Neos Therapeutics, Inc.
Form 10-Q
September 04, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended JUNE 30, 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 o No x

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 September 1, 2015: 15,836,285 shares.

Table of Contents

NEOS THERAPEUTICS, INC.

INDEX

Table of Contents

Special note regarding forward-looking statements

This Quarterly Report on Form 10Q contains forward-looking statements within the meaning of the 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, expec anticipates, could, intends, target, projects, contemplates, believes, estimates, predicts, potential 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, 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;

- the PDUFA goal dates for NT-0102 and NT-0202, and the NDA 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 ADHD 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 USPTO and other governmental patent agencies;

- our ability to achieve profitability; and

- our staffing needs.

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

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

Table of Contents

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.

Table of Contents

PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS.

Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	June 30, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 25,631	$ 13,343
Short term investments		3,000
Accounts receivable, net of allowances of $2,579 and $204, respectively	2,096	367
Inventories	1,703	2,031
Other current assets	235	264
Total current assets	29,665	19,005
Property and equipment, net	5,334	5,831
Intangible assets, net	17,420	18,167
Other assets	3,471	2,227
Total assets	$ 55,890	$ 45,230
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable	$ 1,333	$ 1,257
Accrued expenses	2,430	2,715
Current portion of long-term debt	3,257	1,653
Total current liabilities	7,020	5,625
Long-Term Liabilities:		
Long-term debt, net of current portion	31,198	23,121
Earnout liability	356	756
Deferred gain on leaseback	967	1,383
Deferred rent	1,172	1,189
Warrant liabilities	3,934	1,789

Total long-term liabilities	37,627	28,238
Redeemable Preferred Stock, $0.001 par value		
Series A - 1,170,000 authorized; issued and outstanding; liquidation preference of $5,850 as of June 30, 2015 and at December 31, 2014	1,068	1,068
Series B - 4,000,000 authorized; 3,113,099 issued and outstanding; liquidation preference of $15,565 as of June 30, 2015 and at December 31, 2014	14,730	14,559
Series B-1 - 8,830,000 authorized; 5,461,802 issued and outstanding; liquidiation preference of $62,731 as of June 30, 2015 and $61,647 at December 31, 2014	33,803	32,391
Series C - 13,500,000 authorized; 11,528,483 issued and outstanding as of June 30, 2015 and 8,753,547 issued and outstanding at December 31, 2014 ; liquidation preference of $57,642 at June 30, 2015 and $43,768 at December 31, 2014	54,648	42,131
	104,249	90,149
Stockholders Deficit:		
Common stock, $0.001 par value, 35,000,000 authorized; 887,414 issued and outstanding as of June 30, 2015 and 938,859 and 882,954 issued and outstanding at December 31, 2014, respectively	1	1
Additional paid-in capital	5,069	4,831
Accumulated deficit	(98,076)	(83,614)
Total stockholders deficit	(93,006)	(78,782)
Total liabilities, redeemable preferred stock and stockholders deficit	$ 55,890	$ 45,230

See notes to condensed consolidated financial statements.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Product	$ 1,484	$	$ 1,912	$
Manufacturing				113
Development		25		93
Profit Sharing		30		141
	1,484	55	1,912	347
Cost of Goods Sold	1,659	638	2,754	1,443
Gross loss	(175)	(583)	(842)	(1,096)
Research and development	2,102	3,183	6,422	5,468
Selling and marketing Expenses	602	8	928	11
General and administrative Expenses	1,659	1,404	2,996	2,951
Loss from operations	(4,538)	(5,178)	(11,188)	(9,526)
Interest expense, net	(884)	(618)	(1,641)	(1,637)
Other income, net	208	208	415	410
Change in fair value of earnout and warrant liabilities	(539)		105	
Net loss	$ (5,753)	$ (5,588)	$ (12,309)	$ (10,753)
Net loss	(5,753)	(5,588)	(12,309)	(10,753)
Preferred stock accretion to redemption value	(586)	(265)	(1,070)	(582)
Preferred stock dividends	(544)	(544)	(1,083)	(1,083)
Net loss attributable to common stock	$ (6,883)	$ (6,397)	$ (14,462)	$ (12,418)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	887,397	873,060	886,323	872,176
Net loss per share attributable to common stock, basic and diluted	$ (7.76)	$ (7.33)	$ (16.32)	$ (14.24)

See notes to condensed consolidated financial statements.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT

Six Months Ended June 30, 2015

(In thousands, except shares)

(unaudited)

	Common Stock		Treasury Stock		Additional Paid-in	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2014	**938,859**	**$ 1**	**(55,905)**	**$**	**$ 4,831**	**$ (83,614)**	**$ (78,782)**
Proceeds from exercise of options and warrants	4,460				4		4
Share-based compensation expense					234		234
Cancellation of treasury stock	(55,905)		55,905				
Series B Preferred Stock accretion to redemption value						(171)	(171)
Series B-1 Preferred Stock accretion to redemption value						(329)	(329)
Series B-1 accrued dividend						(1,083)	(1,083)
Series C Preferred Stock accretion to redemption value						(570)	(570)
Net loss						(12,309)	(12,309)
Balance, June 30, 2015	**887,414**	**$ 1**		**$**	**$ 5,069**	**$ (98,076)**	**$ (93,006)**

See notes to condensed consolidated financial statements.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in thousands)

(unaudited)

