Neos Therapeutics, Inc.
Form 424B4
July 24, 2015

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Filed Pursuant to Rule 424(b)(4)
Registration No. 333-205106

PROSPECTUS July 22, 2015

4,800,000 Shares

Common stock

This is an initial public offering of shares of common stock of Neos Therapeutics, Inc. We are selling 4,800,000 shares of common stock. The initial public offering price is $15.00 per share.

Prior to this offering, there has been no public market for the common stock. Our common stock has been approved for listing on the NASDAQ Global Market under the symbol "NEOS."

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See "Risk factors" on page 9.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per share	Total
Initial public offering price	$ 15.00	$ 72,000,000
Underwriting discounts and commissions(1)	$ 1.05	$ 5,040,000
Proceeds to us, before expenses	$ 13.95	$ 66,960,000

(1)

The underwriters will receive compensation in addition to the underwriting discount. See "Underwriting" beginning on page 160.

Funds affiliated with our existing stockholders Deerfield Private Design Fund III, L.P. and Presidio Partners 2007, L.P., and certain other of our existing stockholders, have agreed to purchase an aggregate of approximately 1,022,500 shares of our common stock in this offering at the initial public offering price.

We have granted the underwriters an option for a period of 30 days to purchase up to 720,000 additional shares of common stock.

The underwriters expect to deliver the shares of common stock to investors on or about July 28, 2015.

UBS Investment Bank **BMO Capital Markets** **RBC Capital Markets**

JMP Securities

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You should rely only on the information contained in this prospectus or contained in any free writing prospectus filed with the Securities and Exchange Commission. Neither we nor any of the underwriters have authorized anyone to provide any information or make any representations other than those contained in this prospectus or in any free writing prospectus filed with the Securities and Exchange Commission. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock. Our business, financial condition, results of operations and prospects may have changed since such date.

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No action is being taken in any jurisdiction outside the United States to permit a public offering of the common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

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Prospectus summary

This summary highlights selected information that is presented in greater detail elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections titled "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context otherwise requires, the terms "Neos," "the company," "we," "us" and "our" in this prospectus refer to Neos Therapeutics, Inc.

NEOS THERAPEUTICS, INC.

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. We have a Prescription Drug User Fee Act, or PDUFA, goal date of November 9, 2015 for NT-0102, our methylphenidate XR-ODT. A PDUFA goal date is a review performance goal for the FDA to meet in acting on a new drug application, or NDA. Under PDUFA, as amended by the Food and Drug Administration Safety and Innovation Act, for fiscal year 2015, the FDA agreed to review and act on 90% of standard, non-new molecular entity NDAs, like the one submitted for NT-0102, within 10 months from the FDA's receipt of the NDA submission. We expect to resubmit an NDA for NT-0202, our amphetamine XR-ODT, by the end of July 2015, and submit an NDA for NT-0201, our amphetamine XR liquid suspension, in the third quarter of 2015. If approved, we believe our product candidates will address an unmet need by providing more patient-and caregiver-friendly dosing options not previously available to patients in the $10.7 billion market for ADHD-indicated medications.

Our product candidates incorporate two of the most commonly prescribed medications for the treatment of ADHD, methylphenidate and amphetamine. Our proprietary modified-release drug delivery platform has enabled us to create novel, extended-release ODT and liquid suspension dosage forms of these medications. 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. We expect our patent estate, which we developed internally and which includes composition-of-matter, method-of-manufacture and method-of-use patents and patent applications, some of which are not scheduled to expire until 2032, will provide additional protection for our three branded product candidates.

ADHD is a neurobehavioral disorder characterized by a persistent pattern of inattention and/or hyperactivity/impulsivity that interferes with functioning and/or development. In 2014 alone, 63.1 million prescriptions for medications with ADHD labeling, and principally in extended-release formulations, were written in the United States. We believe that the inability, difficulty or reluctance of many patients to swallow intact tablets and capsules contributes to diminished compliance rates. Such limitations highlight the need for more convenient dosing options such as ODT or liquids. We believe there is a significant market opportunity to provide the two most prescribed medications for ADHD, methylphenidate and amphetamine, in two more convenient and patient-friendly dosage forms, ODT and liquid suspension, which we developed using our proprietary technology platform.

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

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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.

We also believe we can apply our XR-ODT and XR liquid suspension technologies that underlie our branded product candidates and our generic Tussionex to other active pharmaceutical ingredients, or APIs. Our longer-term strategy is to utilize these technologies for the development and approval of additional XR-ODT or XR liquid suspension drug candidates, while leveraging our manufacturing and commercialization experience to reduce costs and effectively reach patients.

Our strategy

Our goal is to be a leading pharmaceutical company focused on the development, manufacture and commercialization of pharmaceutical products that utilize our proprietary modified-release drug delivery technology platform. Key elements of our business strategy to achieve this goal are to:

Obtain U.S. Food and Drug Administration, or FDA, approval for our three branded product candidates in ADHD. In January 2015, we submitted an NDA for the approval of NT-0102, our methylphenidate XR-ODT, and have a PDUFA goal date of November 9, 2015. During 2015, we also expect to resubmit the NDA for NT-0202, our amphetamine XR-ODT, and submit a new NDA for NT-0201, our amphetamine XR liquid suspension.

Establish commercialization capabilities in the United States for any of our product candidates that are FDA approved. We believe that we can effectively commercialize our branded ADHD product candidates, if approved in the United States, with a specialty sales force of approximately 100 representatives. We intend to target the highest volume prescribers to address the unmet need for more patient- and caregiver-friendly dosage forms of the two most prescribed medications for the treatment of ADHD.

Manufacture our proprietary products in our cGMP, FDA-inspected and DEA-registered manufacturing facilities. We believe our manufacturing facilities and years of manufacturing experience are a competitive advantage. We intend to leverage the economic efficiencies afforded by manufacturing our ADHD products in our cGMP and DEA-registered manufacturing facilities.

Leverage our proprietary technology platform to develop additional branded product candidates in CNS and other therapeutic areas with unmet need. We intend to expand our branded product portfolio by identifying existing pharmaceutical products that could be improved upon by utilizing our proprietary modified-release drug delivery technology platform.

Continue to expand our robust intellectual property portfolio covering our novel modified-release drug delivery technology platform and innovative products. We have built a three-tier patent estate consisting of composition-of-matter, method-of-manufacture and method-of-use patents and patent applications. We intend to extend our patent portfolio as we continue to expand upon our drug delivery technologies and identify and develop additional branded product candidates.

Our product candidates and currently marketed product

We have the ability to produce drug-loaded micro-particles with complex release profiles, which allows us to develop ODT or liquid suspension formulations that mimic and can improve existing therapies not otherwise available in XR-ODT or XR liquid suspension form. Utilizing our proprietary modified-release drug delivery technology platform, we are developing our three branded product candidates and currently manufacture and market a generic liquid suspension product. We are developing each of our product candidates to seek FDA approval in accordance with Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the 505(b)(2) regulatory approval pathway. This regulatory

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approval pathway provides an alternate regulatory pathway for approval of a new drug and permits an applicant to rely on a third party's data for approval. Specifically, 505(b)(2) permits the submission of an NDA where one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The table below summarizes our pipeline of product candidates and currently marketed product.

