance and $13.1 million was received after December 31, 2014. On June 30, 2015, a holder of warrants to purchase our Series C preferred stock (Series C warrants) exercised Series C warrants to purchase an aggregate of 150,000 shares of Series C Preferred stock at $5.00 per share, for an aggregate price of $0.75 million. Between July 6 and July 27, 2015, we issued

850,000 shares of its Series C preferred stock to several investors upon the exercise of Series C warrants held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $4.25 million. On March 13, 2015, we received an advance of $5.0 million under our senior debt facility as a result of achievement of a certain regulatory milestone. In addition, on June 10, 2015, we drew down the final $5 million tranche under our senior debt facility prior to meeting the milestones associated with that tranche. We had agreed to prepay the $5.0 million Tranche 4 principal balance together with all accrued and unpaid interest applicable to Tranche 4 on July 31, 2015 if we had not met certain regulatory or financing milestones, or the Tranche 4 Milestones, on or before July 31, 2015. We did meet the Tranche 4 Milestones stated in the LSA prior to July 31, 2015; therefore, we did not prepay the $5.0 million Tranche 4 principal balance on July 31, 2015. We believe that the $75.0 million net proceeds from our recently completed IPO and our existing cash will be sufficient to fund our operations for at least the next 12 months.

Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity. Accordingly, our cash equivalents are invested primarily in money market funds which are

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currently providing only a minimal return.

Cash flows

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

	Nine Months Ended September 30,		Increase (Decrease)
	2015	2014	
	(in thousands)		
Net Cash (used in) provided by:			
Net Cash used in operating activities	$ (14,919)	$ (13,465)	$ (1,454)
Net Cash provided by (used in) investing activities	2,344	(1,889)	4,233
Net Cash provided by financing activities	102,128	13,845	88,283
Net increase (decrease) in cash and cash equivalents	$ 89,553	$ (1,509)	$ 91,062

Cash used in operating activities

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

Net cash used in operating activities was $14.9 million and $13.5 million for the nine months ended September 30, 2015 and 2014, respectively. The $1.5 million increase in net cash used from operating activities was primarily due to the $5.7 million increase in our net losses, as discussed above, partially offset by a $2.4 million increase in noncash items and a $1.8 million decrease in the usage of cash from working capital changes. The increase in noncash items was principally due to the changes in the fair value of the warrant and earnout liabilities in 2015, an increase in the amortization of costs to acquire all of the rights to commercialize and derive future profits from Tussionex ANDA in August 2014 and an increase in share-based compensation expense. The decrease in usage of cash from working capital changes resulted primarily from a $2.1 million increase in accounts payable and accrued expenses due to the timing of vendor invoicing and payments and an increase in accruals for outside services, partially offset by a $0.3 million decrease in accounts receivable due to timing of customer payments.

Cash provided by (used in) investing activities

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

Net cash provided by investing activities was $2.3 million for the nine months ended September 30, 2015 as compared to net cash used in investing activities of $1.9 million for the nine months ended September 30, 2014, both of which principally resulted from the net sale or purchase, respectively, of short term investments, offset by a $0.6 million increase in 2015 capital expenditures, primarily in association with the expansion of our controlled substances vault and a $6.3 million cash outflow in 2014 for the acquisition all of the rights to commercialize and derive future profits from Tussionex ANDA in August 2014.

Cash provided by financing activities.

Net cash provided by financing activities of $102.1 million in the nine months ended September 30, 2015 primarily resulted from net cash proceeds of $77.0 million from our IPO reduced by $1.8 million of cash public offering costs; $13.0 million,

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net of issuance costs, received from the sale of 2,624,936 shares of our Series C preferred stock and the issuance of Series C warrants for 1,197,218 shares of Series C preferred stock; proceeds of $10.0 million from the remaining drawdowns under the LSA (see Credit Facilities below for details); $5.0 million from the exercise of 1,000,000 of Series C warrants and $0.1 million from the exercise of employee stock options, partially offset by $1.2 million of principal payments under the sales leasebacks. Net cash provided by financing activities of $13.8 million in the nine months ended September 30, 2014 was primarily related to proceeds of $9.9 million, net of issuance costs, received from the sale of 1,986,586 shares of our Series C preferred stock, proceeds of $15.0 million from the issuance of notes to our new lender, offset by $10.2 million in payments under the previous term loan and $0.6 million of deferred financing costs, and $0.8 million of proceeds from the sale leaseback of equipment, partially offset by $1.1 million of principal payments under the sale leasebacks.

Credit facilities

In March 2014, we entered into an LSA with 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 our assets, except our intellectual property and assets under capital lease. The first draw of $10.0 million (Tranche 1), was issued during March 2014 and was used in its entirety to repay outstanding principal under a previous credit facility. The second draw of $5.0 million (Tranche 2), was issued in September 2014. The third draw (Tranche 3) in the amount of $5.0 million was issued in March 2015. In June 2015, we further amended the LSA and the fourth draw of $5.0 million (Tranche 4), was issued prior to achieving 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 as we fulfilled the conditions set forth in the LSA, as amended, at which time 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 we prepay our 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 our ability to transfer assets, engage in a change of control, merge or acquire with or into another entity, incur additional indebtedness, repurchase or redeem stock or other equity interest other than pursuant to employee stock repurchase plans or other similar agreements, make investments and engage in transactions with affiliates. Upon an event of default, the lender 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 September 30, 2015, we were in compliance with the covenants under our LSA, as amended.

In December 2011, we issued to Essex Capital Corporation, (Essex), a subordinated note (Note), in the aggregate principal amount of $5.8 million. Interest accrues and adds to the principal balance until such time as we achieve positive EBITDA for three consecutive months. In June 2012, we amended and restated the Note, resulting in an extension of the maturity date from June 2014 to March 2017 and the conversion of $1.0 million of outstanding principal amount into 200,000 shares of our Series B redeemable convertible preferred stock. The conversion was executed in December 2012 and the Note was amended to reflect the new aggregate principal amount of $5.3 million. In December 2013, the Note was amended and restated to reflect the addition of accrued interest due at maturity with a new aggregate principal amount of $5.9 million. In July 2014, the interest rate on the Note was reduced to 6% for the period from July 2014 through June 2015 pursuant to an amendment to the Note entered into as consideration for the $128,000 payment which we made to Essex as part of the Settlement and Release of Claims Agreement with Essex and a third party. This agreement resolved certain issues and disputes whereby Essex paid $256,000 to the third party, we paid Essex $128,000 and Essex agreed to reduce the interest rate on the Note from 10% to 6% for the July 2014 through June 2015. The third party released both Essex and us from any and all claims. As of September 30, 2015, the aggregate principal amount of the Note was

$5.9 million and $883,000 in interest had been accrued through September 30, 2015.

During the years ended December 31, 2014 and 2013, we entered into five 42-month agreements with Essex for the sale-leaseback of existing and newly acquired assets with a total capitalized cost of $795,000 and $5.5 million, respectively, and a bargain purchase option at the end of the respective lease, all of which are classified as capital leases. The approximate imputed interest rate on these leases is 14.5%. See Contractual commitments and obligations below for future payments under these leases.