	Six Months Ended June 30,	
	2015	**2014**
Cash Flows From Operating Activities:		
Net loss	$ (12,309)	$ (10,753)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	843	814
Amortization of intangible assets	747	404
Changes in fair value of warrant and earnout liabilities	(105)	
Amortization of patents	12	
Amortization and write-off of senior debt fees	280	436
Gain on sale of equipment	(416)	(408)
Provision for bad debts		(49)
Share-based compensation expense	234	77
Interest accrued on note payable	198	305
Change in deferred rent	(17)	58
Changes in operating assets and liabilities:		
Accounts receivable	(1,729)	(53)
Inventories	328	134
Other current assets	29	(79)
Other assets	(124)	(80)
Accounts payable	(211)	5
Accrued expenses	(556)	182
Net cash used in operating activities	(12,796)	(9,007)
Cash Flows From Investing Activities:		
Net proceeds from sale (purchase) of short-term investments	3,000	(7,000)
Capital expenditures	(346)	(72)
Net cash provided by (used in) investing activities	2,654	(7,072)
Cash Flows From Financing Activities:		
Proceeds from senior debt note	10,000	10,000
Proceeds from sale of equipment		795
Net proceeds from issuance of stock	13,801	9,905
Payments made on borrowings	(797)	(10,930)
Payments of initial public offering costs	(574)	
Deferred financing costs		(398)
Net cash provided by financing activities	22,430	9,372
Increase (decrease) in cash and cash equivalents	12,288	(6,707)

Cash and Cash Equivalents:				
Beginning		13,343		11,947
Ending	$	25,631	$	5,240
Supplemental Noncash Investing and Financing Activities:				
Initial public offering costs included in accounts payable and accrued expenses	$	558	$	
Issuance of stock warrants	$	2,131	$	
Preferred Stock Dividend	$	1,083	$	1,083
Supplemental Cash Flow Information:				
Interest paid	$	1,106	$	907

See notes to condensed consolidated financial statements.

Table of Contents

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 six months ended June 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 drug 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, 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 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 one-for-2.4 reverse stock split of the Company s common stock (that 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 their Series C preferred stock to

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

several existing 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 $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 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

There have been no 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 June 30, 2015, the consolidated financial statements include the accounts of the Company and its two 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 was acquired by the Company on June 29, 2015. The amounts attributable to the noncontrolling interest were not material to the consolidated financial statements. 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 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.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 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, or 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 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 U.S. Drug Enforcement Agency 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 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 the Company s product by its previous commercialization partner. Historical trend of Medicaid rebates will be continually monitored and may result in future adjustments to such estimates.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 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 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 commercial partner, net of discounts, returns and allowances incurred by the Company s 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 June 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 June 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.

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.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Warrants: Certain warrants to purchase the Company s redeemable convertible preferred stock are classified as liabilities and are recorded at fair value as estimated by the Company using third party valuation analyses. These warrants are revalued at each subsequent balance sheet date with fair value changes recognized as reductions or increases in other income (expense), net in the Company s consolidated statement of operations.

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 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 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 six months ended June 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, or the JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period and, as a result, will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Recent accounting pronouncements: In July 2015, the Financial Accounting Standards Board (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.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

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

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	June 30, 2015	June 30, 2014
Series A Redeemable Convertible Preferred Stock (as converted)	487,494	487,494
Series B Redeemable Convertible Preferred Stock (as converted)	1,297,100	1,297,100
Series B-1 Redeemable Convertible Preferred Stock (as converted)	2,275,733	2,275,733
Series C Redeemable Convertible Preferred Stock (as converted)	4,803,492	3,022,306
Series C Redeemable Convertible Preferred Stock Warrants (as converted)	819,650	25,000
Common Stock Warrants (as converted)	337,133	337,133
Stock options	776,910	404,175

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:

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	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 June 30, 2015			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Cash and cash equivalents	$ 25,631	$	$	$ 25,631
Short term investments				
Earnout liability			356	356
Series C Redeemable Preferred Stock Warrants			3,934	3,934
	$ 25,631	$	$ 4,290	$ 29,921

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 include the fair values of the earnout liability and the outstanding warrants to purchase Series C Redeemable Convertible Preferred Stock. 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 Series C Redeemable Convertible Preferred Stock Warrants issued with the senior debt were as follows:

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	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
	(Dollars in thousands, except $5 Exercise Price)		
Date of Valuation	**12/31/2014**	**3/31/2015**	**6/30/2015**
Valuation Method	PWERM and Option Pricing	PWERM and Option Pricing	PWERM and Option Pricing
Dividend yield (per share)	0	0	0
Exercise price	$5	$5	$5
Volatility (annual)	60%	60%	60%
Risk-free rate (annual)	.25% - 2.47%	.19% - 2.31%	.14% - 2.83%
Contractual term (years)	1 - 5	.75 - 5	.5 - 5
Number of warrants	170,000	170,000	170,000
Fair value of liability at valuation date	$ 454	$ 486	$ 573

The methodologies and significant inputs used in the determination of the fair value of the Series C Redeemable Convertible Preferred Stock Warrants issued with the Series C Redeemable 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
	(Dollars in thousands, except $5 Exercise Price)				
Date of Valuation	**12/31/2014**	**1/31/2015**	**2/28/2015**	**3/31/2015**	**6/30/2015**
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
Exercise price	$5	$5	$5	$5	$5
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
Fair value of liability at valuation date	$1,335	$1,052	$1,079	$3,233	$3,361

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

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

Significant changes to these assumptions would result in increases/decreases to the fair value of the outstanding warrants to purchase Series C Redeemable Convertible Preferred Stock and the earnout liability.

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	(400)	119	176
Warrants exercised			(281)
Balance at June 30, 2015	$ 356	$ 573	$ 3,361

The reductions in fair value of the earnout liability shown above resulted from new information regarding the projected impact of the U.S. 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 PWERM weighting of the IPO scenario.