Product	Active drug and indication	Formulation	Status
NT-0102	Methylphenidate for ADHD	XR-ODT	PDUFA Goal Date of November 9, 2015
NT-0202	Amphetamine for ADHD	XR-ODT	Resubmit NDA by the end of July 2015
NT-0201	Amphetamine for ADHD	XR Liquid Suspension	Submit NDA in Q3 2015
Generic Tussionex	Hydrocodone and chlorpheniramine for cough and upper respiratory symptoms of a cold	XR Liquid Suspension	Currently approved and marketed

NT-0102: Methylphenidate XR-ODT for the Treatment of ADHD. We believe our most advanced product candidate, NT-0102, if approved, will be the first methylphenidate XR-ODT for the treatment of ADHD, providing onset-of-effect within one hour and with a 12-hour duration. NT-0102 contains methylphenidate loaded onto a mixture of immediate-release and polymer-coated delayed-release resin particles, which are formulated and compressed into an ODT along with other typical tableting excipients using our patented rapidly disintegrating ionic masking, or RDIM, technology. The result is methylphenidate with an *in vivo* extended-release profile delivered through a tablet that quickly disintegrates in the mouth without the need for water.

NT-0202: Amphetamine XR-ODT for the Treatment of ADHD. We believe NT-0202, if approved, will be the first amphetamine XR-ODT for the treatment of ADHD. NT-0202 contains amphetamine loaded onto a mixture of immediate-release and polymer-coated delayed-release resin particles, which are formulated and compressed into an ODT along with other typical tableting excipients using our patented RDIM technology. The result is amphetamine with an *in vivo* extended-release profile delivered through a tablet that quickly disintegrates in the mouth without the need for water. We submitted a 505(b)(2) NDA for NT-0202 in December 2012. In May 2013, the FDA issued a Discipline Review Letter identifying certain deficiencies in the NDA. Following our response to that letter, the FDA issued a Complete Response Letter in September 2013, which outlined additional requirements for data to support our NDA and meant that the agency could not approve the NDA in its present form.

NT-0201: Amphetamine XR Liquid Suspension for the Treatment of ADHD. NT-0201 contains amphetamine loaded onto a mixture of immediate-release and polymer-coated delayed-release resin particles, and using our patented dynamic time release suspension, or DTRS, technology, we are able to create an amphetamine XR liquid suspension. NT-0201 is designed to be shelf stable for 24 months, without requiring refrigeration or reconstitution.

Generic Tussionex. We manufacture and market a generic equivalent to the branded product Tussionex. Our generic Tussionex is a hydrocodone polistirex and chlorpheniramine polistirex XR liquid suspension that is a Schedule II narcotic, antitussive and antihistamine combination. This product is indicated for the relief of cough and upper respiratory symptoms associated with allergies or colds in adults and children six years of age and older.

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Risks related to our business and industry

Our business, financial condition, results of operations and prospects are subject to numerous risks. These risks as more fully described in the section entitled "Risk factors" immediately following this summary, include the following:

- 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.

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

- 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.

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

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

- If our sole facility becomes damaged or inoperable or we are required to vacate our facility, our ability to manufacture our product candidates and our generic Tussionex for commercialization, or future potential product candidates for clinical development, may be jeopardized.

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

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

Corporate information

Our predecessor company was incorporated in Texas in November 1994. In June 2009, we completed a reorganization pursuant to which substantially all of the capital stock of the predecessor company was acquired by a newly formed Delaware corporation, named Neos Therapeutics, Inc. Our principal executive offices are located at 2940 N. Hwy 360, Grand Prairie, TX 75050. Our telephone number is 972-408-1300. We maintain a web site at www.neostx.com. The reference to our web site is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our web site is not a part of this prospectus.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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The offering

Common stock offered by us	4,800,000 shares
Common stock to be outstanding after this offering	14,488,716 shares
Option to purchase additional shares from us	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to an additional 720,000 shares from us.
Use of proceeds	We estimate that the net proceeds from the sale of shares of our common stock that we are selling in this offering will be approximately $65.0 million (or approximately $75.0 million if the underwriters' option to purchase additional shares in this offering is exercised in full), based upon the initial public offering price of $15.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds of this offering for the pre-commercialization planning of our three lead product candidates, NT-0102, NT-0202 and NT-0201, for the commercialization of our three lead product candidates, if approved, and for working capital and other general corporate purposes. See "Use of proceeds" for additional information.
Risk factors	See "Risk factors" for a discussion of factors you should carefully consider before deciding to invest in our common stock.
NASDAQ Global Market trading symbol	"NEOS"

Funds affiliated with our existing stockholders Deerfield Private Design Fund III, L.P. and Presidio Partners 2007, L.P., and certain other of our existing stockholders, have agreed to purchase an aggregate of approximately 1,022,500 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same discount from any shares of our common stock purchased by these stockholders as they will from any other shares of our common stock sold to the public in this offering.

The number of shares of common stock to be outstanding after this offering is based on 9,688,716 shares of common stock outstanding as of March 31, 2015.

The number of shares of our common stock to be outstanding after this offering excludes the following:

- 627,745 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2015 at a weighted-average exercise price of $4.80 per share;

- 407,966 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 at a weighted-average exercise price of $2.09 per share;

- 811,317 shares of common stock issuable upon the exercise of redeemable convertible preferred stock warrants outstanding as of March 31, 2015 at an exercise price of $12.00 per share, 249,998 of which have been exercised as of the date of this prospectus and 561,319 of which

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automatically exercise using the net issuance method upon the closing of this offering, unless previously exercised. The exercise price of these warrants which automatically exercise using the net issuance method will be equal to the initial public offering price set forth on the cover page of this prospectus;

149,582 shares of common stock issuable upon the exercise of stock options granted under our Neos Therapeutics, Inc. 2009 Equity Plan, or 2009 Equity Plan, since March 31, 2015 at an exercise price of $10.73 per share; and

767,330 shares of common stock that will be available for future issuance under our 2015 Stock Option and Incentive Plan, or the 2015 Plan, to be effective as of immediately prior to the effectiveness of the registration statement of which this prospectus is a part. Of these shares, options to purchase an aggregate of 37,500 shares of common stock were granted to certain non-employee directors effective immediately after the effectiveness of the registration statement of which this prospectus is a part. The exercise price of the option grants is equal to the initial public offering price set forth on the cover page of this prospectus. No additional shares of common stock will be reserved for issuance under our 2009 Plan following the closing of this offering.