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Capital resources and funding requirements

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 any of our product candidates. We expect to continue to incur operating losses in the future over the next several years as we seek regulatory approval for our product candidates and build commercial infrastructure to support sales and marketing of these product candidates. We believe that our existing cash and cash equivalents, together with the net proceeds of our IPO, will be sufficient to fund our anticipated operating requirements into the first quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, resulting in the use of our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital required to become profitable. Our future funding requirements will depend on many factors, including:

- the costs and timing involved in obtaining regulatory approvals for our product candidates;
- the timing and number of product candidates for which we obtain regulatory approval;
- the costs of developing our anticipated sales, marketing and distribution capabilities;
- the market acceptance of our product candidates, if approved, and related success in commercializing and generating sales from our product candidates if approved by the regulatory authorities;
- the costs of our manufacturing capabilities to support our commercialization activities, including any costs associated with adding new capabilities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the number and characteristics of new product candidates that we pursue; and
- our ability to hire qualified employees at salary levels consistent with our estimates to support our growth and development, including additional general and administrative personnel as a result of becoming a public company, and sales and marketing personnel as we evolve into a commercial organization.

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

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements, as well as reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments

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about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to the notes to our audited financial statements included elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

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

We sell our 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. These wholesalers then resell the product to retail customers such as food, drug and mass merchandisers.

We expect that manufacturing, profit sharing and development revenue will end as we have terminated our development and manufacturing agreement. As a result of our acquisition of the rights to commercialize and derive future profits from the Tussionex ANDA, we will utilize our manufacturing capability to derive revenue directly from sales made by us, rather than through our former commercial partner.

Net product sales

Net product sales for our generic Tussionex 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. Wholesaler distribution fees are incurred on the management of these products by wholesalers and are recorded within net product sales based on definitive contractual agreements. We estimate 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 our third party logistics provider, or 3PL, with respect to its inventory levels and sell-through to the wholesalers customers, data available from third parties regarding prescriptions written for our products, as well as actual experience as reported by our customers and former commercialization partners. For sales of our new product candidates where no history of product returns will exist at the time of sale to facilitate the estimation of product returns, we anticipate that we will initially recognize sales based on product sell-through to end customers

using data available from third parties; therefore, some revenue may be deferred until sufficient product return history is generated. 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

Our 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 6 months prior to expiry date to 12 months post expiry date. Product returns of our generic Tussionex are estimated based upon data available from sales of our product by our previous 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 DEA reclassified 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 our 3PL to either be relabeled or

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returned. This new ruling was effective October 6, 2014. As such, we established reserves for the estimated returns of such product outstanding at our wholesalers as of October 6, 2014. We had no inventory labeled as Schedule III at our 3PL as of the effective date.

Medicaid rebates

Our product is 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 our product by our previous commercialization partner. Historical trend of Medicaid rebates will be continually monitored and may result in future adjustments to such estimates.

Wholesaler chargebacks

Our products are subject to certain programs with wholesalers whereby pricing on products is discounted below wholesaler list price to participating entities. These entities purchase products through wholesalers at the discounted price, and the wholesalers charge the difference between their acquisition cost and the discounted price back to us. Chargebacks are accounted for by establishing an accrual in an amount equal to our estimate of chargeback claims at the time of product sale based on information provided by our distributor. Due to estimates and assumptions inherent in determining the amount of chargebacks, the actual amount of claims for chargebacks may be different from our estimates, which may result in adjustments to such reserves.

Manufacturing

Manufacturing revenue is derived from product manufactured by us and sold by our former commercial partner under a development and manufacturing agreement. Manufacturing revenue is derived from a contractual supply price paid to us by our former commercial partner.

Profit sharing

Profit sharing revenue is recorded as the product is sold by our former commercial partner. The profit share is our share of the net profits after taking into account net revenue, which is gross product sales by our former commercial partner, net of discounts, returns and allowances incurred by our former commercial partner, less collaboration expenses.

Development revenue

Development revenue from the development and manufacturing agreement has been recognized as the related services are completed. Development revenue in the form of milestone payments is recognized upon achievement of the related milestones and provided that collectability is reasonably assured and other revenue recognition criteria are met. Amounts received under cost reimbursement arrangements for production and research and development are recorded as offsets to the costs incurred and not recognized as revenue.

Research and development expenses

Research and development expenses include costs incurred in performing research and development activities, personnel related expenses, laboratory and clinical supplies, facilities expenses, overhead expenses, fees for contractual services, including preclinical studies, clinical trials and raw materials. We estimate clinical trial expenses based on the services received pursuant to contracts with research institutions and CROs which conduct and manage clinical trials on our behalf. We accrue service fees based on work performed, which relies on estimates of total costs incurred based on milestones achieved, patient enrollment and other events. The majority of our service providers invoice us in arrears, and to the extent that amounts invoiced differ from our estimates of expenses incurred, we accrue for additional costs. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and cash flows. To date, we have not experienced any events requiring us to make material adjustments to our accruals for service fees. If we do not identify costs that we incurred or if we underestimate or overestimate the level of services performed, our actual expenses could differ from our estimates which could materially affect our results of operations. Adjustments to our accruals are recorded as changes in estimates become evident. In addition to accruing for expenses incurred, we may also record payments made to service providers as prepaid expenses that we will recognize as expense in future periods as services are rendered.

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Share-based compensation expense

Share-based compensation awards, including grants of employee stock options and restricted stock and modifications to existing stock options, are recognized in the statement of operations based on their fair values. Compensation expense related to awards to employees is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. The fair value of our share-based awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends. Due to the previous lack of a public market for the trading of its common stock and a lack of company-specific historical and implied volatility data, prior to the IPO, we have historically utilized third party valuation analyses to determine the fair value. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
General and Administrative				
Options	$ 291	$ 36	$ 480	$ 68
Restricted Stock	27	23	72	68
	$ 318	$ 59	$ 552	$ 136

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

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	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015
Estimated dividend yield	0%	0%
Expected stock price volatility	60%	60%
Weighted-average risk-free interest rate	1.57%	1.60%
Expected life of option in years	5	5
Weighted-average option fair value at grant	$ 12.767	$ 10.054

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

Given the absence of an active market for our common stock prior to our IPO, our board of directors was required to estimate the fair value of our common stock at the time of each option grant primarily based upon valuations performed by a third party valuation firm. In determining fair value for our common stock, the third party valuation firm determined the fair value of our common stock on the date of grant based on several factors, including:

- our stage of development and business strategy;

- the price per share at which our redeemable convertible preferred stock was issued to investors and the rights, preferences and privileges of the redeemable convertible preferred stock relative to the common stock;

- our financial condition and book value;

- economic and competitive elements affecting us, our industry and our target markets;

- our projected operating results;

- a comparative analysis of our financial condition and operating results with those of publicly-owned companies engaged in similar lines of business;

- the current and historical relationship between the reported stock prices and revenue and earnings levels of selected publicly traded companies engaged in similar lines of business;

- important developments relating to the results of our three branded product candidates; and

- the likelihood of achieving a liquidity event for our outstanding shares of stock.