Note 6. Inventories

Inventories at the indicated dates consist of the following:

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	June 30, 2015	December 31, 2014
	(in thousands)	
Raw materials	$ 714	$ 646
Work in progress		82
Finished goods	1,270	1,499
Inventory at cost	1,984	2,227
Inventory reserve	(281)	(196)
	$ 1,703	$ 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 June 30, 2015 and 2014, approximately $208,000 per period, and for the six months ended June 30, 2015 and 2014 approximately $416,000 and $408,000, 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:

	June 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	(5,336)	(4,589)

	$	17,420	$ 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 in both the three months ended June 30, 2015 and 2014 and amortization expense of $390,000 was recorded for both the six months ended June 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

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

generated by the sale and manufacture of the product under a development and manufacturing agreement, and Cornerstone had commercialization rights to the product. The Company paid $4.2 million to Cornerstone to buy out their 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 June 30, 2015, resulting in a $42,000 increase in the estimated fair value of the earnout which is recorded in other income (expense), net in the Company s consolidated statement of operations for the three months ended June 30, 2015. The net decrease of $400,000 for the six months ended June 30, 2015 resulted from new information regarding the projected impact of the U.S. 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 their 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 $171,000 and $343,000, respectively, for the three and six months ended June 30, 2015 and there was no amortization for the three and six months ended June 30, 2014.

Note 9. Other assets

Other assets at the indicated dates consist of the following:

	June 30, 2015	December 31, 2014
	(in thousands)	
Patents	$ 2,161	$ 2,051
Deposits	178	176
Deferred Offering Costs	1,132	
	$ 3,471	$ 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 six months ended June 30, 2015, $6,000 and $12,000, respectively, of patent amortization expense was recorded. There was no patent amortization expense for the three and six months ended June 30, 2014.

Note 10. Long-term debt

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

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	June 30, 2015	December 31, 2014
	(in thousands)	
Senior debt, net of discount of $1,462 and $1,743	$ 24,600	$ 14,320
10% subordinated note payable to a related party	6,644	6,446
Capital leases, maturing through August 2017	3,211	4,008
	34,455	24,774
Less current portion	(3,257)	(1,653)
Long-term debt	$ 31,198	$ 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, or 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, or Tranche 2, was issued during September 2014. 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, or 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 June 30, 2015, the Company was in compliance with the covenants under the LSA, as amended.

In connection with the LSA, the Company issued to Hercules 60,000 warrants in March 2014 and 110,000 warrants in September 2014 (Series C Warrants) to purchase shares of the Company s Series C Redeemable Convertible Preferred Stock at the then current price of $5.00 per share. These warrants will become 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.

The fair value of the 60,000 Series C 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 Series C 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.

End of term charge amortization totaled $76,000 and $151,000 for the three and six months ended June 30, 2015, respectively. Debt discount amortization to interest expense for the senior debt totaled $65,000 and $129,000 for the three

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

and six months ended June 30, 2015, respectively. At the end of the three and six months ended June 30, 2015, the warrant fair values were remeasured and the changes in fair value of approximately $87,000 and $119,000, respectively, have been recorded in other income (expense), net in the Company s consolidated statements of operations. No change in fair value of these warrants was recorded in the three and six months ended June 30, 2014.

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 six months ended June 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, or 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 July 31, 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 June 30, 2015, the aggregate principal amount of the Note was $5.9 million, and $511,000 and $709,000 in interest had been accrued through the year ended December 31, 2014 and through the six months ended June 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 $123,000 and $172,000 for the three months ended June 30, 2015 and June 30, 2014, respectively, and $261,000 and $338,000 for the six months ended June 30, 2015 and 2014, respectively.

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

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Period ending:		**June 30, 2015 (in thousands)**
2015	$	3,257
2016		17,357
2017		15,303
Future principal payments	$	35,917
Less unamortized debt discount		(1,462)
Less current portion of long-term debt		(3,257)
Total long-term debt	$	31,198

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

	June 30, 2015		**December 31, 2014**	
	Authorized Shares	**Issued and Outstanding Shares**	**Authorized Shares**	**Issued and Outstanding Shares**
Common Stock	35,000,000	887,414	35,000,000	938,859
Series A Preferred Stock	1,170,000	1,170,000	1,170,000	1,170,000
Series B Preferred Stock	4,000,000	3,113,099	4,000,000	3,113,099
Series B-1 Preferred Stock	8,830,000	5,461,802	8,830,000	5,461,802
Series C Preferred Stock	13,500,000	11,528,483	13,500,000	8,753,547
Total Shares Issued		22,160,798		19,437,307
Treasury Stock		0		(55,905)
Total Outstanding Shares		22,160,798		19,381,402
Total Authorized Shares	62,500,000		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 one-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.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Authorized Shares

In connection with the completion 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 warrants issued with the LSA 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 Stockholders Deficit; and

- the cashless exercise of warrants issued in conjunction with the Series C preferred stock financing to purchase 947,185 shares of Series C convertible preferred stock into 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 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 six months ended June 30, 2015 or in the year ended December 31, 2014. As of June 30, 2015, warrants to purchase 337,133 shares of common stock remained outstanding, and expire in 2016. Between July 7 and August 27, 2015, the Company issued a total of 99,062 shares of its common stock to several investors upon the exercise of warrants held by those 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 six months ended June 30, 2015. The Company issued 1,499,935 shares in December 2014 and 2,624,936 shares during the three months ended March 31, 2015 of Series C preferred stock. In addition, the Company issued a warrant to purchase one additional share of Series C at a purchase price of $ 5.00 per share for every two purchased shares of Series C, provided the investor purchased its pro-rata share of the Series C. In the event that the Company s Series C is converted into common stock or another class of the Company s stock (called Conversion Stock) during the warrant exercise period, then the warrants will become exercisable for the Conversion Stock and the exercise price of those warrants shall be ratably adjusted. The Company issued warrants to purchase 749,967 shares of Series C preferred stock in December 2014 and 1,197,218 shares of Series C preferred stock during the six months ended June 30, 2015 (see warrant liability section below). On June 30, 2015, the Company issued a total of 150,000 shares of its Series C preferred stock to an investor upon the exercise of warrants held by that investor at an exercise price of $5.00 per share, for an aggregate exercise price of $750,000. Between July 6 and July 27, 2015, the Company issued 850,000 shares of its Series C preferred stock to several investors upon the exercise of warrants held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $4.25 million (See Note 17).