Except as otherwise indicated, all information contained in this prospectus reflects or assumes:

a 1-for-2.4 reverse stock split of our common stock effected on July 10, 2015;

the amendment and restatement of our certificate of incorporation and bylaws, which will occur immediately prior to the closing of this offering;

the conversion of all of our shares of redeemable convertible preferred stock outstanding as of March 31, 2015 into 8,801,319 shares of common stock, which will occur automatically upon the closing of this offering;

no exercise of stock options or warrants on or after March 31, 2015; and

no exercise by the underwriters of their option to purchase up to an additional 720,000 shares of common stock in this offering.

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Summary financial data

The following summary financial statements for the three months ended March 31, 2014 and 2015 are derived from unaudited financial statements appearing elsewhere in this prospectus. The following summary financial data for the years ended December 31, 2013 and 2014 are derived from our audited financial statements appearing elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the captions "Selected consolidated financial data" and "Management's discussion and analysis of financial condition and results of operations." Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

Statement of operations data:

	Year Ended December 31,		Three months Ended	
	2013	2014	March 31, 2014	March 31, 2015
			(unaudited)	(unaudited)
	(in thousands, except share and per share data)			
Total Revenue	$ 1,044	$ 758	$ 292	$ 428
Cost of Goods Sold	2,534	3,354	805	1,095
Research and Development	9,974	10,601	2,285	4,320
Selling, General and Administrative Expenses	5,624	5,275	1,550	1,663
Interest and Other Expense (Income)	1,512	2,377	817	(94)
Net Loss from continuing operations	$ (18,600)	$ (20,849)	$ (5,165)	$ (6,556)
Loss from discontinued operations	$ (437)	$	$	$
Net Loss	$ (19,037)	$ (20,849)	$ (5,165)	$ (6,556)
Preferred Stock Accretion to Redemption Value	(1,227)	(1,118)	(317)	(484)
Preferred Stock Dividends	(2,185)	(2,185)	(539)	(539)
Net Loss Attributable to Common Stock	$ (22,449)	$ (24,152)	$ (6,021)	$ (7,579)
Net Loss per Share *Basic and Diluted(1)*	$ (28.45)	$ (27.56)	$ (6.91)	$ (8.56)
Shares Used to Compute Net Loss per Share *Basic and Diluted*	788,964	876,318	871,282	885,237

(1) See Note 4 to the notes to our audited financial statements for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

Our consolidated balance sheet as of March 31, 2015 is presented on

an actual basis;

a pro forma basis, giving effect to the automatic conversion of all shares of our redeemable convertible preferred stock outstanding as of March 31, 2015 into 8,801,319 shares of common stock immediately prior to the closing of this offering and the effectiveness of our amended and restated certificate of incorporation which will occur upon closing of this offering, as if such conversion had occurred and our amended and restated certificate of incorporation had become effective on March 31, 2015; and

a pro forma as adjusted basis, giving effect to (a) the pro forma adjustments and (b) the sale of 4,800,000 shares of common stock by us in this offering, based on the initial public offering price

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of $15.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information set forth in the table below is illustrative only and will be adjusted based on the actual public offering expenses paid by us.

Balance sheet data:

	As of March 31, 2015		
	Actual	Pro Forma	Pro Forma as Adjusted
	(Unaudited) (in thousands)		
Cash and Cash Equivalents	$ 26,169	$ 26,169	$ 91,129
Short-Term Investments			
Working Capital	22,425	22,425	87,603
Total Assets	54,624	54,624	119,366
Long-Term Debt, net of Current Portion	26,124	26,124	26,124
Warrant Liability	3,719		
Redeemable Convertible Preferred Stock	102,088		
Stockholders' (Deficit) Equity	(86,260)	19,547	84,507

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Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our consolidated financial statements and the related notes appearing at the end of this prospectus, before making a decision to invest in our common stock. If any of the risks actually occur, our business, financial condition, results of operations and prospects could be harmed. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment.

RISKS RELATED TO 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;

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

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

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

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

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

may change its approval policies or adopt new regulations; or

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

On December 27, 2012, we submitted an NDA for NT-0202 to the FDA, which the agency subsequently accepted for filing. On May 29, 2013, we received a Discipline Review Letter that found deficiencies in the "quality" section of our NDA and, among other things, raised issues with our proposal to scale-up the manufacturing process for the commercial product. Ultimately, on September 24, 2013, the FDA issued a Complete Response Letter, stating that it could not approve the NDA for NT-0202 in its present form. We believe that we 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 NDAs for NT-0202 and NT-0201 for the treatment of attention deficit hyperactivity disorder are not sufficiently complete to permit a substantive review.

We intend to resubmit to the FDA a complete response to the NDA for NT-0202 by the end of July 2015 and to submit to the FDA an NDA for NT-0201 during the third quarter of 2015, both of which will be indicated for the treatment of ADHD. Within 60 days of the agency's receipt of each 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

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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
- 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 determines that our resubmission of the NDA for NT-0202 is incomplete or 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 accept our resubmission of the NDA for NT-0202 or file the NDA for NT-0201. If the agency determines that the responses provided in the resubmission of the NDA for NT-0202 are inadequate or refuses to file the NDA for NT-0201, we will need to address the deficiencies cited by the FDA, which could substantially delay the review process.

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Risk factors

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

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expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

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

Our 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.

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Risk factors

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.

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

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

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

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

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

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

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

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

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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.

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.

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Risk factors

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

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where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

Even after a product is approved, we will remain subject to ongoing 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.

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.

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Risk factors

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. On June 19, 2015, we responded to the FDA and we have implemented corrective action related to this observation. If we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, we will not be able to secure and/or maintain regulatory approval for our product candidates. If the FDA finds deficiencies at our manufacturing facility and does not approve our NDA for any of our product candidates or if it withdraws any such approval in the future, our ability to develop or market any of our product candidates will be impacted.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including notice to physicians, withdrawal of the product from the market or suspension of manufacturing. Manufacturers are also subject to annual drug product and facility user fees that may be substantial. If we are unable to generate sales of our product candidates, the user fee requirements could be difficult to pay.

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

- issue untitled or warning letters asserting that we are in violation of the FDCA;
- impose restrictions on the marketing or manufacturing of any product candidate or product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, or require disgorgement;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us; or
- seize the product.

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

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

In addition, the FDA's regulations or policies may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or

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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;
- properly price and obtain adequate coverage and reimbursement of the product by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements; and
- manage our growth and spending as costs and expenses increase due to commercialization.

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

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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.

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,

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acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our XR-ODT or XR liquid suspension, or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens petitions with the FDA in an attempt to persuade the FDA that our products, or the nonclinical studies or clinical trials that support their approval, contain deficiencies or that new regulatory requirements be placed on the product candidate or drug class of the product candidate. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

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

- the 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

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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 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

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changes in records are instituted only by authorized personnel. On June 19, 2015, we responded to the FDA and we have implemented corrective action related to this observation. 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 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 such product candidates.

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

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

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

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

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

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unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such product candidate or successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates. The FDA recently conducted a cGMP and pre-approval inspection related to our NDA for NT-0102 from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. On June 19, 2015, we responded to the FDA and we have implemented corrective action related to this observation.