The valuations we obtained were prepared in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (the Practice Aid), which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its common stock. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. Prior to August 2014, we generally used the income approach, utilizing the discounted cash flow method to determine our value and allocating to classes of equity using an option pricing model. Since August 2014, we utilized the Probability-Weighted Expected Return Method (PWERM), to determine the value attributable to common stock based on a private company scenario and an initial public offering scenario. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. For each scenario, we utilized the discounted cash flow

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method to determine our value, allocated to classes of equity using an option pricing model and applied the PWERM approach, weighted based on management s expectations, yielding an estimated marketable, minority fair value of our common stock. A discount for lack of marketability (DLOM), based on an option based approach (put option) was then applied, yielding a fair value of our common stock on a non-marketable basis. The material assumptions involved to estimate the fair value of our common stock are the estimated timing of commercial launch dates for our product candidates, the probability weighting of the private company scenario and the initial public offering scenario, the timeline to liquidity under each scenario and the DLOM under each scenario. .

After the closing of our IPO, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported by the NASDAQ Global Market on the date of grant.

Intangible assets

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

Warrant liability

We account for our warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on our balance sheet at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense), net, in the statements of operations. Our Series C warrants and Hercules Warrants were classified as liabilities, and we estimated the fair value of these liabilities using option pricing models and assumptions that were based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for expected volatility, contractual term, dividend yield, and risk-free interest rate (see Notes 5, 10 and 11 in the notes to our financial statements above). In connection with the completion of our IPO, all the outstanding Series C warrants and Hercules Warrants automatically converted into warrants to purchase shares of common stock. Upon closing the IPO, the Series C warrants were exchanged in a cashless exercise for 947,185 shares of Series C preferred stock which converted into 78,926 shares of our common stock. The Hercules Warrants to purchase 170,000 pre-split shares of Series C preferred stock were converted into warrants to purchase 70,833 shares of the Company s common stock and the warrant liability was reclassified to Additional Paid in Capital within Stockholders Equity (Deficit) because the converted warrants met the definition of an equity instrument under derivative accounting guidance.

CONTRACTUAL COMMITMENTS AND OBLIGATIONS

The following tables reflect summaries of our estimates of future material contractual obligations as of September 30, 2015. Future events could cause actual payments to differ from these estimates.

	Total	< 1 Yr	1-3 Yrs.	3-5 Yrs	Thereafter
			(In thousands)		

Loan and Security Agreement	$ 30,181	6,120	24,061		
Related Party Note Payable	8,134		8,134		
Capital Leases for Equipment	3,129	2,319	810		
Earnout Liability	353		353		
Operating lease for facility	9,226	907	1,898	1,948	4,473
	$ 51,023	$ 9,346	$ 35,256	$ 1,948	$ 4,473

We have drawn down $25.0 million of the LSA, as amended, as of September 30, 2015. The payments above are inclusive of related interest amounts as of September 30, 2015.

In addition to the commitments shown above, in response to a lawsuit brought against us by Shire LLC, or Shire, for infringement of certain of Shire s patents, we entered into a settlement agreement and an associated license agreement with Shire for a non-exclusive license to certain patents for certain activities with respect to our NDA No. 204326 for an extended-release orally disintegrating amphetamine Polistrex tablet in July 2014. Under the terms of the license agreement,

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we are required to pay a lump sum, non-refundable license fee of an amount less than $1.0 million due no later than thirty days after receiving regulatory approval by the FDA of our NDA. We will also pay a single digit royalty on net sales of the subject product during the life of the patents. Due to the uncertainty of when or if these royalties will be made, they are not presented in the table above. Upon receiving such approval by the FDA, the license fee will be capitalized and amortized over 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.

OFF-BALANCE SHEET ARRANGEMENTS

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

RECENT ACCOUNTING PRONOUNCEMENTS

See Note 3 to the Notes to Condensed Consolidated Financial Statements in Item 1 above for further discussion of recent accounting pronouncements.

JOBS ACT

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

ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk

We are exposed to market risk related to changes in interest rates as it impacts our interest income. As of September 30, 2015, we had cash and cash equivalents of $102.9 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates as our cash equivalents are invested in interest-bearing money market funds. The goals of our investment

policy are liquidity and capital preservation to fund our operations. Due to the short-term duration and low risk profile of our cash equivalents portfolio, a 10% change in interest rates would not have a material effect on interest income we recognize or the fair market value of our investments. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates.

Interest risk

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

Effects of Inflation

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

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

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As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, with the participation of our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures were effective. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control

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

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS.

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q and in our other public filings in evaluating our business. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

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

We are heavily dependent on the success of our lead product candidates NT-0102, NT-0202 and NT-0201. We cannot give any assurance that we will receive regulatory approval for such product candidates or any other product candidates, which is necessary before they

can be commercialized.

Our business and future success are substantially dependent on our ability to successfully and timely obtain regulatory approval for and commercialize our lead product candidates, NT-0102, our methylphenidate extended-release orally disintegrating tablet (XR-ODT), NT-0202, our amphetamine XR-ODT, and NT-0201, our amphetamine XR liquid suspension, for the treatment of attention deficit hyperactivity disorder (ADHD), and any other product candidates that we may identify and pursue. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application (NDA), from the U.S. Food and Drug Administration (FDA), or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. Satisfaction of regulatory requirements can be protracted, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. For example, on November 10, 2015, we announced that we received a Complete Response Letter from the FDA for our NDA for NT-0102. We will need to satisfactorily address the deficiencies the FDA identified and may identify in order to obtain the FDA s approval of our NDA. We cannot predict whether we will obtain regulatory approval to commercialize our product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any delay or setback in the regulatory approval or commercialization of any of these product candidates could adversely affect our business.

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

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

- could determine that we cannot rely on the 505(b)(2) regulatory approval pathway for NT-0102, NT-0202, NT-0201 or any other product candidate that we may identify and develop;

- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate safety and effectiveness of any of our product candidates for any indication;

- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the safety risks outweigh clinical and other benefits of our product candidates;

- may require us to conduct additional bioequivalence studies to demonstrate that the proposed commercial product is bioequivalent to the batch used in clinical trials;

- may disagree with our trial design or our interpretation of data from nonclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;

- may determine that we inappropriately relied on a certain listed drug or drugs for our 505(b)(2) NDA or that approval of our applications for NT-0102, NT-0202, NT-0201 or any other product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs;

- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the active pharmaceutical ingredient, or API, used in our product candidates;

- may identify deficiencies in our own manufacturing processes or our proposed scale-up of the manufacturing processes or facilities for the production of our product candidates;

- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;

- may change its approval policies or adopt new regulations; or

- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

On December 27, 2012, we submitted an NDA for NT-0202 to the FDA, which the agency subsequently accepted for filing. On May 29, 2013, we received a Discipline Review Letter that found deficiencies in the quality section of our NDA and, among other things, raised issues with our proposal to scale-up the manufacturing process for the commercial product. Ultimately, on September 24, 2013, the FDA issued a Complete Response Letter, stating that it could not approve the NDA for NT-0202 in its present form. We believe that we have addressed all of the concerns raised by the FDA which resulted in the issuance of the Complete Response Letter in our resubmission of our NDA for NT-0202. Nonetheless, the FDA could deny approval of our NDA for NT-0202 on the same grounds as identified before or another ground as outlined above.