Dividends: From and after the date of the issuance of Series B-1, dividends at the rate per annum of 8% of the Series B-1 original issuance price of $5.00 accrued on such shares of Series B-1. Dividends accrued from day to day, whether or not

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

declared, and were cumulative. The accruing dividends shall be payable in additional shares of Series B-1, valued at the Series B-1 original issuance price, unless the board of directors of the Company elects 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 completion of the Company s IPO, all rights with respect to the Preferred Stock of the Company were terminated, including the right to receive undeclared dividends. The Series B-1 cumulative dividends were never declared by the Company s board of directors. (See Note 17).

Redemption: The holders of a majority of the outstanding shares of Series C, Series B-1 and Series B, voting together as a single class, can require the Company to redeem the Series C, Series B-1 and Series B 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 shall redeem, on a pro rata basis in accordance with the number of shares of Series C, Series B-1 and Series B owned by each holder, that number of outstanding shares of Series C, Series B-1 and Series B. If the Company does not have sufficient funds legally available to redeem on any redemption date, the Company shall redeem a pro rata portion of each holder s Series C, Series B-1 and Series B out of funds legally available.

The Series C, Series B-1 and Series B is redeemable on November 1, 2017, and their carrying value will be 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 June 30, 2015. The amount of accretion recorded for the three and six months ended June 30, 2015 and for the three and six months ended June 30, 2014 for Series C amounted to $335,000, $570,000, $21,000 and $45,000, respectively. The amount of accretion recorded for the three and six months ended June 30, 2015 and for the three and six months ended June 30, 2014 for Series B-1 was $165,000, $329,000, $161,000 and $354,000, respectively. The amount of accretion recorded for the three and six months ended June 30, 2015 and for the three and six months ended June 30, 2014 for Series B amounted to $86,000, $171,000, $83,000 and $184,000, respectively.

In the event of a deemed liquidation event, the holders of a majority of the outstanding shares of Series C, Series B-1 and Series B can require the Company to redeem such preferred stock. Based on the June 30, 2015 and December 31, 2014 capitalization, the maximum redemption payment would be $127,826,000 and $126,831,000, respectively. Since it is presently not probable that a deemed liquidation event will occur, no additional accretion has been recorded on the Series C, Series B-1, Series B or Series A. The Company s Third Amended and Restated Certificate of Incorporation, as amended, does not limit the amount that the Company could be required to pay upon redemption or the number of shares the entity could be required to issue at conversion.

In accordance with the conversion provision of the Company s Third Amended and Restated Certificate of Incorporation, as amended, which was triggered upon completion of the Company s IPO, all rights with respect to the Preferred Stock of the Company were terminated, including redemption rights. (See Note 17).

Warrant liability: In connection with the December 2014 $7.5 million additional Series C financing (see above), the Company issued warrants to purchase an aggregate 749,967 shares of the Series C. The proceeds from the December 2014 additional Series C 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 warrants is 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 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.

The proceeds from the 2015 additional Series C 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 warrants is accounted for as a warrant liability and periodically adjusted to fair value through the statement of operations. The related preferred stock discount is amortized as preferred stock accretion to redemption value over the remaining term until the redemption date using the effective interest method. The fair value of the 1,197,218 Series C Warrants was $2,131,000, with the residual $10,916,000, net of legal fees of $78,000, allocated to the 2,624,936 shares of Series C.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

At March 31, 2015, the warrant fair values were remeasured and a reduction in fair value of approximately $234,000 has been recorded in other income (expense), net in the Company s consolidated statements of operations. At June 30, 2015, the warrant fair values were remeasured and an increase in fair value of approximately $129,000 has been recorded in other income (expense), net in the Company s consolidated statements of operations for the second quarter, for a net reduction in the warrant fair value of $105,000 for the six months ended June 30, 2015.

On June 30, 2015, warrants for 150,000 shares of Series C preferred stock were exercised as described above, resulting in a $281,000 decrease in the warrant liability.

Note 12. Stock options, restricted stock and performance stock options

In November 2009, the Company adopted the Neos Therapeutics, Inc. 2009 Equity Plan (2009 Plan) that superseded the 1999 Incentive Stock Option Plan (1999 Plan) and reserved 688,059 shares for issuance under the 2009 Plan. Over time, the shares reserved for issuance under the 2009 Plan were increased to 1,375,037. 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 Neos Therapeutics, Inc. 2015 Stock Option and Incentive Plan (2015 Plan). The board of directors adopted the 2015 Plan to be effective immediately prior to the IPO and initially reserved 767,330 shares of common stock for issuance under the 2015 Plan (See Note 17).