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

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

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

Our Grand Prairie facility was formerly operated by our predecessor, PharmaFab, Inc., or PharmaFab. In April 2007, the FDA announced entry of a Consent Decree of Permanent Injunction, or the Consent Decree, against PharmaFab, one of its subsidiaries and two of its officials, including Mark Tengler, who was, at the time, PharmaFab's president, or jointly, the Defendants. The Consent Decree arose out of several perceived cGMP deficiencies related to the manufacture of unapproved drugs or Drug Efficacy Study Implementation, or DESI, drugs that we no longer manufacture. Pursuant to the Consent Decree, the Defendants were permanently restrained and enjoined from directly or indirectly

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manufacturing, processing, packing, labeling, holding or distributing any prescription drugs that are not the subject of an NDA or an abbreviated NDA. Among other things, the Consent Decree also granted the FDA the ability to, without prior notice, inspect PharmaFab's place of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of the Consent Decree. The FDA has inspected the Grand Prairie facility several times since the Consent Decree was entered, and we have been able to manufacture and ship our generic Tussionex and drug products for our clinical trials. We also continue to have a cGMP expert conduct an annual audit and submit these audit reports and our responses to the FDA. For our most recent annual audit by a cGMP expert in November 2014, the cGMP expert concluded our corrective actions satisfactorily addressed observations noted by the cGMP expert in its audit report. However, on May 22, 2015, the FDA's Dallas District Office identified three ongoing cGMP deviations based on our response to the audit report related to batch failure investigations, quality control unit procedures, and in-process specifications. We implemented corrective actions and submitted additional information in our response to the FDA pursuant to the Consent Decree. Although we may apply for relief from the Consent Decree in the future, there is no guarantee that such relief will be granted or that we will be in compliance with the requirements of the Consent Decree.

If we are unable to produce the required commercial quantities of NT-0102, NT-0202 or NT-0201 to meet market demand for NT-0102, NT-0202 and NT-0201 on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of NT-0102, NT-0202 or NT-0201, we will suffer damage to our reputation and commercial prospects and we will be unable to generate potential revenues.

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

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

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

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

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

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

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

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

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Risk factors

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

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

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

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

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

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

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additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

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

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

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

- Pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded drugs to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. The aggregated industry-wide fee is expected to total $28.0 billion through 2019. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

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

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

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

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

We are subject to numerous environmental, health and safety laws and regulations. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials.

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Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

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

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

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

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our product candidates for which we may receive regulatory approval may not be

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available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

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

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

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Risk factors

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

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

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

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

We currently have $5.0 million in product liability insurance coverage in the aggregate, which may not be adequate to cover any and all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. In addition, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

RISKS RELATED TO OUR BUSINESS AND FINANCIAL POSITION

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

Our company has limited operating history commercializing branded products. To date, we have focused primarily on developing our lead product candidates, NT-0102, NT-0202, and NT-0201. Our lead product candidates will require substantial additional resources before we will be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales, if approved. There can be no assurance that any of our product candidates will ever achieve regulatory approval or generate any revenue. We do not anticipate generating any revenue from sales of NT-0102, NT-0202, NT-0201 or any of our other product candidates in the near term, if ever. We have incurred significant net losses of $5.2 million and $6.6 million for the three months

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ended March 31, 2014 and 2015, respectively, and $19.0 million and $20.8 million for the years ended December 31, 2013 and 2014, respectively. As of March 31, 2015, we had an accumulated deficit of $91.2 million. We have devoted most of our financial resources to manufacturing operations and product development. To date, we have financed our operations primarily through the sale of equity and debt securities and payments received under collaborative arrangements. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our increased expenses, but we expect to continue to incur substantial expenses, which we expect will increase as we expand our development activities and build a specialty sales force and commercialization infrastructure. Our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to the clinical trials we have already completed. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

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

Developing future potential product candidates, conducting clinical trials, establishing raw material supplier relationships and manufacturing and marketing drugs are expensive and uncertain processes. Although we believe the proceeds of this public offering, together with our cash, cash equivalents and marketable securities and anticipated future product revenues, will be sufficient to allow us to fund the commercialization of NT-0102, NT-0202 and NT-0201, if approved, we may need to obtain additional capital through equity offerings, debt financing, payments under new or existing licensing and research and development collaboration agreements, or any combination thereof, in order to become cash flow positive and to develop and commercialize additional product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

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

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

- the timing of any regulatory approvals of NT-0102, NT-0202 and NT-0201;
- the costs of establishing sales, marketing, distribution and commercial manufacturing capabilities for our products;
- if approved, our ability to successfully launch NT-0102, NT-0202 and NT-0201 and to continue to increase the level of sales in the marketplace;
- the rate of progress and cost of our trials and other product development programs for our other potential product candidates;

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

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

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

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

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

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

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

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

Since our inception, we have had significant operating losses. As of March 31, 2015, we had an accumulated deficit of $91.2 million. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to develop and seek marketing approval for our product candidates. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our secured credit facility or promissory note. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not

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favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations, finance our operations, our research and development efforts and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail or eliminate one or more of our programs.

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

Our quarterly operating results may fluctuate significantly.

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

- any delays in regulatory review and approval of our product candidates;
- our ability to establish an effective sales and marketing infrastructure;
- variations in the level of expenses related to our commercialization efforts and the development of additional clinical programs;
- competition from existing products or new products that may emerge;
- the level of market acceptance for any approved product candidates and underlying demand for that product and wholesalers' buying patterns;
- regulatory developments affecting our products and product candidates;
- our dependency on third-party manufacturers to supply components of our product candidates;
- potential side effects of our future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- any intellectual property infringement lawsuit in which we may become involved; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

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

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Risk factors

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

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

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

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

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Our independent registered public accounting firm considered our internal controls over financial reporting as of December 31, 2014 for purposes of expressing an opinion on our financial statements but not for purposes of expressing an opinion on the effectiveness of our internal controls, and two significant deficiencies in internal controls were identified in connection with the preparation of our financial statements. The first significant deficiency was due to inadequate design and implementation of general controls surrounding our information technology, or IT, and the second significant deficiency was due to inadequate maintenance and administration of our stock option program. We are taking steps to remedy both significant deficiencies, including with respect to the IT deficiency, engaging an independent third party to perform an assessment of internal controls over our IT systems that support financial reporting processes in our efforts to prepare for compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and to identify opportunities for improving our IT general controls

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environment. With respect to the stock option program deficiencies, we are implementing new approval and documentation procedures and controls governing all such grants. In addition, we are in the process of implementing a new third party software solution for managing and accounting for stock-based compensation. We are in the very early stages of the costly and challenging process of compiling our system of internal controls over financial reporting and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may discover future deficiencies in our internal controls over financial reporting, including those identified through testing conducted by us in connection with Section 404 of the Sarbanes-Oxley Act or subsequent testing by our independent registered public accounting firm. Such deficiencies may be deemed to be significant deficiencies or material weaknesses and may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

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

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

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

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RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering a product or our technology, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description, non-enablement or a patent-barring event, such as a

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public disclosure, use or sale of the invention more than a year before the filing date of the application. Grounds for an unenforceability assertion could, for example, be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution, or that a third party challenging one of our patents would not assert that a patent-barring event had occurred. If a plaintiff or a defendant were to prevail on a legal assertion of invalidity and/or unenforceability against one or more of our patents, we would lose at least part, and perhaps all, of the patent protection for one or more of our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

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

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

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

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

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parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

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

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

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

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

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

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

We may be exposed to, or threatened with, future litigation by third parties alleging that our products or product candidates infringe their intellectual property rights. If one of our products or product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize the applicable approved products and product candidates unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the

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patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our approved products, pending a trial on the merits, which may not occur for several years.

