Neos Therapeutics, Inc.
Form 10-K
March 15, 2017

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2016

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission File Number 001-36292

NEOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**27-0395455**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2940 N. Highway 360
Grand Prairie, TX 75050
(972) 408-1300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Vipin Garg, President and Chief Executive Officer
Neos Therapeutics, Inc.
2940 N. Highway 360
Grand Prairie, TX 75050
(972) 408-1300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Title of each class	Name of each exchange on which registered
Common stock, par value $0.001 per share	The NASDAQ Global Market

Securities registered pursuant to section 12(b) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o Yes ý No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o Yes ý No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ý Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ý Yes o No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (do not check if smaller reporting company	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). o Yes ý No

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold on the NASDAQ Global Market on June 30, 2016 was $143.7 million.

As of March 14, 2017, there were 22,560,635 shares of the registrant's common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the Registrant's 2017 Annual Meeting of Stockholders. Such Definitive Proxy Statement will be filed with the Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2016.

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Special note regarding forward-looking statements

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

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

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

our product research and development activities, including the timing and progress of our clinical trials, and projected expenditures;

issuance of patents to us by the U.S. Patent and Trademark Office and other governmental patent agencies;

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our ability to achieve profitability;

our staffing needs; and

the additional risks, uncertainties and other factors described under the caption "Risk Factors" in this Report on Form 10-K.

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

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K 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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

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PART I

ITEM 1. Business

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 one product and two 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 received approval from the U.S. Food and Drug Administration, or FDA, for Adzenys XR-ODT, our amphetamine XR-ODT, on January 27, 2016. On December 20, 2016, we announced that we had resubmitted a new drug application, or NDA, for Cotempla XR-ODT, our methylphenidate XR-ODT, following the completion of a bioequivalence bridging study. We have a Prescription Drug User Fee Act, or PDUFA, goal date of June 19, 2017 for Cotempla XR-ODT. In addition, on November 17, 2016, we announced that we had submitted an NDA for NT-0201, our amphetamine XR liquid suspension. We have a PDUFA goal date of September 15, 2017 for NT-0201. A PDUFA goal date is a review performance goal for the FDA to meet in acting on an 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 percent of standard, non-new molecular entity NDAs, like the one we submitted for NT-0201, within ten months from the FDA's receipt of the NDA submission, and for Class 2 resubmissions, such as the one we resubmitted for Cotempla XR-ODT, within six months of the FDA's receipt of the NDA resubmission. We believe Adzenys XR-ODT and, if approved, our other product candidates will address an unmet need by providing more patient- and caregiver-friendly dosing options not previously available to patients in the $10.4 billion market for ADHD-indicated medications.

Our branded product and 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. We believe Adzenys XR-ODT is the first amphetamine XR-ODT, and if approved, Cotempla XR-ODT will be the first methylphenidate XR-ODT 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 branded product and two product candidates.

In 2016, 70.4 million prescriptions for medications with ADHD labeling, and principally in extended-release formulations, were written in the United States. The vast majority of currently available dosage forms for ADHD are tablets and capsules. Despite once-daily dosing of these extended-release formulations, we believe there is a significant opportunity to improve compliance rates. Up to 54% of the pediatric population and 40% of the adult population have reported difficulties with swallowing tablets and capsules. 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. To our knowledge, we are the only company that has succeeded to date in commercializing an XR-ODT formulation of any ADHD medication, even though ODT are among the most preferred dosage forms of pharmaceutical products. We believe, therefore, there is a significant market opportunity to provide two of the 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.

We plan to focus on commercialization in the United States using our own commercial infrastructure. We currently have a specialty sales force of approximately 125 representatives targeting

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the highest-volume prescribers of ADHD medication. We manufacture Adzenys XR-ODT and intend to manufacture our ADHD product candidates 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 also currently use these facilities to manufacture our generic equivalent to the branded product, Tussionex, an XR liquid suspension of hydrocodone and chlorpheniramine indicated for the relief of cough and upper respiratory symptoms of cold.

We believe we can apply our XR-ODT and XR liquid suspension technologies that underlie our branded product and product candidates and our generic Tussionex to other active pharmaceutical ingredients, or APIs, as well. 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. Patients with central nervous system, or CNS, conditions, such as stroke, Parkinson's disease and Alzheimer's disease often have difficulty swallowing their medication and would benefit from ODT and liquid suspension dosage forms. We have completed feasibility studies on several product candidates thus far. We plan to complete feasibility work on approximately a dozen potential product candidates by mid-2017 and then select two to three candidates for further clinical development. We intend to utilize the regulatory pathway provided by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the 505(b)(2) regulatory approval pathway, for our product candidates using only APIs from approved drug products and incorporating our proprietary drug delivery platform to create branded product candidates. This streamlined development and approval pathway should allow us to initiate clinical trials in approximately 18 months after drug discovery and submit an NDA in as few as 36 months.