The 2009 Plan allowed the Company to grant options to purchase shares of the Company s common stock. Options may be 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. As of June 30, 2015 and December 31, 2014, 7,717 and 277,298 shares of common stock, respectively, remain available for grant under the 2009 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. Given the absence of an active market for the Company s common stock prior to its IPO, the Company s board of directors was required to estimate the fair value of its common stock at the time of each option grant primarily based upon valuations performed by a third party valuation firm. The weighted-average key assumptions used in determining the fair value of options granted during the periods indicated are as follows:

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
Estimated dividend yield	0%	0%
Expected stock price volatility	60%	60%
Weighted-average risk-free interest rate	1.70%	1.67%
Expected life of option in years	5	5
Weighted-average option fair value at grant	$ 5.568	$ 5.235

Total compensation cost that has been charged to selling, general and administrative expense related to stock options was $115,000 and $189,000 for the three and six months ended June 30, 2015, respectively, and $21,000 and $32,000 for the three and six months ended June 30, 2014, respectively. At June 30, 2015, there was $1,708,000 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 8.8 years. For the six months ended June 30, 2015, the Company issued 4,443 shares of the Company s common stock upon the exercise of outstanding stock options and received proceeds of $4,000 and realized no tax benefit from the exercised stock options.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

A summary of outstanding and exercisable options under the 2009 Plan as of June 30, 2015 and December 31, 2014 and the activity from December 31, 2014 through June 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	271,661	10.096	
Exercised	(4,443)	0.877	
Expired, forfeited or cancelled	(2,083)	3.689	
Outstanding at June 30, 2015	776,910	$ 5.942	$ 5,359
Exercisable at June 30, 2015	177,200	$ 1.716	$ 1,971

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 June 30, 2015 was 8.8 and 7.1 years, respectively. The option exercise price for all options granted in the six months ended June 30, 2015 ranged from $9.32 to $10.73 per share.

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 $22,000 and $45,000 for the three and six months ended June 30, 2015, respectively, and $22,000 and $45,000 for the three and six months ended June 30, 2014, respectively, has been charged to selling, general and administrative expenses. At June 30, 2015 and 2014, there was $212,000 and $301,000, respectively, of unrecognized compensation cost related to restricted stock. No vested restricted stock awards were settled during the six months ended June 30, 2015.

The Company had 106,537 shares of nonvested restricted stock with a weighted average fair value of $2.55 as of June 30, 2015 and December 31, 2014. For the six months ended June 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.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 $1,172,000 and $1,189,000 at June 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 $60,000 and $119,000 for the three and six months ended June 30, 2015, respectively, and $59,000 and $126,000 for the three and six months ended June 30, 2014, respectively. Rent expense, excluding the share of operating expenses, for the three and six months ended June 30, 2015 was $218,000 and $436,000, respectively, and $229,000 and $455,000 for the three and six months ended June 30, 2014, respectively.

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 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 June 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% for the July 19, 2014 through July 31, 2015 period. 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 July 6 and July 27, 2015, the Company issued 850,000 shares of its Series C preferred stock to several investors upon the exercise of warrants held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $4.25 million.

Between July 7 and August 27, 2015, the Company issued a total of 99,062 shares of its common stock to several investors upon the exercise of warrants held by those investors at an exercise price of $0.0024 per share.

On July 10, 2015, the Company filed an amendment to its amended and restated certificate of incorporation, effecting a one-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.

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.

Table of Contents

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Effective upon closing of the IPO, the board of directors determined not to grant any further awards under the 2009 Plan. The board of directors adopted the 2015 Plan to be effective immediately prior to the closing of the IPO and initially reserved 767,330 shares of common stock for issuance under the plan (See Note 12). 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 are to be 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.

Immediately following closing of the Company s IPO on July 28, 2015, the Company filed the Fourth Amended and Restated Certificate of Incorporation authorizing 100,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock.

Table of Contents

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.

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. We have a Prescription Drug User Fee Act, or PDUFA, goal date of November 9, 2015 for NT-0102, our methylphenidate XR-ODT, which has a provisionally accepted trade name of Cotempla XR-ODT . On July 30, 2015, we announced that we had resubmitted a New Drug Application (NDA) to the FDA for NT-0202, our amphetamine XR-ODT and we have a 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, in the third 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. 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. We have funded our operations principally through private placements of our common stock, redeemable convertible preferred stock, bank and other lender financings and through payments received under collaborative arrangements.

On August 28, 2014, we completed an acquisition of all of the rights to the Tussionex Abbreviated New Drug Application, or Tussionex ANDA, which include the rights to produce, develop, market and sell, as well as all the profits from such selling activities, our generic Tussionex, which we previously owned the rights to manufacture, but which was marketed and sold by the generic drug division of Cornerstone Biopharma, Inc., or Cornerstone. These rights were acquired from the collaboration

Table of Contents

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, $5.8 million and $5.6 million for the three months ended June 30, 2015 and 2014, respectively, and $12.3 million and $10.8 million for the six months ended June 30, 2015 and 2014, respectively. As of June 30, 2015, we had an accumulated deficit of approximately $98.1 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 (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.

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 drug 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.

Table of Contents

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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			

NT-0102 Methylphenidate ODT	$ 91	$ 555	$ 2,510	$ 842
NT-0202 Amphetamine ODT	33	268	81	282
NT-0201 Amphetamine Liquid	113	584	147	758
Other Research and Development Activities (1)	1,865	1,776	3,684	3,586
	$ 2,102	$ 3,183	$ 6,422	$ 5,468

(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.

We have a PDUFA goal date of November 9, 2015 for NT-0102. 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

Table of Contents

have a PDUFA goal date of January 27, 2016. We expect to submit an NDA for NT-0201, our amphetamine XR liquid suspension, in the third quarter of 2015. Any further actions required by the FDA may result in further research and development expenses. For additional information regarding the PDUFA review process, see Government Regulation NDA and FDA review process in the final prospectus dated as of July 22, 2015.

Selling, general and administrative

Selling, general and administrative, or SG&A, expenses consist primarily of salaries and related costs for personnel, including share-based compensation expense for our employees in executive, finance, human resources and selling functions. Other SG&A expenses include facility-related costs not otherwise included in research and development expenses or cost of goods sold, and professional fees for business development, market research, accounting, tax and legal services.