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

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

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

Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory approval pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the

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30-month stay. However, even if the third party does not sue within the 45-day time limit, thereby invoking the 30-month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45-day limit. By way of example, when we initially submitted our NT-0202 NDA in December 2012 and in response to our Paragraph IV certification, Shire LLC, or Shire, initiated a lawsuit against us claiming patent infringement against certain of Shire's patents. We settled with Shire in July 2014. As part of our settlement, among other things, we stipulated that the commercial manufacture, use, selling, offering for sale or importing of NT-0202 would infringe on certain Shire patents and that such patent claims are valid and enforceable with respect to our NT-0202 NDA, but that such stipulations do not preclude us from filing new regulatory applications containing a Paragraph IV certification citing such patents. We also entered into a non-exclusive license agreement with Shire for certain of Shire's patents with respect to our NT-0202 NDA. Under the terms of the license agreement, if we obtain FDA approval of our NT-0202 NDA, we are required to pay a lump-sum, non-refundable license fee no later than thirty days after receiving such approval and a single-digit royalty on net sales of NT-0202 during the life of Shire's patents.

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

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

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

Some of our employees were previously employed at other companies, including actual or potential competitors. We may also engage advisors and consultants who are concurrently employed at other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors, or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former employer or in violation of an agreement with or legal obligation in favor of another party. Litigation may be necessary to defend against these claims.

In addition, while we generally require our employees, consultants, advisors and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor

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or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer or former employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims.

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

RISKS RELATED TO OUR COMMON STOCK AND THIS OFFERING

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

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

- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully execute our commercialization strategy with respect to NT-0102, NT-0202 or NT-0201, if approved, or any other approved potential product candidate in the future;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- inability to manufacture adequate amounts of product supply or obtain adequate amounts of components of our product supply for our product candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to the use of our generic Tussionex, NT-0102, NT-0202, NT-0201 or any future potential product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;

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

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

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

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

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

additions or departures of key scientific or management personnel;

changes in the market valuations of similar companies;

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

trading volume of our common stock.

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

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

As of March 31, 2015, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately 81% of our voting stock. Based upon the number of shares to be sold in this offering as set forth on the cover page of this prospectus, upon the closing of this offering, that same group will beneficially own approximately 56% of our outstanding voting stock. In addition to the above ownership, entities associated with our existing stockholders Deerfield Private Design Fund III, L.P. and Presidio Partners 2007, L.P., and certain other of our existing stockholders have agreed to purchase an aggregate of approximately 1,022,500 shares of our common stock in this offering at the initial public offering price. The previously discussed ownership percentage upon the closing of this offering does not reflect the potential purchase of any shares in this offering by such stockholders. Upon the purchase of the approximately 1,022,500 shares of our common stock in this offering, the number of shares of our common stock beneficially owned by our executive officers, directors, 5% or greater stockholders and their affiliates will, in the aggregate, increase to 62% of our common stock, based on the initial public offering price of $15.00 per share. Therefore, even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $10.40 per share, based on the initial public offering price of $15.00 per share and our pro forma as adjusted net tangible book value as of March 31, 2015. For more information on the dilution you may suffer as a result of investing in this offering, see "Dilution."

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering and the exercise of stock options granted to our employees. The exercise of any of these options would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

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Risk factors

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

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. Substantially all of our existing stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days after the date of this prospectus. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the public offering. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares prior to this offering will become eligible for sale upon expiration of the lock-up period. See "Shares eligible for future sale." In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled "Use of proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

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

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

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Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

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

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

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

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

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

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

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

Prior to this offering there has been no public market for shares of our common stock. Although our common stock has been approved for listing on the NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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

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

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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Risk factors

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

Our amended and restated certificate of incorporation, as we expect it to be in effect upon the closing of this offering, will provide that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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Special note regarding forward-looking statements

This prospectus 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," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this 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 date for NT-0102, the NDA resubmission date for 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;
- our staffing needs; and
- our use of proceeds from this offering.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

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Special note regarding forward-looking statements

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in "Risk factors" and elsewhere in this prospectus. 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 prospectus. 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 prospectus 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 prospectus to reflect events or circumstances after the date of this prospectus 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.

Market and industry data

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

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Use of proceeds

We estimate that the net proceeds from the sale of shares of our common stock that we are selling in this offering will be approximately $65.0 million, based upon the initial public offering price of $15.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds would be approximately $75.0 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock and facilitate our access to public equity markets. We currently intend to use the net proceeds that we will receive from this offering for as follows:

- approximately $12.1 million for pre-commercialization planning of our three lead product candidates, NT-0102, NT-0202 and NT-0201;
- approximately $28.7 million for commercialization of our three lead product candidates, if approved; and
- the remainder for working capital, capital expenditures and general corporate purposes, including investing further in research and development efforts.

We cannot specify with certainty the particular uses of the net proceeds that we will receive from this offering or the amounts we actually spend on the uses set forth above. Accordingly, we will have broad discretion in using these proceeds. Pending the use of proceeds from this offering as described above, we plan to invest the net proceeds that we receive in this offering in short-term and intermediate-term interest-bearing obligations, investment-grade investments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Dividend policy

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors. Our ability to pay dividends on our common stock is limited by restrictions under the terms of our credit facility with Hercules Technology III, L.P. In addition, any future indebtedness that we may incur could preclude us from paying dividends. Investors should not purchase our common stock with the expectation of receiving cash dividends.

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Capitalization

The following table sets forth our cash, cash equivalents and capitalization as of March 31, 2015:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 8,801,319 shares of common stock upon the closing of this offering and the filing of our amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of 4,800,000 shares of our common stock offered in this offering, based on the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with our audited consolidated financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the heading "Selected consolidated financial data" and "Management's discussion and analysis of financial condition and results of operations."