On October 16, 2015, we received notification from the FDA stating that, as part of its ongoing review of our NDA for NT-0102, or Cotempla XR-ODT, it has identified deficiencies that preclude discussion of labeling and post marketing requirements/commitments at this time. The FDA stated that this notification does not reflect a final decision on the information under review. 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 to-be-marketed drug product, including an assessment of food effect, and to provide validation and three months of stability data. If we are unable to satisfactorily address the agency s concerns, the FDA could deny approval of our NDA for NT-0102.

Notwithstanding the approval of many products by the FDA pursuant to 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA s interpretation of 505(b)(2). If the FDA changes its

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interpretation of 505(b)(2), or if the FDA s interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any 505(b)(2) application that we submit. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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

We intend to submit to the FDA an NDA for NT-0201, which will be indicated for the treatment of ADHD, following receipt of written feedback from the FDA to incorporate our understanding of the FDA s expectations for the acceptance and subsequent review of such NDA. The FDA s feedback is expected in the fourth quarter of 2015. Within 60 days of the agency s receipt of the NDA, the FDA will make a threshold determination of whether the NDA is sufficiently complete to permit a substantive review. This 60-day review is referred to as the filing review. If the NDA is sufficiently complete, the FDA will file the NDA. If the agency refuses to file the NDA, it will notify us and state the reason(s) for the refusal. The FDA may refuse to file an NDA for various reasons, including, but not limited to, if:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within

45 days of the patent owner s receipt of notice triggers a one-time, automatic, 30-month stay of the FDA s ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity (NCE), listed in the Orange Book for the listed drug has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) submissions and require us to submit traditional NDAs under 505(b)(1), which would require extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and additional costs. These factors, among others, may limit our ability to commercialize our product candidates successfully.

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

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

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

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

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

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

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

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

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

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

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

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

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

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

- increased amortization expenses;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to motivate key employees of any acquired businesses.

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

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

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

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;

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- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations (CROs), contract manufacturing organizations, or CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;

- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;

- difficulties obtaining IRB approval to conduct a clinical trial at a prospective site;

- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;

- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;

- difficulties maintaining contact with subjects after treatment, which results in incomplete data;

- receipt by a competitor of marketing approval for a product targeting an indication that our product targets;

- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and

- varying interpretations of data by the FDA and similar foreign regulatory agencies.

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

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;

- unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and

- lack of adequate funding to continue the clinical trial.

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

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

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RISKS RELATED TO COMMERCIALIZATION

We have never generated any revenues from the sales of our branded product candidates, and we may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate revenues from sales of our branded product candidates. We have only generated revenues from the sale of our generic Tussionex and contract manufacturing, which contract manufacturing operations were discontinued in 2013. We have not generated any revenues from product sales of our own branded product candidates and have incurred significant operating losses.

Our ability to generate product revenues is dependent on our ability to receive regulatory approval of NT-0102, NT-0202 and NT-0201, and our ability to successfully commercialize these products. Our ability to successfully commercialize our product candidates depends on, among other things, our ability to:

- obtain regulatory approvals for NT-0102, NT-0202 and NT-0201;

- if regulatory approvals are received, manufacture commercial quantities of our product candidates at acceptable cost levels; and

- successfully establish sales and marketing capabilities to commercialize our product candidates.

Even if any of our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercialization. It is possible that we will never have sufficient product sales revenues to achieve profitability.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We have just started building an organization for the sale, marketing and distribution of NT-0102, NT-0202 or NT-0201. As a result, we must finish building this organization, and/or enter into a marketing collaboration with a third party, in order to commercialize NT-0102, NT-0202 and NT-0201. Although we intend to establish a focused, specialty sales and marketing organization of approximately 100 representatives to promote any of our approved products in the United States, we have only just started building such an organization and do not yet have any such capabilities. The establishment and development of our own sales force in the United States to market NT-0102, NT-0202 and NT-0201 will be expensive and time consuming and could delay any product launch. We cannot be certain that we will be able to successfully develop this capacity, and even if we do, the cost of establishing and maintaining such an organization may exceed the benefit of doing so.

Our prior experience in the marketing, sale and distribution of pharmaceutical products is limited to our generic Tussionex, and we have no prior experience in marketing, sale and distribution of branded pharmaceutical products. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, effectively manage a geographically dispersed sales and marketing team and successfully negotiate with managed care and third-party payors. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

We also intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States and intend to also enter into strategic partnerships with third parties for certain aspects of our commercialization efforts within the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

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

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

In addition, manufacturers and their facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (cGMPs). These cGMP regulations cover all aspects of manufacturing relating to our generic Tussionex, NT-0102, NT-0202 and NT-0201. As such, we are subject to continual review and periodic inspections to assess compliance with cGMP and must continue to expend time, money and resources in all areas of regulatory compliance, including manufacturing, production and quality control. We also continue to have a cGMP expert conduct an annual audit and submit these audit reports and our responses to the FDA, and may be inspected by the FDA at any time as a result of the Consent Decree entered into by our predecessor, which is discussed below. Although for our most recent annual audit by the cGMP expert in November 2014, the expert concluded that our corrective actions satisfactorily addressed the observations noted in its report, on May 22, 2015, the FDA s Dallas District Office identified three ongoing cGMP deviations in our response to the audit related to batch failure investigations, quality control unit procedures, and in-process specifications. We implemented corrective actions and submitted additional information in our response to the FDA.

Moreover, the facilities used by us to manufacture NT-0102, NT-0202 and NT-0201 will be subject to pre-approval inspections after we submit our NDAs to the FDA. For example, the FDA recently conducted a cGMP and pre-approval inspection related to our NDA for NT-0102 from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. We have implemented corrective action related to this observation and have responded, to the FDA, and the FDA has closed the investigation. If we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, we will not be able to secure and/or maintain regulatory approval for our product candidates. If the FDA finds deficiencies at our manufacturing facility and does not approve our NDA for any of our product candidates or if it withdraws any such approval in the future, our ability to develop or market any of our product candidates will be impacted.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is

manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including notice to physicians, withdrawal of the product from the market or suspension of manufacturing. Manufacturers are also subject to annual drug product and facility user fees that may be substantial. If we are unable to generate sales of our product candidates, the user fee requirements could be difficult to pay.

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

- issue untitled or warning letters asserting that we are in violation of the FDCA;

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- impose restrictions on the marketing or manufacturing of any product candidate or product;

- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, or require disgorgement;

- suspend or withdraw regulatory approval;

- suspend any ongoing clinical trials;

- refuse to approve a pending NDA or supplements to an NDA submitted by us; or

- seize the product.

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

Similar requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

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

The commercial success of our product candidates, if approved, depends upon attaining market acceptance by physicians, patients, third-party payors and the medical community.

To date, we have expended significant time, resources, and effort on the development of NT-0102, NT-0202 and NT-0201, and a substantial majority of our resources are now focused on preparing for the commercial launch in the United States, if approved, of NT-0102 as early as the second quarter of 2017, NT-0202 in the second quarter of 2016 and NT-0201 in the first quarter of 2017. Accordingly, our ability to generate significant product revenue will depend almost entirely on our ability to successfully obtain final marketing approval for and commercialize NT-0102, NT-0202 and NT-0201. We may not sell NT-0102, NT-0202 or NT-0201 in the United States until the FDA grants final marketing approval and, therefore, our planned commercial launch of NT-0102, NT-0202 and NT-0201 in the United States could experience unanticipated delays or problems and may be prohibited altogether, notwithstanding its tentative approval by the FDA.