We expect that our SG&A 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.

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 and warrant liabilities.

RESULTS OF OPERATIONS

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

Revenues

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

	Three Months Ended June 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Product	$ 1,484	$	$ 1,484	not applicable
Profit Sharing		30	(30)	not applicable
Development		25	(25)	not applicable
	$ 1,484	$ 55	$ 1,429	2,598.2%

Total revenues were $1.5 million for the three months ended June 30, 2015, an increase of $1.4 million or 2,598.2%, from the three months ended June 30, 2014. All $1.5 million of product revenue in the three months ended June 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 a $0.1 million decrease in development and profit sharing revenue due to reduced

Table of Contents

development work related to our generic Tussionex and to the termination of our development and manufacturing agreement in August 2014.

Cost of goods sold

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

	Three Months Ended June 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Cost of Goods Sold	$ 1,659	$ 638	$ 1,021	160.0%

The total cost of goods sold was $1.7 million for the three months ended June 30, 2015, an increase of $1.0 million or 160.0%, from the three months ended June 30, 2014. This increase was primarily due to a $0.6 million increase in raw material costs due to the increased sales of Tussionex, $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 $0.2 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 three months ended June 30, 2015 and 2014:

	Three Months Ended June 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Research & Development Expenses	$ 2,102	$ 3,183	$ (1,081)	(34.0)%

Research and development expenses were $2.1 million for the three months ended June 30, 2015, a decrease of $1.1 million or 34.0%, from the three months ended June 30, 2014. This decrease was primarily due to a $1.1 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.

Selling, general and administrative expenses

The following table summarizes our SG&A expenses for the three months ended June 30, 2015 and 2014:

Table of Contents

	Three Months Ended June 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Sales and Marketing	$ 602	$ 8	$ 594	7,425.0%
General and Administrative	1,659	1,404	255	18.2%
Total Selling, General and Administrative Expenses	$ 2,261	$ 1,412	$ 849	60.1%

The total SG&A expenses were $2.3 million for the three months ended June 30, 2015, an increase of $0.9 million or 60.1%, from the $1.4 million for the three months ended June 30, 2014. Sales and marketing professional services increased by $0.3 million due to the pre-commercialization market research, advertising, publications, corporate communications and public relations expenses incurred in the first three months of 2015 for the NT-0102 and NT-0202 product candidates. Salary and compensation expense increased $0.4 million in the three months ended June 30, 2015 primarily due to a $0.2 million increase due to the addition of personnel as part of commercialization efforts for our generic Tussionex and initial ramp up for our new product candidates, a $0.1 million increase in 2015 due to the addition of contract labor in support of our IPO and a $0.1 million increase in compensation related to share-based payments. In addition, G&A Professional Fees expenses increased by $0.3 million related to the engaging of consultants primarily for audit, tax, financial analysis, government pricing and business development. These increased costs were offset by a $0.2 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 three months ended June 30, 2015 and 2014:

	Three Months Ended June 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Interest Expense	$ 884	$ 618	$ 266	43.0%

The total interest expense was $0.9 million for the three months ended June 30, 2015, an increase of $0.3 million or 43.0%, from the $0.6 million for the three months ended June 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 June 30, 2015 and 2014:

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Other Income, net	$ (331)	$ 208	$ (539)	(259.1)%

Table of Contents

Other income (expense), net was $(0.3) million expense for the three months ended June 30, 2015, a decrease of $0.5 million or 259.1%, from the $0.2 million for the three months ended June 30, 2014. This increase resulted from the increases in the fair values of our earnout and warrant liabilities as a result of the measurement of their fair value which gave increased PWERM weighting to the IPO scenario.

Six months ended June 30, 2015 compared to the six months ended June 30, 2014

Revenues

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

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Product	$ 1,912	$	$ 1,912	not applicable
Manufacturing		113	(113)	not applicable
Profit Sharing		141	(141)	not applicable
Development		93	(93)	not applicable
	$ 1,912	$ 347	$ 1,565	451.0%

Total revenues were $1.9 million for the six months ended June 30, 2015, an increase of $1.6 million or 451.0%, from the six months ended June 30, 2014. All $1.9 million of product revenue in the six months ended June 30 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 $0.1 million decrease in development revenues for the six months ended June 30, 2015 was primarily due to reduced development work related to our generic Tussionex. In addition, the manufacturing and profit sharing revenues decreased by $0.2 million primarily due to the termination of our development and manufacturing agreement in August 2014.

Cost of goods sold

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

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Cost of Goods Sold	$ 2,754	$ 1,443	$ 1,311	90.9%

The total cost of goods sold was $2.8 million for the six months ended June 30, 2015, an increase of $1.3 million or 90.9%, from the six months ended June 30, 2014. This increase was primarily due to $0.6 million increase in raw material costs due to the increased sales of Tussionex, $0.4 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.

Table of Contents

Research and development expenses

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

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Research & Development Expenses	$ 6,422	$ 5,468	$ 954	17.4%

Research and development expenses were $6.4 million for the six months ended June 30, 2015, an increase of $0.9 million or 17.4%, from the $5.5 million for the six months ended June 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 and a $0.1 amortization of the annual FDA facility fee for 2015 for our generic Tussionex. These increases were offset by a $1.3 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, a $0.1 million decrease in consulting firm services related to the filing of our NDA applications and a $0.1 million decrease in research and development salaries and benefits as employees efforts were refocused on the commercial production of our generic Tussionex.