	As of March 31, 2015		
	Actual	Pro Forma	Pro Forma as Adjusted
	(unaudited) (in thousands of dollars except share and per share data)		
Cash and Cash Equivalents	26,169	26,169	91,129
Short-Term Investments			
Long-Term Debt, including current portion	29,619	29,619	29,619
Long-Term Liabilities:			
Warrant Liabilities	3,719		
Redeemable Convertible Preferred Stock, $0.001 par value, 27,500,000 shares authorized, 21,123,384 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	102,088		
Stockholders' (Deficit) Equity:			
Preferred stock, $0.001 par value, no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, $0.001 par value, 35,000,000 shares authorized; 887,397 issued and outstanding, actual; 100,000,000 shares authorized, 9,688,716 shares issued and outstanding, pro forma; 100,000,000 authorized, 14,488,716 shares issued and outstanding, pro forma as adjusted	1	10	15
Additional paid-in capital	4,932	107,011	171,966
Warrants		3,719	3,719
Accumulated deficit	(91,193)	(91,193)	(91,193)
Total stockholders' (deficit) equity	(86,260)	19,547	84,507
Total Capitalization	$ 49,166	$ 49,166	114,126

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Capitalization

The information above is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

The actual, pro forma and pro forma as adjusted information set forth in the table above excludes the following:

- 627,745 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2015 at a weighted-average exercise price of $4.80 per share;

- 407,966 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 at a weighted-average exercise price of $2.09 per share;

- 811,317 shares of common stock issuable upon the exercise of redeemable convertible preferred stock warrants outstanding as of March 31, 2015 at an exercise price of $12.00 per share, 249,998 of which have been exercised as of the date of this prospectus and 561,319 of which automatically exercise using the net issuance method upon the closing of this offering, unless previously exercised. The exercise price of these warrants which automatically exercise using the net issuance method will be equal to the initial public offering price set forth on the cover page of this prospectus;

- 149,582 shares of common stock issuable upon the exercise of stock options granted under our 2009 Equity Plan since March 31, 2015 at an exercise price of $10.73 per share; and

- 767,330 shares of common stock that will be available for future issuance under our 2015 Stock Option and Incentive Plan, or the 2015 Plan, to be effective as of immediately prior to the effectiveness of the registration statement of which this prospectus is a part. Of these shares, options to purchase an aggregate of 37,500 shares of common stock were granted to certain non-employee directors effective immediately after the effectiveness of the registration statement of which this prospectus is a part. The exercise price of the option grants is equal to the initial public offering price set forth on the cover page of this prospectus. No additional shares of common stock will be reserved for issuance under our 2009 Plan following the closing of this offering.

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Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities and our redeemable convertible preferred stock, which is not included within stockholders' equity (deficit), by the number of shares of common stock outstanding. Our historical net tangible book value (deficit) as of March 31, 2015 was $(104.1) million, or $(117.25) per share. Our pro forma net tangible book value as of March 31, 2015 was $1.8 million, or $0.18 per share, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as of March 31, 2015 into an aggregate of 8,801,319 shares of common stock, which conversion will occur immediately prior to the closing of this offering.

After giving effect to the sale by us of 4,800,000 shares of common stock in this offering at the initial public offering price of $15.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2015 would have been $66.7 million, or $4.60 per share. This represents an immediate increase in pro forma net tangible book value of $4.42 per share to our existing stockholders and immediate dilution of $10.40 per share to investors purchasing shares of common stock in this offering at the initial public offering price. The following table illustrates this dilution on a per share basis to new investors:

Initial public offering price per share		$ 15.00
Historical net tangible book value per share as of March 31, 2015	$ (117.25)	
Pro forma increase in net tangible book value per share attributable to the conversion of redeemable convertible preferred stock	117.43	
Pro forma net tangible book value per share as of March 31, 2015	0.18	
Increase in net tangible book value per share attributable to new investors in this offering	4.42	
Pro forma as adjusted net tangible book value per share after this offering		4.60
Dilution in net tangible book value per share to new investors		$ 10.40

If the underwriters exercise their option to purchase additional shares from us in full, the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering would be $5.05 per share, and the dilution in pro forma net tangible book value per share to new investors in this offering would be $9.95 per share.

The following table presents, on a pro forma as adjusted basis as of March 31, 2015, after giving effect to the conversion of all outstanding shares of our redeemable convertible preferred stock into common stock immediately prior to the closing of this offering, the differences between the existing stockholders and the new investors purchasing shares of our common stock in this offering with respect to the number of shares purchased from us, the total consideration paid or to be paid to us, which includes net proceeds received from the issuance of common stock and redeemable convertible preferred stock, cash received from the exercise of stock options, and the average price per share paid

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Dilution

or to be paid to us at the offering price of $15.00 per share before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Average price
	Number	Percent	Amount	Percent	per share
	(in thousands, except share and per share data)				
Existing stockholders(1)	9,688,716	67%	107,021	60%	$ 11.05
New investors	4,800,000	33%	72,000	40%	15.00
Total	14,488,716	100%	179,021	100%	

(1) Funds affiliated with our existing stockholders Deerfield Private Design Fund III, L.P. and Presidio Partners 2007, L.P., and certain other of our existing stockholders, have agreed to purchase an aggregate of approximately 1,022,500 shares of our common stock in this offering at the initial public offering price. The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases in this offering by such stockholders.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares. If the underwriters exercise their option to purchase additional shares in full from us, our existing stockholders would own 64% and our new investors would own 36% of the total number of shares of our common stock outstanding upon the closing of this offering.

The number of shares of our common stock to be outstanding after this offering is based on the number of shares of our common stock outstanding as of March 31, 2015 and excludes:

627,745 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2015 at a weighted-average exercise price of $4.80 per share;

407,966 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 at a weighted-average exercise price of $2.09 per share;

811,317 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 at an exercise price of $12.00 per share, 249,998 of which have been exercised as of the date of this prospectus and 561,319 of which automatically exercise using the net issuance method upon closing of this offering, unless previously exercised. The exercise price of these warrants which automatically exercise using the net issuance method will be equal to the initial public offering price set forth on the cover page of this prospectus;

149,582 shares of common stock issuable upon exercise of stock options granted under our 2009 Equity Plan since March 31, 2015 at an exercise price of $10.73 per share; and

767,330 shares of common stock that will be available for future issuance under our 2015 Stock Option and Incentive Plan, or the 2015 Plan, to be effective as of immediately prior to the effectiveness of the registration statement of which this prospectus is a part. Of these shares, options to purchase an aggregate of 37,500 shares of common stock were granted to certain non-employee directors effective immediately after the effectiveness of the registration statement of which this prospectus is a part. The exercise price of the option grants is equal to the initial public offering price set forth on the cover page of this prospectus. No additional shares of common

stock will be reserved for issuance under our 2009 Plan following the closing of this offering.

New investors will experience further dilution if any of our outstanding options or warrants are exercised, new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities in the future.