Our ability to successfully commercialize NT-0102, NT-0202 and NT-0201 will depend on, among other things, our ability to:

- establish relationships with third-party suppliers for the manufacture of NT-0102, NT-0202 and NT-0201;

- manufacture and produce, through a validated process, sufficiently large quantities and inventory of NT-0102, NT-0202 and NT-0201 to permit successful commercialization;

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

- establish collaborations with third parties for the commercialization of our products in countries outside the United States, and such collaborators ability to obtain regulatory and reimbursement approvals in such countries;

- secure widespread acceptance of our products by physicians, health care payors, patients and the medical community;

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- properly price and obtain adequate coverage and reimbursement of the product by governmental authorities, private health insurers, managed care organizations and other third-party payors;

- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements; and

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

There are no guarantees that we will be successful in completing these tasks. Successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective. If we are unable to successfully complete these tasks, we may not be able to commercialize NT-0102, NT-0202 and NT-0201 in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

In addition, we have begun, and will need to continue, investing substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in anticipation of the planned commercial launch of NT-0102, NT-0202 and NT-0201. We have committed and will continue to commit these additional resources prior to obtaining final approval of any of NT-0102, NT-0202 or NT-0201 from the FDA. If we are unable to successfully obtain final FDA approval of any of our product candidates or complete these activities, or experience unanticipated delays or problems, our costs could substantially increase and our business, financial condition and results of operations will be adversely affected. In addition, we have certain revenue expectations with respect to the sale of NT-0102, NT-0202 and NT-0201. If we cannot successfully commercialize and achieve those revenue expectations with respect to NT-0102, NT-0202 and NT-0201, our anticipated revenues and liquidity will be materially adversely impacted.

Moreover, even if we are able to timely launch NT-0102, NT-0202 or NT-0201, their continued commercial success may be largely dependent on the capability of third-party collaborators. Such third-party collaborators may not deploy the resources we would like them to, and our revenue would then suffer. In addition, we could become embroiled in disputes with these parties regarding the terms of any agreements, their performance or intellectual property rights. Any dispute could disrupt the sales of our products and adversely affect our reputation and revenue. In addition, if any of our manufacturing or collaboration partners fail to effectively perform under our arrangements for any reason, we may not be able to find a suitable replacement partner on a timely basis or on acceptable terms.

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

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, amphetamine XR is currently marketed in the United States by Shire under the brand name Adderall XR, and methylphenidate is marketed in the United States by Janssen under the brand name Concerta, and by Novartis

under the brand names Focalin XR and Ritalin LA. Further, makers of branded drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Shire, Noven, Alcobra, Highland Therapeutics, Sunovian, Neurovance and Rhodes Pharmaceuticals. Tris Pharmaceuticals is also working in this space to reformulate existing methylphenidate and amphetamine medications and has recently received approval for an amphetamine-based XR liquid suspension for the treatment of ADHD and recently submitted an NDA for a methylphenidate-based XR chewable.

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

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

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

- the efficacy and safety of our product and product candidates, including as relative to marketed products and product candidates in development by third parties;

- the time it takes for our product candidates to complete clinical development and receive marketing approval;

- the ability to maintain a good relationship with regulatory authorities;

- the ability to commercialize and market any of our product candidates that receive regulatory approval;

- the price of our product and product candidates that receive regulatory approval, including in comparison to branded or generic competitors;

- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;

- the ability to protect intellectual property rights related to our product and product candidates;

- the ability to manufacture on a cost-effective basis and sell commercial quantities of our product and product candidates that receive regulatory approval; and

- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other healthcare providers.

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

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

We expect to compete against branded drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our product candidates will be clinically differentiated from branded drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our product candidates against other drugs, the opportunity for our product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

Once an NDA, including a 505(b)(2) application, is approved, the covered product becomes a listed drug that, in turn, can be cited by potential competitors in support of approval of an ANDA. The FDCA, implementing regulations and other applicable laws provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic

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equivalents, which must meet the same quality standards as the listed drugs, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices.

Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product, such as NT-0102, NT-0202 and NT-0201, if approved, can be lost to the generic version. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our product candidates.

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

We are subject to extensive regulation in connection with the preparation and manufacture of our product candidates and potential product candidates for clinical trials and commercial sale. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMPs and equivalent foreign standards. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our generic Tussionex, NT-0102, NT-0202 and NT-0201, as well as any of our future potential product candidates, are highly regulated processes and technically complex. We, along with our third-party suppliers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to the FDA s GLP and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure to comply with cGMP regulations or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems must also pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. For example, the FDA recently conducted a cGMP and pre-approval inspection related to our NDA for NT-0102 from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. We have implemented corrective action related to this observation and have responded to the FDA, and the FDA has closed the investigation. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

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

As a result, our business, financial condition and results of operations may be materially harmed.

We rely on limited sources of supply for NT-0102, NT-0202, NT-0201 and our generic Tussionex, and any disruption in the chain of supply may impact production and sales of NT-0102, NT-0202, NT-0201 and our generic Tussionex, and cause delays in developing and commercializing our product candidates and currently manufactured and commercialized product.

Our NDAs for NT-0102 and NT-0202, and the NDA we plan to submit for NT-0201, include our proposed manufacturing process for each product candidate. Any change to our manufacturing process, facilities or suppliers could require that we amend our NDA. Also, because of our proprietary processes for manufacturing our product candidates, we cannot

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immediately transfer manufacturing activities for NT-0102, NT-0202, NT-0201 or our generic Tussionex to an alternate supplier, and a change of facilities would be a time-consuming and costly endeavor. This would also require us to supplement our NDA filings to include the change of manufacturing site. Any changes to our manufacturing process would involve substantial cost and could result in a delay in our desired clinical and commercial timelines. We are also reliant on a limited number of suppliers for resin, drug compounds, coating and other component substances of our final product candidates and product. If any of these single-source suppliers were to breach or terminate its supply agreement, if any, with us or otherwise not supply us, we would need to identify an alternative source for the supply of component substances for our product candidates and product. Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our product candidates or product could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates or a decrease in sales of our generic Tussionex, which could harm our financial position and commercial potential for our product candidates and product. Any alternative vendor would also need to be qualified through an NDA supplement which could result in further delay, including delays related to additional clinical trials. The FDA, U.S. Drug Enforcement Administration (DEA), or other regulatory agencies outside of the United States may also require additional studies if we enter into agreements with new suppliers for the manufacture of NT-0102, NT-0202 and NT-0201 and our generic Tussionex that differ from the suppliers used for clinical development of such product candidates.

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

If we fail to produce our product or product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face penalties from wholesalers and contracted retailers of our product and delays in the development and commercialization of our product candidates.