Selling, general and administrative expenses

The following table summarizes our SG&A expenses for the six months ended June 30, 2015 and 2014:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Sales and Marketing	$ 928	$ 11	$ 917	8,336.4%
General and Administrative	2,996	2,951	45	1.5%
Total Selling, General and Administrative Expenses	$ 3,924	$ 2,962	$ 962	32.5%

The total SG&A expenses were $3.9 million for the six months ended June 30, 2015, an increase of $0.9 million or 32.5%, from the $3.0 million for the six months ended June 30, 2014. Sales and marketing professional services increased by $0.5 million due to the pre-commercialization market research, advertising agency costs, publications, corporate communications and public relations expenses incurred in the first six months of 2015 for the NT-0102 and NT-0202 product candidates. Salary and compensation expense increased $0.6 million in the six months ended June 30, 2015 primarily due to a $0.3 million increase due to the addition of personnel as part of commercialization efforts for our generic Tussionex and for the commercialization of our new product candidates, a $0.2 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 and in support of our IPO and a $0.1 million increase in compensation related to share-based payments. In addition, G&A Professional Fees expenses increased by $0.4 million related to the engaging of consultants primarily for audit, tax, financial analysis, government pricing and business development. These increased costs were 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 six months ended June 30, 2015 and 2014:

Table of Contents

	Six Months Ended June 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Interest Expense	$ 1,641	$ 1,637	$ 4	0.2%

The total interest expense was $1.6 million for the six months ended June 30, 2015, unchanged from the $1.6 million for the six months ended June 30, 2014. The interest on senior debt increased by $0.2 million due to higher interest in 2015 due to the increased senior debt balance. This increase was offset by a $0.1 million decrease in subordinated debt interest due to the reduction in the interest rate on the note from 10% to 6% in 2015 pursuant to the Settlement and Release of Claims Agreement with Essex and a third party (see Note 16) and a $0.1 million reduction in capital lease interest due the reduced capital lease balances resulting from the lease payments.

Other income (expense), net

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

	Six Months Ended June 30,			
	2015	2014	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Other Income, net	$ 520	$ 410	$ 110	26.8%

Other income was $0.5 million for the six months ended June 30, 2015, an increase of $0.1 million or 26.8%, from the $0.4 million for the six months ended June 30, 2014. This change was due to the year-to-date effect of the remeasurements of the fair values which included a decrease in the fair value of the earnout liability in the first quarter of 2015 resulting primarily from new information regarding the projected impact of the U.S. 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, which was partially offset by a second quarter increase in fair values of the earnout and warrant liabilities due to the increased PWERM weighting to the IPO scenario.

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 June 30, 2015, we had $25.6 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 our Series C preferred stock warrants exercised 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 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

Table of Contents

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 currently providing only a minimal return.

Cash flows

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

	Six Months Ended June 30,		Increase (Decrease)
	2015	2014	
	(in thousands)		
Net Cash (used in) provided by:			
Net Cash used in operating activities	$ (12,796)	$ (9,007)	$ (3,789)
Net Cash provided by (used in) investing activities	2,654	(7,072)	9,726
Net Cash provided by financing activities	22,430	9,372	13,058
Net increase (decrease) in cash and cash equivalents	$ 12,288	$ (6,707)	$ 18,995

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 $12.8 million and $9.0 million for the six months ended June 30, 2015 and 2014, respectively. The $3.8 million increase in net cash used from operating activities was primarily due to the $1.6 million increase in our net losses, as discussed above, a $0.1 million increase in noncash items and a $2.4 million increase in the usage of cash from working capital changes. The decrease in noncash items was principally due to 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, partially offset by the higher fees and costs paid as a result of the prepayment of a prior credit facility in 2014 as compared with the 2015 amortization of loan fees and costs under the Loan and Security Agreement with Hercules Technology III, L.P., or Hercules, as amended, or the LSA, the reduced interest accrued on the subordinated related party note and the changes in the fair value of the earnout and warrant liabilities in 2015. The increase in usage of cash from working capital charges resulted primarily from a $1.7 million increase in accounts receivable due to sales of our Tussionex generic product and $1.0 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.

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.

Table of Contents

Net cash provided by investing activities was $2.7 million for the six months ended June 30, 2015 as compared to net cash used in investing activities of $7.1 million for the six months ended June 30, 2014, both of which principally resulted from the net sale or purchase, respectively, of short term investments, partially offset by $0.3 million increase in 2015 capital expenditures, primarily in association with the expansion of our controlled substances vault.

Cash provided by financing activities.

Net cash provided by financing activities of $22.4 million in the six months ended June 30, 2015 primarily resulted from proceeds of $13.8 million, net of issuance costs, received from the sale of 2,624,936 shares of our Series C preferred stock and the exercise of warrants for 150,000 shares of Series C preferred stock and proceeds of $10.0 million from the remaining drawdowns under the LSA (see Credit Facilities below for details), partially offset by $0.6 million of deferred IPO costs and $0.8 million of principal payments under the sales leasebacks. Net cash provided by financing activities of $9.4 million in the six months ended June 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 $10.0 million from the issuance of notes to our new lender, offset by $10.2 million in payments under the previous term loan and $0.4 million of deferred financing costs, and $0.8 million of proceeds from the sale leaseback of equipment, partially offset by $0.7 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, or 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, or Tranche 2, was issued in September 2014. 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, or Tranche 4, was issued prior to achieving the Tranche 4 milestones as described below. 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.

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 June 30, 2015, we were in compliance with the covenants under our LSA, as amended.

In December 2011, we issued to Essex Capital Corporation, or Essex, a subordinated note, or 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 July 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

Table of Contents

10% to 6% for the July 2014 through July 2015 period. The third party released both Essex and us from any and all claims. As of June 30, 2015, the aggregate principal amount of the Note was $5.9 million and $708,000 in interest had been accrued through June 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.