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Selected consolidated financial data

The following selected statements of operations data for the three months ended March 31, 2014 and 2015, and the balance sheet data as of March 31, 2015 are derived from unaudited financial statements appearing elsewhere in this prospectus. The following selected statements of operations data for the years ended December 31, 2013 and 2014, and the balance sheet data as of December 31, 2013 and 2014 are derived from our audited financial statements appearing elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the caption "Management's discussion and analysis of financial condition and results of operations." Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

Statement of operations data:

	Year ended December 31,		Three months ended March 31,	
	2013	2014	2014	2015
			(Unaudited)	
	(in thousands, except share and per share data)			
Total Revenue	$ 1,044	$ 758	$ 292	$ 428
Cost of Goods Sold	2,534	3,354	805	1,095
Research and Development	9,974	10,601	2,285	4,320
Selling, General and Administrative Expenses	5,624	5,275	1,550	1,663
Interest and Other Expense (Income)	1,512	2,377	817	(94)
Net Loss from continuing operations	$ (18,600)	$ (20,849)	$ (5,165)	$ (6,556)
Loss from discontinued operations	$ (437)	$	$	$
Net Loss	$ (19,037)	$ (20,849)	$ (5,165)	$ (6,556)
Preferred Stock Accretion to Redemption Value	(1,227)	(1,118)	(317)	(484)
Preferred Stock Dividends	(2,185)	(2,185)	(539)	(539)
Net Loss Attributable to Common Stock	$ (22,449)	$ (24,152)	$ (6,021)	$ (7,579)
Net Loss per Share B*asic and Diluted(1)*	$ (28.45)	$ (27.56)	$ (6.91)	$ (8.56)
Shares Used to Compute Net Loss per Share *Basic and Diluted*	788,964	876,318	871,282	885,237

(1) See Note 4 to the notes to our audited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share.

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Selected consolidated financial data

Balance sheet data:

	December 31, 2013	December 31, 2014	March 31, 2015
			(Unaudited)
	(in thousands)		
Cash and Cash Equivalents	$ 11,947	$ 13,343	$ 26,169
Short-Term Investments	7,497	3,000	
Working Capital	14,303	13,380	22,425
Total Assets	41,878	45,230	54,624
Long-Term Debt, net of Current Portion	16,454	23,121	26,124
Warrant Liability		1,789	3,719
Redeemable Convertible Preferred Stock	70,836	90,149	102,088
Stockholders' Deficit	(54,844)	(78,782)	(86,260)

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Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected consolidated financial" and the consolidated financial statements and related notes that are included elsewhere in this prospectus. 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" or in other parts of this prospectus.

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. We expect to resubmit a new drug application, or NDA, for NT-0202, our amphetamine XR-ODT, by the end of July 2015 and 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. 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. We

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have raised approximately $125 million of capital to date, including $25 million of venture capital debt.

On August 28, 2014, we completed an acquisition of all of the rights to the Tussionex Abbreviated New Drug Application, or Tussionex ANDA, which include the rights to produce, develop, market and sell, as well as all the profits from such selling activities, our generic Tussionex, which we previously owned the rights to manufacture, but which was marketed and sold by the generic drug division of Cornerstone Biopharma, Inc., or Cornerstone. These rights were acquired from the collaboration of the Company, Cornerstone and Coating Place, Inc. Prior to the acquisition, we shared profits generated by the sale and manufacture of the product under a development and manufacturing agreement with those companies.

We have incurred significant losses in each year since our reorganization in 2009. Our net losses were $19.0 million and $20.8 million for the years ended December 31, 2013 and 2014, respectively, and $5.2 million and $6.6 million for the three months ended March 31, 2014 and 2015, respectively. As of March 31, 2015, we had an accumulated deficit of approximately $91.2 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.

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

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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.

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:

	Year ended December 31,		Three months ended March 31,	
	2013	2014	2014	2015
			(Unaudited)	(Unaudited)
	(in thousands)			
NT-0102 Methylphenidate ODT	$ 2,089	$ 1,641	$ 287	$ 2,419
NT-0202 Amphetamine ODT	829	762	174	34
NT-0201 Amphetamine Liquid	625	822	14	48
Other Research and Development Activities(1)	6,431	7,376	1,810	1,819
	$ 9,974	$ 10,601	$ 2,285	$ 4,320

(1) Includes unallocated product development cost, salaries and wages, occupancy and depreciation and amortization.

We expect that our research and development expenses will fluctuate over time as we seek regulatory approval of our 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 this offering and revenues, if any, from our product candidates.

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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. We expect to resubmit an NDA for NT-0202 by the end of July 2015 and submit an NDA for NT-0201 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."

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 statements of operations.

Other income (expense), net

Other income and expense to date has primarily consisted of amortization of the net gain recorded on the sale-leaseback of our property and equipment. These sale-leaseback financings occurred in five separate transactions, each with a 42-month lease term. The gains on the transactions are being recognized on a straight-line basis over the respective 42-month lease term (see Note 8 to the notes to our audited financial statements included elsewhere in this prospectus).

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Management's discussion and analysis of financial condition and results of operations

RESULTS OF OPERATIONS

Three months ended March 31, 2014 compared to the three months ended March 31, 2015

Revenues

The following table summarizes our revenues for the three months ended March 31, 2014 and 2015:

	Three months ended March 31,		Increase	% Increase
	2014	2015	(decrease)	(decrease)
	(Unaudited)			
	(in thousands)			
Product	$	$ 428	$ 428	N/A
Manufacturing	113		(113)	(100.0)%
Profit Sharing	111		(111)	(100.0)%
Development	68		(68)	(100.0)%
	$ 292	$ 428	$ 136	46.6%

Total revenues were $0.4 million for the three months ended March 31, 2015, an increase of $0.1 million or 46.6%, from the three months ended March 31, 2014. All $0.4 million of product revenue in the three months ended March 31, 2015 was generated from net sales of our generic Tussionex for which we acquired all commercialization and profit rights in August 2014. This was partially offset by decreases in development, profit sharing and manufacturing revenue. The $0.1 million decrease in development revenues for the three months ended March 31, 2015 was primarily due to reduced development work related to our generic Tussionex. In addition, the manufacturing and profit sharing revenues combined 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 three months ended March 31, 2014 and 2015:

	Three months ended March 31,		Increase	% Increase
	2014	2015	(decrease)	(decrease)
	(Unaudited)			
	(in thousands)			
Cost of Goods Sold	$ 805	$ 1,095	$ 290	36.0%

The total cost of goods sold was $1.1 million for the three months ended March 31, 2015, an increase of $0.3 million or 36.0% from the three months ended March 31, 2014. This increase was primarily due to $0.2 million of amortization of the intangibles resulting from the acquisition of the rights to commercialize and derive future profits from Tussionex ANDA and a $0.1 million increase in other cost of goods sold, principally due to distribution costs incurred for the shipment of our generic Tussionex and audits of suppliers in 2015.