Our total revenues increased to $9.2 million for the year ended December 31, 2016, from $3.8 million for the year ended December 31, 2015 and $0.8 million for the year-ended December 31, 2014, all of which was generated in the United States.

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:

Leverage our commercialization capabilities in the United States for Adzenys XR-ODT with any of our product candidates that are FDA approved.

We believe that we can effectively commercialize Adzenys XR-ODT and our branded ADHD product candidates, if approved in the United States, with a specialty sales force of approximately 125 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 in the $10.4 billion market for ADHD-indicated medications. We plan to commercialize our products outside of the United States after receiving the required approvals in those countries through partnerships and collaborations.

Obtain FDA approval for our two branded product candidates in ADHD.

On December 20, 2016, we announced that we had resubmitted an NDA for Cotempla XR-ODT, our methylphenidate XR-ODT, and have a PDUFA goal date of June 19, 2017. In addition, on November 17, 2016, we announced that we had submitted an NDA for NT-0201, our amphetamine XR liquid suspension, and have a PDUFA goal date of September 15, 2017.

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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. We believe that we will have sufficient capacity to supply commercial quantities for all of our ADHD product candidates, if approved.

Utilize 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. We plan to focus our development efforts on approved drug products for which we believe we can secure composition-of-matter patent protection and utilize the 505(b)(2) regulatory approval pathway. We plan to explore product opportunities in several therapeutic areas, including CNS and gastrointestinal indications.

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. If issued and listed in the FDA's publication of approved drug products with therapeutic equivalence evaluations, or the Orange Book, we believe that these patents will provide additional market protection for our FDA-approved products.

ADHD

Market and current treatment options

ADHD is a neurobehavioral disorder characterized by a persistent pattern of inattention and/or hyperactivity/impulsivity that interferes with functioning and/or development. ADHD can have a profound impact on an individual's life, causing disruption at school, work, and home and in relationships. It is one of the most common developmental disorders in children and often persists into adulthood. In 2011, an estimated 11% of children in the United States ages 4 to 17 had previously received an ADHD diagnosis. A 2006 study estimated 4.4% of adults in the United States experience ADHD symptoms. Current ADHD treatment guidelines recommend a multi-faceted approach that uses medications in conjunction with behavioral interventions.

In 2016, 70.4 million prescriptions for medications with ADHD labeling were written in the United States and generated $10.4 billion in sales. Approximately 90% of these prescriptions were for stimulant medications, such as methylphenidate and amphetamine, which have been the standard of care for several decades. Methylphenidate and amphetamine prescriptions generated $3.4 billion and $5.7 billion in sales, respectively, in 2016 in the United States. A few non-stimulant medications are also available, but evidence of their efficacy for treating ADHD symptoms is less compelling. The market for ADHD medications outside of the United States is less developed, but we believe will continue to grow as recognition and awareness of the disorder increase.

Limitations of existing treatment options

Extended-release, or long acting, dosage forms of stimulant medications are the standard of care for treating ADHD, making up approximately 60% of ADHD prescriptions. Most of these

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extended-release dosage forms allow for once-daily dosing in the morning, which eliminates the need to re-dose during the day. However, even with once-daily dosing, there is great potential for improvement. The vast majority of currently available dosage forms for ADHD are tablets and capsules. We believe that the inability, difficulty or reluctance of many patients to swallow intact tablets and capsules contributes to diminished compliance rates.

Up to 54% of the pediatric population has difficulty swallowing tablets and capsules, and this can be especially problematic in children with ADHD. For many of these patients, swallowing difficulties can persist into adolescence and adulthood, with 40% of adults reporting pill-swallowing difficulties that result in skipping doses or discontinuing their medication altogether. In addition, ADHD medications are typically administered in the morning, which is often the busiest and most chaotic period for families.

Some extended-release products do offer alternative dosing options, such as opening the capsule to sprinkle contents over food, but labeling for these products generally includes a caveat that such manipulation may impair the efficacy and/or safety of the product. These alternatives may also be difficult or inconvenient for the caregiver and disruptive to an already difficult and chaotic morning routine. Thus, a significant need remains for more patient- and caregiver-friendly dosage forms of ADHD medications in once-daily dosing forms.