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.

Table of Contents

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 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 10Q, 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 a 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 previous 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.

Table of Contents

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

Profit sharing

Profit sharing revenue is recorded as the product is sold by our 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 commercial partner, net of discounts, returns and allowances incurred by our commercial partners, 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.

Table of Contents

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

Share-based compensation expense

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
General and Administrative				
Options	$ 115	$ 21	$ 189	$ 32
Restricted Stock	22	22	45	45
	$ 137	$ 43	$ 234	$ 77

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

Table of Contents

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:

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
Estimated dividend yield	0%	0%
Expected stock price volatility	60%	60%
Weighted-average risk-free interest rate	1.70%	1.67%
Expected life of option in years	5	5
Weighted-average option fair value at grant	$ 5.568	$ 5.235

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 earning 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*, or 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

Table of Contents

Method, or PWERM, to determine the value attributable to common stock based on a private company scenario and an initial public offering scenario. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. For each scenario, we utilized the discounted cash flow method to determine our value, allocated to classes of equity using an option pricing model and applied the PWERM approach, weighted based on management s expectations, yielding an estimated marketable, minority fair value of our common stock. A discount for lack of marketability, or 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 drug 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.

On July 9, 2015, the Board of Directors approved option grants to purchase an aggregate of 37,500 shares of common stock to certain non-employee directors, to be effective immediately after the effectiveness of our registration statement. The exercise price of these option grants was equal to the IPO price of $15.00. .

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.

Based on the IPO price of $15.00 per share, the intrinsic value of stock options outstanding at June 30, 2015 and December 31, 2014 was $7.0 million and $5.8 million, respectively, of which $2.4 million and $2.1 million, respectively, related to stock options that were vested and $4.6 million and $3.8 million related to stock options that were unvested and unvested, each at the respective date.

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 convertible preferred stock 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, 11 and 12 in the notes to our financial statements above). In connection with the completion of our IPO on July 28, 2015, all the outstanding warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock. As a result of the IPO and warrant conversion, we reclassified the warrant liability as stockholders equity as of July 28, 2015 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 June 30, 2015. Future events could cause actual payments to differ from these estimates.

Table of Contents

	Total	< 1 Yr	1-3 Yrs.	3-5 Yrs	Thereafter
			(In thousands)		
Loan and Security Agreement	30,788	3,902	26,886		
Related Party Note Payable	8,102		8,102		
Capital Leases for Equipment	3,662	2,131	1,531		
Earnout Liability	356		356		
Operating lease for facility	9,452	907	1,885	1,935	4,725
	$ 52,360	$ 6,940	$ 38,760	$ 1,935	$ 4,725

We have drawn down $25.0 million of the LSA, as amended, as of June 30, 2015. The payments above are inclusive of related interest amounts as of June 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, 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, or the JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities

Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk

We are exposed to market risk related to changes in interest rates as it impacts our interest income. As of June 30, 2015, we had cash and cash equivalents of $25.6 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

Table of Contents

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

Interest risk

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

Effects of Inflation

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

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, 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 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.

Table of Contents

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, or XR-ODT, NT-0202, our amphetamine XR-ODT, and NT-0201, our amphetamine XR liquid suspension, for the treatment of attention deficit hyperactivity disorder, or ADHD, and any other product candidates that we may identify and pursue. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, from the U.S. Food and Drug Administration, or FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. Satisfaction of regulatory requirements can be protracted, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. We cannot predict whether we will obtain regulatory approval to commercialize our product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any delay or setback in the regulatory approval or commercialization of any of these product candidates could adversely affect our business.

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, including in pediatric patients;

Table of Contents

- 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 will address all of the concerns raised by the FDA which resulted in the issuance of the Complete Response Letter. 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.

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

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

We intend to submit to the FDA an NDA for NT-0201 during the third quarter of 2015, which will be indicated for the treatment of ADHD. 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, or FDCA, or the FDA s regulations;

- the NDA does not contain a statement that each nonclinical laboratory study was conducted in compliance with the Good Laboratory Practices, or 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, or 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, or 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

Table of Contents

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

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

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

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

We intend to seek FDA approval through the 505(b)(2) regulatory approval pathway for each of our product candidates described in this 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

Table of Contents

one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

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

Our 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, or 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, or 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.

Table of Contents

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

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

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

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

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

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

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

- exposure to unknown liabilities;

- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;

- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

- higher than expected acquisition and integration costs;

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

- increased amortization expenses;

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

- inability to motivate key employees of any acquired businesses.

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

- receipt by a competitor of marketing approval for a product targeting an indication that our product targets, such that we are not first to market with our product candidate;

- 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.

Table of Contents

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.

Table of Contents

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 do not currently have an organization for the sale, marketing or distribution of NT-0102, NT-0202 or NT-0201. As a result, we must build this organization, 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 currently have no such organization or 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 would 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 may 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.

Table of Contents

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, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product s approval may contain requirements for potentially costly post-approval trials and surveillance to monitor the safety and efficacy of the product or the imposition of a REMS program. The holder of an approved NDA may be required to conduct post-approval clinical studies in one or more pediatric population.

Prescription drug advertising, marketing and promotion are subject to federal, state and foreign regulations, which include requirements for direct-to-consumer advertising, off-label promotion, 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, or 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;

Table of Contents

- 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 in the second quarter of 2016 NT-0202 in the third 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;

Table of Contents

- 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, including conducting post-approval studies; 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 submitted an NDA for an amphetamine-based XR liquid suspension and 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

Table of Contents

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

Table of Contents

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 are implementing corrective action related to this observation and will respond to the FDA. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

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

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

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

Table of Contents

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, or 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 su