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Management's discussion and analysis of financial condition and results of operations

Research and development expenses

The following table summarizes our research and development expenses for three months ended March 31, 2014 and 2015:

	Three months ended March 31,		Increase	% Increase
	2014	2015	(decrease)	(decrease)
	(Unaudited)			
	(in thousands)			
Research & Development Expenses	$ 2,285	$ 4,320	$ 2,035	89.1%

Research and development expenses were $4.3 million for the three months ended March 31, 2015, an increase of $2.0 million or 89.1% from the three months ended March 31, 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 million amortization of the annual FDA facility fee for 2015 for our generic Tussionex. These increases were offset by a $0.2 million decrease in clinical expense, primarily as a result of the completion of our classroom study of NT-0102, and a $0.2 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 three months ended March 31, 2014 and 2015:

	Three months ended March 31,		Increase	% Increase
	2014	2015	(decrease)	(decrease)
	(Unaudited)			
	(in thousands)			
Sales and Marketing	$ 3	$ 326	$ 323	10,766.7%
General and Administrative	1,547	1,337	(210)	(13.6)%
Total Selling, General and Administrative Expenses	$ 1,550	$ 1,663	$ 113	7.3%

The total SG&A expenses were $1.7 million for the three months ended March 31, 2015, an increase of $0.1 million or 7.3% from the $1.6 million for the three months ended March 31, 2014. Sales and marketing professional services increased by $0.2 million due to the pre-commercialization market research and publications expenses incurred in the first three months of 2015 for the NT-0102 and NT-0202 product candidates. Salary and compensation expense increased $0.2 million in the three months ended March 31, 2015 primarily due to a $0.1 million increase in compensation related to share-based payments and a $0.1 million increase due to the addition in August 2014 of sales personnel as part of commercialization efforts for our generic Tussionex. In addition, consulting and business development expenses increased by $0.1 million related to the engaging of consultants for financial analysis, government pricing and business development. These increased costs were offset by a $0.4 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.

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Interest expense

The following table summarizes interest expense for the three months ended March 31, 2014 and 2015:

	Three months ended March 31,		Increase	% Increase
	2014	2015	(decrease)	(decrease)
	(Unaudited)			
	(in thousands)			
Interest Expense	$ (1,019)	$ (757)	$ (262)	(25.7)%

The total interest expense was $0.8 million for the three months ended March 31, 2015, a decrease of $0.3 million or 25.7% from the $1.0 million for the three months ended March 31, 2014. This decrease was principally due to a decrease of $0.4 million of amortization of costs and fees resulting from the repayment of $10.0 million of senior debt in March 2014. This was partially offset by 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 March 31, 2014 and 2015:

	Three months ended March 31,		Increase	% Increase
	2014	2015	(decrease)	(decrease)
	(Unaudited)			
	(in thousands)			
Other Income, net	$ 202	$ 851	$ 649	321.3%

Other income was $0.9 million for the three months ended March 31, 2015, an increase of $0.7 million from the $0.2 million of other income for the three months ended March 31, 2014. The increase resulted primarily from the change in the fair values of the earnout liability and the warrant liabilities due to new information regarding the projected impact of the DEA's reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance and a review of the anticipated launch dates of our three ADHD product candidates.

Year ended December 31, 2013 compared to the year ended December 31, 2014

Revenues

The following table summarizes our revenues for the years ended December 31, 2013 and 2014:

	Year ended December 31,		Increase	% Increase
	2013	2014	(decrease)	(decrease)
	(in thousands)			
Product	$	$ 316	$ 316	N/A
Manufacturing	137	113	(24)	(17.5)%
Profit Sharing	226	169	(57)	(25.2)%
Development	681	160	(521)	(76.5)%
	$ 1,044	$ 758	$ (286)	(27.4)%

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Management's discussion and analysis of financial condition and results of operations

Total revenues were $0.8 million for the year ended December 31, 2014, a decrease of $0.3 million or 27.4%, from the year ended December 31, 2013. The $0.5 million or 76.5% decrease in development revenues for the year ended December 31, 2014 was primarily due to reduced development work related to our generic Tussionex as we completed various stability programs and shifted our efforts toward launching commercialization in September 2013. In addition, the manufacturing and profit sharing revenues combined decrease of $0.1 million or 22.3% was primarily due to the termination of our three-way profit split development and manufacturing agreement in August 2014. These decreases were partially offset by $0.3 million of product revenue due to net sales of our generic Tussionex after our acquisition of all commercialization and profit rights to our generic Tussionex in August 2014.

Cost of goods sold

The following table summarizes our cost of goods sold for the years ended December 31, 2013 and 2014:

	Year ended December 31,		Increase	% Increase
	2013	2014	(decrease)	(decrease)
	(in thousands)			
Cost of Goods Sold	$ 2,534	$ 3,354	$ 820	32.4%

The total cost of goods sold was $3.4 million for the year ended December 31, 2014, an increase of $0.8 million or 32.4% from the year ended December 31, 2013. This increase was primarily due to a $0.8 million increase in production cost of our generic Tussionex as a result of increased sales and indirect costs associated with scaling up of commercial manufacturing. In addition, the increase was due to manufacturing overhead expenses which were not capitalizable into inventory and were recognized as period expenses.

Research and development expenses

The following table summarizes our research and development expenses for the years ended December 31, 2013 and 2014:

	Year ended December 31,		Increase	% Increase
	2013	2014	(decrease)	(decrease)
	(in thousands)			
Research & Development Expenses	$ 9,974	$ 10,601	$ 627	6.3%

Research and development expenses were $10.6 million for the year ended December 31, 2014, an increase of $0.6 million or 6.3% from the year ended December 31, 2013. This increase was primarily due to a $0.5 million increase in third party costs related to the preparation of our NDA submissions and a $0.5 million increase in depreciation and amortization costs primarily due to additional depreciation on new equipment and increased amortization of equipment financed under sale-leaseback agreements. These decreases were partially offset by a net $0.3 million decrease in clinical expense, primarily as a result of the completion of our classroom study of NT-0102, and a $0.1 million decrease in salary expense.

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Management's discussion and analysis of financial condition and results of operations

Selling, general and administrative expenses

The following table summarizes our SG&A expenses for the years ended December 31, 2013 and 2014:

	Year ended December 31,		Increase	% Increase
	2013	2014	(decrease)	(decrease)
	(in thousands)			
Sales and Marketing	$ 153	$ 212	$ 59	38.6%
General and Administrative	5,471	5,063	(408)	(7.5)%
Total Selling, General and Administrative Expenses	$ 5,624	$ 5,275	$ (349)	(6.2)%

The total SG&A expenses were $5.3 million for the year ended December 31, 2014, a decrease of $0.3 million or 6.2% from the year ended December 31, 2013. Salary and compensation expense increased $0.4 million in the year ended December 31, 2014 due to incentive compensation related to achievement of certain performance milestones. In addition, salary and compensation increased $0.5 million due to a restructuring of the executive team to bring on additional industry experience. In the year ended December 31, 2014, we also incurred an additional $0.1 million in marketing and professional consultants expenses related to the commercialization of our generic Tussionex. These increased costs were offset by a $1.0 million decrease in legal and professional services, due to the termination and settlement of litigation related to the Paragraph IV certification of our NT-0202 product candidate in July 2014, and a $0.3 million decrease related to a market research study for our product candidates conducted in the year ended December 31, 2013.

Interest expense

The following table summarizes interest expense for the years ended December 31, 2013 and 2014:

Year ended December 31,		Increase	% Increase
2013	2014	(decrease)	(decrease)
&#82			