We currently depend on third-party suppliers for the supply of the APIs for our product and product candidates, including drug substance for nonclinical research, clinical trials and commercialization. For NT-0102, NT-0202, NT-0201 and our generic Tussionex, we currently rely on single suppliers for raw materials including APIs, which we use to manufacture, produce and package final dosage forms. In particular, we have an exclusive supply agreement with Coating Place, Inc., or CPI, pursuant to which CPI (i) is the exclusive supplier of the active ingredient complexes in our generic Tussionex and (ii) has agreed to not supply anyone else engaged in the production of generic Tussionex with such active ingredient complexes. Any future curtailment in the availability of raw materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs. We are subject to penalties from wholesalers and contracted retailers if we do not deliver our generic Tussionex in quantities that meet their demand, and in the future we may enter into agreements with similar penalties for NT-0102, NT-0202 and NT-0201, if approved. Any such delays could trigger these penalty provisions, which would have a negative impact on our business.

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

and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial.

Manufacturers of pharmaceutical products need to comply with cGMP requirements enforced by the FDA through their facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the

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maintenance of records and documentation. We may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such product candidate or successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates. The FDA recently conducted a cGMP and pre-approval inspection related to our NDA for NT-0102 from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. We have implemented corrective action related to this observation and have responded to the FDA, and the FDA has closed the investigation.

If any of NT-0102, NT-0202 or NT-0201 is approved and we fail to manufacture the product in sufficient quantities and at acceptable quality and pricing levels, or fail to obtain adequate DEA quotas for controlled substances, or to fully comply with cGMP regulations, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may be unable to generate potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. In order to meet anticipated demand for NT-0102, NT-0202 and NT-0201, if approved, we have installed specialized processing equipment in our Grand Prairie, Texas facilities, which we believe will produce sufficient quantities of NT-0102, NT-0202 and NT-0201, if approved, for commercialization. We purchase raw materials and components from various suppliers in order to manufacture NT-0102, NT-0202 and NT-0201. If we are unable to source the required raw materials from our suppliers, or if we do not obtain DEA quotas or receive inadequate DEA quotas, we may experience delays in manufacturing NT-0102, NT-0202 and NT-0201, and may not be able to meet our customers demands for NT-0102, NT-0202 and NT-0201.

In addition, we must comply with federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

Our Grand Prairie facility was formerly operated by our predecessor, PharmaFab, Inc. (PharmaFab). In April 2007, the FDA announced entry of a Consent Decree of Permanent Injunction (the Consent Decree), against PharmaFab, one of its subsidiaries and two of its officials, including Mark Tengler, who was, at the time, PharmaFab s president, or jointly, the Defendants. The Consent Decree arose out of several perceived cGMP deficiencies related to the manufacture of unapproved drugs or Drug Efficacy Study Implementation (DESI), drugs that we no longer manufacture. Pursuant to the Consent Decree, the Defendants were permanently restrained and enjoined from directly or indirectly manufacturing, processing, packing, labeling, holding or distributing any prescription drugs that are not the subject of an NDA or an abbreviated NDA. Among other things, the Consent Decree also granted the FDA the ability to, without prior notice, inspect PharmaFab s place of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of the Consent Decree. The FDA has inspected the Grand Prairie facility several times since the Consent Decree was entered, and we have been able to manufacture and ship our generic Tussionex and drug products for our clinical trials. We also continue to have a cGMP expert conduct an annual audit and submit these audit reports and our responses to the FDA, and may be inspected by the FDA at any time as a result of the Consent Decree entered into by our predecessor. Although for our most recent annual audit by the cGMP expert in November 2014, the expert concluded that our corrective actions satisfactorily addressed the observations noted in its report, on May 22, 2015, the FDA s Dallas District Office identified three ongoing cGMP deviations in our response to the audit related to batch failure investigations, quality control unit procedures, and in-process specifications. We

implemented corrective actions and submitted additional information in our response to the FDA pursuant to the Consent Decree. Although we may apply for relief from the Consent Decree in the future, there is no guarantee that such relief will be granted or that we will be in compliance with the requirements of the Consent Decree.

If we are unable to produce the required commercial quantities of NT-0102, NT-0202 or NT-0201 to meet market demand for NT-0102, NT-0202 and NT-0201 on a timely basis or at all, or if we fail to comply with applicable laws for the

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manufacturing of NT-0102, NT-0202 or NT-0201, we will suffer damage to our reputation and commercial prospects and we will be unable to generate potential revenues.

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If we are unable to support demand for NT-0102, NT-0202 and NT-0201 and any future product candidates, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage the evolution of our drug delivery technology platform, our business could suffer.

As our volume grows, we will need to continue to increase our workflow capacity for customer service, improve our billing and general process, expand our internal quality assurance program and extend our platform to support product production at a larger scale within expected turnaround times. We may need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of NT-0102, NT-0202 and NT-0201, if approved. Portions of our process are not automated and will require additional personnel to scale. We may also need to purchase additional equipment, some of which can take several months or more to procure, set up and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our facilities to accommodate such required expansion.

As additional products, such as NT-0102, NT-0202 and NT-0201, are commercialized, we will need to incorporate new equipment, implement new technology systems and laboratory processes and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

If our sole facility becomes damaged or inoperable or we are required to vacate our facility, our ability to manufacture our product candidates and our generic Tussionex for commercialization, or future potential product candidates for clinical development, may be jeopardized. Our inability to continue manufacturing adequate supplies of NT-0102, NT-0202 and NT-0201, if approved, could adversely affect our ability to generate revenues.

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

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all. An inability to continue manufacturing adequate supplies of NT-0102, NT-0202, NT-0201 or our generic Tussionex at our Grand Prairie, Texas facilities could result in a disruption in the supply of NT-0102, NT-0202 and NT-0201, if approved, or our generic Tussionex, to physicians and pharmacies, which would adversely affect our ability to generate revenues.

If other patient-friendly forms of extended-release amphetamine or methylphenidate are approved and successfully commercialized, especially if approved before NT-0102, NT-0202 or NT-0201, our business would be materially harmed.

Other third parties may seek approval to manufacture and market their own versions of extended-release amphetamine or methylphenidate in patient-friendly dosage forms for the treatment of ADHD in the United States. If any of these parties obtain FDA approval of such a competitive product before we do, they may be entitled to three years of marketing exclusivity. Such exclusivity would, for example, delay the commercialization of NT-0102 and, as a result, we may never achieve significant market share for this product. Consequently, revenues from product sales of these products would be similarly delayed and our business, including our development programs, and growth prospects would suffer. Even if any of our product candidates are approved before a competitor, we may not be entitled to any marketing exclusivity and, other than

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under circumstances in which third parties may infringe or are infringing our patents, we may not be able to prevent the submission or approval of another full NDA for any competitor s product candidate.

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

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

Entities must register annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, including those for thefts or losses of any controlled substances, and to obtain authorization to destroy any controlled substances. Registered entities also must follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Security requirements vary by controlled substance schedule with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration. The DEA also has a production and procurement quota system that controls and limits the availability and production of Schedule I or II controlled substances. If we or any of our suppliers of raw materials that are DEA-classified as Schedule I or II controlled substances are unable to receive any quota or a sufficient quota to meet demand for our products, if any, our business would be negatively impacted.

Products containing controlled substances may generate public controversy. As a result, these products may have their marketing approvals withdrawn. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of our product or product candidates.

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

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

- Mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans.

- The 340B Drug Pricing Program under the Public Health Service Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities.

- Pharmaceutical companies are required to offer discounts on branded drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the Donut Hole.

- Pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company s market share of prior year total sales of branded drugs to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. The aggregated industry-wide fee is expected to total $28.0 billion through 2019. Since we expect our branded

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

Despite initiatives to invalidate the Affordable Care Act, the U.S. Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate. Additionally, there are legal challenges to the Affordable Care Act in lower courts on other grounds. We will not know the full effects of the Affordable Care Act until applicable federal and state agencies issue regulations or guidance under the law. Although it is too early to determine the effect of the Affordable Care Act, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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

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

Additionally, drug prices are under significant scrutiny, and along with other health care costs, continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate, including on a global basis. As a result, our business and reputation may be harmed, our stock price may be adversely impacted and experience periods of volatility, and our results of operations may be adversely impacted.

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

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

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

these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

In addition, the market for NT-0102, NT-0202 and NT-0201 will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient

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access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

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

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

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

For our product and any product candidates that obtain regulatory approval and are marketed in the United States, our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to health information privacy and security regulation by U.S. federal and state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

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

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

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

statements relating to healthcare matters;

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

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

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

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

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

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We face a risk of product liability exposure related to the testing of our product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products.

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

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

RISKS RELATED TO OUR BUSINESS AND FINANCIAL POSITION

We have incurred significant operating losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

Our company has limited operating history commercializing branded products. To date, we have focused primarily on developing our lead product candidates, NT-0102, NT-0202, and NT-0201. Our lead product candidates will require substantial additional resources before we will be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales, if approved. There can be no assurance that any of our product candidates will ever achieve regulatory approval or generate any revenue. We do not anticipate generating any revenue from sales of NT-0102, NT-0202, NT-0201 or any of our other product candidates in the near term, if ever. We have incurred significant net losses of $16.0 million and $21.7 million for the nine months ended September 30, 2014 and 2015,

respectively, and $19.0 million and $20.8 million for the years ended December 31, 2013 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of $107.7 million. We have devoted most of our financial resources to manufacturing operations and product development. To date, we have financed our operations primarily through the sale of equity and debt securities and payments received under collaborative arrangements. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our increased expenses, but we expect to continue to incur substantial expenses, which we expect will increase as we expand our development activities and build a specialty sales force and commercialization infrastructure. Our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to the clinical trials we have already completed. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

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

Developing future potential product candidates, conducting clinical trials, establishing raw material supplier relationships and manufacturing and marketing drugs are expensive and uncertain processes. Although we believe our cash, cash equivalents and marketable securities and anticipated future product revenues, will be sufficient to allow us to fund the commercialization of NT-0102 and NT-0202, if approved, we may need to obtain additional capital through equity offerings, debt financing, payments under new or existing licensing and research and development collaboration agreements, or any combination thereof, in order to become cash flow positive and to develop and commercialize additional product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

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

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

- the timing of any regulatory approvals of NT-0102, NT-0202 and NT-0201;

- the costs of establishing sales, marketing, distribution and commercial manufacturing capabilities for our products;

- if approved, our ability to successfully launch NT-0102, NT-0202 and NT-0201 and to continue to increase the level of sales in the marketplace;

- the rate of progress and cost of our trials and other product development programs for our other potential product candidates;

- the costs and timing of in-licensing additional product candidates or acquiring other complementary technologies, assets or companies;

- the actions of our competitors and their success in selling competitive product offerings; and

- the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to delay, reduce the scope of or eliminate commercialization efforts for one or more of our product candidates or development programs for future potential product candidates.

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

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

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

In December 2013, we reissued a promissory note to Essex Capital Corporation (Essex), which was later amended in July 2014 and March 2015, for an aggregate principal amount of approximately $5.9 million. In March 2014, we entered into a secured credit facility pursuant to a loan and security agreement among Hercules Technology III, L.P. (Hercules), as lender, which was subsequently amended in September 2014, and promissory notes issued in favor of Hercules, providing for term loans of up to an aggregate of $25.0 million. All obligations under our secured credit facility are secured by substantially all of our existing property and assets (excluding our intellectual property and assets under capital lease), subject to certain exceptions. These debt financings may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity.

Since our inception, we have had significant operating losses. As of September 30, 2015, we had an accumulated deficit of $107.7 million. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to develop and seek marketing approval for our product candidates. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our secured credit facility or promissory note. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations, finance our operations, our research and development efforts and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail or eliminate one or more of our programs.

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

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly and annual fluctuations. We expect that any revenues we generate will fluctuate from quarter to quarter and year to year as a result of the timing of our commercialization efforts and seasonal trends with respect to ADHD diagnosis and use of medicinal products in the management of this disorder. Once we commercialize one or more of our product candidates, our net loss and other operating results will be affected by numerous factors, including:

- any delays in regulatory review and approval of our product candidates;
- our ability to establish an effective sales and marketing infrastructure;

- variations in the level of expenses related to our commercialization efforts and the development of additional clinical programs;

- competition from existing products or new products that may emerge;

- the level of market acceptance for any approved product candidates and underlying demand for that product and wholesalers buying patterns;

- regulatory developments affecting our products and product candidates;

- our dependency on third-party manufacturers to supply components of our product candidates;

- potential side effects of our future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;

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- any intellectual property infringement lawsuit in which we may become involved; and

- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation s ability to use its pre-change net operating loss carry-forwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With our initial public offering (IPO), our most recent private placement and other transactions that have occurred over the past three years, we may have triggered an ownership change limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry-forwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

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

We are highly dependent on the principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are at will employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical trials or to receive regulatory approval for our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Our independent registered public accounting firm considered our internal controls over financial reporting as of December 31, 2014 for purposes of expressing an opinion on our financial statements but not for purposes of expressing an opinion on the effectiveness of our internal controls, and two significant deficiencies in internal controls were identified in connection with the preparation of our financial statements. The first significant deficiency was due to inadequate design and implementation of general controls surrounding our information technology (IT), and the second significant deficiency was due to inadequate maintenance and administration of our stock option program. We are taking steps to remedy both significant deficiencies, including with respect to the IT deficiency, engaging an independent third party to perform an assessment of internal controls over our IT systems that support financial reporting processes in our efforts to prepare for compliance with the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), and to identify opportunities for improving our IT general controls environment. With respect to the stock option program deficiencies, we are implementing new approval and documentation procedures and controls governing all such grants. In addition, we are in the process of implementing a new third party software solution for managing and accounting for stock-based compensation. We are in the very early stages of the costly and challenging process of compiling our system of internal controls over financial reporting and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may discover future deficiencies in our internal controls over financial reporting, including those identified through testing conducted by us in connection with Section 404 of the Sarbanes-Oxley Act or subsequent testing by our independent

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registered public accounting firm. Such deficiencies may be deemed to be significant deficiencies or material weaknesses and may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

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

We may rely on third parties to perform many essential services for any products that we commercialize, including distribution, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize NT-0102, NT-0202 or NT-0201 will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of NT-0102, NT-0202 and NT-0201, if approved, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management and cash collection. We would substantially rely on these third-party providers to perform services for us. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, our ability to deliver product to meet commercial demand may be significantly impaired. In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient or if they fail to comply with various requirements, we could be subject to regulatory sanctions.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

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

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

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

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

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many

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countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

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

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

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

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

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

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

We may be exposed to, or threatened with, future litigation by third parties alleging that our products or product candidates infringe their intellectual property rights. If one of our products or product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize the applicable approved

products and product candidates unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our approved products, pending a trial on the merits, which may not occur for several years.

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

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management s attention from our core business;

- third parties bringing claims against us may have more resources than us to litigate claims against us;

- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner s attorneys fees;

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- a court prohibiting us from selling our product or any product candidate approved in the future, if any, unless the third party licenses its rights to us, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and

- redesigning any of our products and product candidates so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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

Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory approval pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA s Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay. However, even if the third party does not sue within the 45-day time limit, thereby invoking the 30-month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45-day limit. By way of example, when we initially submitted our NT-0202 NDA in December 2012 and in response to our Paragraph IV certification, Shire LLC (Shire), initiated a lawsuit against us claiming patent infringement against certain of Shire s patents. We settled with Shire in July 2014. As part of our settlement, among other things, we stipulated that the commercial manufacture, use, selling, offering for sale or importing of NT-0202 would infringe on certain Shire patents and that such patent claims are valid and enforceable with respect to our NT-0202 NDA, but that such stipulations do not preclude us from filing new regulatory applications containing a Paragraph IV certification citing such patents. We also entered into a non-exclusive license agreement with Shire for certain of Shire s patents with respect to our NT-0202 NDA. Under the terms of the license agreement, if we obtain FDA approval of our NT-0202 NDA, we are required to pay a lump-sum, non-refundable license fee no later than thirty days after receiving such approval and a single-digit royalty on net sales of NT-0202 during the life of Shire s patents.

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

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

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

Some of our employees were previously employed at other companies, including actual or potential competitors. We may also engage advisors and consultants who are concurrently employed at other organizations or who perform services for other

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entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors, or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party s former employer or in violation of an agreement with or legal obligation in favor of another party. Litigation may be necessary to defend against these claims.

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

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATED TO OUR COMMON STOCK

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

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA s review of that NDA;

- failure to successfully execute our commercialization strategy with respect to NT-0102, NT-0202 or NT-0201, if approved, or any other approved potential product candidate in the future;

- adverse results or delays in clinical trials, if any;

- significant lawsuits, including patent or stockholder litigation;

- inability to obtain additional funding;

- failure to successfully develop and commercialize our product candidates;

- changes in laws or regulations applicable to our product candidates;

- inability to manufacture adequate amounts of product supply or obtain adequate amounts of components of our product supply for our product candidates, or the inability to do so at acceptable prices;

- unanticipated serious safety concerns related to the use of our generic Tussionex, NT-0102, NT-0202, NT-0201 or any future potential product candidates;

- adverse regulatory decisions;

- introduction of new products or technologies by our competitors;

- failure to meet or exceed product development or financial projections we provide to the public;

- failure to meet or exceed the estimates and projections of the investment community;

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- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- additions or departures of key scientific or management personnel;

- changes in the market valuations of similar companies;

- sales of our common stock by us or our stockholders in the future; and

- trading volume of our common stock.

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

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

As of September 30, 2015, our executive officers, directors, 5% or greater stockholders and their affiliates, including shares purchased in the IPO by members of that group and their affiliated entities, beneficially own approximately 59% of our outstanding voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. Substantially all of our existing stockholders prior to the IPO are subject to lock-up agreements with the underwriters of our IPO that restrict the stockholders ability to transfer shares of our common stock which agreements will expire on January 18, 2016. The lock-up agreements limit the number of shares of common stock that may be sold until that date. Approximately 10,422,546 of our shares will become eligible for sale upon expiration of the lock-up period, although a portion of such shares held by our affiliates will be subject to volume limitations and other conditions pursuant to Rule 144 of the Securities Act. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended (the Securities Act), subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

We will have considerable discretion in the application of our existing cash and cash equivalents, including the net proceeds from our IPO. We expect to use our existing cash to fund pre-commercialization planning and commercialization and for

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working capital and general corporate purposes, including funding the costs of operating as a public company. In addition, pending their use, we may invest our existing cash in short- and intermediate-term, investment-grade, interest-bearing securities. We may use these proceeds for purposes that do not yield a significant return or any return at all for our stockholders.

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

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

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) in 2020, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior March 31st, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth

companies.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

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We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

An active trading market for our shares may never develop or be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The IPO price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the IPO price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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

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

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

- limiting the removal of directors by the stockholders;

- creating a classified board of directors;

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

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

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inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

Unregistered Sales of Equity Securities

During the nine months ended September 30, 2015, the Company issued a total of 101,431 shares of its common stock to several investors upon the exercise of Series B-1 warrants held by those investors at an exercise price of $0.0024 per share. Between October 1 and October 28, 2015, the Company issued 112,402 shares of its common stock to several investors upon the exercise of Series B-1 warrants held by those investors at an exercise price of $0.0024 per share.

On June 30, 2015, we issued a total of 150,000 shares of our Series C preferred stock to an investor upon the exercise of Series C warrants held by that investor at an exercise price of $5.00 per share, for an aggregate exercise price of $750,000. Between July 6 and July 27, 2015, we issued 850,000 shares of our Series C preferred stock to several investors upon the exercise of Series C warrants held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $4.25 million.

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

Use of Proceeds

On July 13, 2015, we commenced our initial public offering (IPO) pursuant to a registration statement on Form S-1 (File No. 333-205106) that was declared effective by the SEC on July 22, 2015. On July 28, 2015, we closed our IPO whereby we sold 5,520,000 shares of common stock, at a public offering price of $15.00 per share for an aggregate offering price of $82.8 million, which includes 720,000 shares of common stock resulting from the underwriters exercise of their over-allotment option at the IPO price on July 23, 2015. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were $75.0 million. The managing underwriters of the IPO were UBS Securities, LLC, BMO Capital Markets Corp., RBC Capital Markets, LLC and JMP Securities, LLC. No offering expenses were paid or are payable directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

The net proceeds from the offering have been invested in highly-liquid money market funds. There has been no material change in the expected use of the net proceeds from our IPO as described in the Final Prospectus. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 24, 2015.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Internal Control Over Financial Reporting

Pursuant to Section 404(a) of the Sarbanes-Oxley Act, commencing the year following our first annual report required to be

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filed with the SEC, our management will be required to report on the effectiveness of our internal control over financial reporting. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

ITEM 6. EXHIBITS

		Incorporated by Reference to:			
Exhibit No.	**Description**	**Form or Schedule**	**Exhibit No.**	**Filing Date with SEC**	**SEC File Number**
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-Q	3.1	9/4/15	001-37508
3.2	Amended and Restated By-Laws of the Registrant.	10-Q	3.2	9/4/15	001-37508
4.1	Specimen Common Stock Certificate of the Registrant.	S-1	4.1	7/13/15	333-205106
10.1	Senior Executive Cash Incentive Bonus Plan				
31.1	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
31.2	Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.				
101.INS	XBRL Instance Document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				

101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Link Document.

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

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SIGNATURES

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

Neos Therapeutics, Inc.

Date:	November 13, 2015	By:	/s/ Vipin Garg Vipin Garg *President and Chief Executive Officer*
Date:	November 13, 2015	By:	/s/ Richard Eisenstadt Richard Eisenstadt Chief Financial Officer (*Principal Financial and Accounting Officer*)