Market receptivity to novel dosage forms for the treatment of ADHD

The most prescribed extended-release medications for ADHD, Concerta® and Adderall XR® (and each of their generic equivalents), are long-acting versions of previously short-acting methylphenidate and amphetamine medications, respectively. While these products address the need for once-daily dosing, Concerta and Adderall XR are only available as tablets and capsules, respectively, and may be difficult for some patients to swallow.

This limitation led to the development of a transdermal methylphenidate patch, Daytrana®. While the methylphenidate transdermal patch offered a non-oral delivery method, it created additional issues related to dose variability, patch placement and premature patch removal. Adverse events such as skin irritation and accidental exposure from discarded patches also deterred Daytrana's utilization. Despite these shortcomings, Daytrana achieved approximately a 3% share of the overall methylphenidate extended-release market in 2014.

In January 2013, an extended-release liquid formulation of methylphenidate, Quillivant XR™, was launched by Pfizer, providing a new dosing option. In April 2016, Pfizer launched Quillichew ER™, an extended-release chewable formulation of methylphenidate and Tris Pharmaceuticals launched an extended-release liquid formulation of amphetamine, Dyanavel XR™. In 2016, Quillivant XR had approximately 636,000 prescriptions and gross sales of approximately $192.0 million. Quillivant XR captured a 0.9% share of the ADHD market in the fourth quarter of 2016.

We launched our amphetamine extended-release ODT, Adzenys XR-ODT, on May 16, 2016, and through December 31, 2016, we had 30,339 total prescriptions, generating $8.2 million in gross sales in 2016, of which $5.5 million was in the fourth quarter of 2016. We captured a 0.1% share of the ADHD market in the fourth quarter of 2016.

The market acceptance of these novel formulations, despite their limitations, further demonstrates the significant unmet need and opportunity for novel, patient- and caregiver-friendly dosage forms in the treatment of ADHD. We believe that XR-ODT and XR liquid suspension would be preferred and clinically beneficial dosage forms for the treatment of ADHD patients with swallowing aversion. In a survey commissioned by us, when asked to project their next 100 dextroamphetamine/amphetamine prescriptions, a sample of 51 pediatricians and psychiatrists said they would prescribe a once-daily controlled-release ODT dextroamphetamine/amphetamine four times as often as they would prescribe a

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once-daily controlled-release liquid dextroamphetamine/amphetamine (13.3 vs. 3.4 out of their next 100 ADHD patients receiving dextroamphetamine/amphetamine). In a study of adult patients with a CNS disorder, 61% of patients chose an ODT, in comparison with 27% who chose a conventional tablet and 12% who were indifferent. However, to our knowledge, we are the first company to date to commercialize an XR-ODT formulation of any ADHD medication. We believe there is a significant market opportunity to provide the two most prescribed medications for ADHD, methylphenidate and amphetamine, in two patient-friendly dosage forms, ODT and liquid suspension.

Our product and product candidates address an unmet need for ADHD patients

Our proprietary modified-release drug delivery technology platform has enabled us to create XR-ODT and XR liquid suspension formulations of methylphenidate and amphetamine. We have achieved this by combining two key drug delivery attributes in each of our product and two product candidates:

An extended-release profile, which allows for once daily dosing; and

An ODT or liquid suspension dosage form, which allows for easier administration and ingestion.

We have developed an XR-ODT product, an XR-ODT product candidate and an XR liquid suspension product candidate, each of which addresses an unmet need. Adzenys XR-ODT and, if approved, Cotempla XR-ODT, may be the first XR-ODT products for the treatment of ADHD. We believe that our XR-ODT products have unique attributes to improve compliance and, if approved, could offer significant advantages over other solid oral dosage forms that can help simplify the morning routine in households with ADHD-diagnosed children. These advantages include:

Ease of administration and ingestion because they disintegrate rapidly in the mouth and may be taken without water;

Taste-masking of bitter ADHD medications, with flavoring options;

Prevention of "cheeking", the practice of hiding medication in the mouth and later spitting it out rather than swallowing it; and

Convenient single-unit blister-packaging, which is both portable and discrete.

Our product candidate, NT-0201, is a ready-to-use, XR liquid suspension that does not require reconstitution or refrigeration, and offers an attractive dosing option for younger children who prefer to ingest liquid medicine.

We believe that an XR-ODT, such as Adzenys XR-ODT and Cotempla XR-ODT, and an XR liquid suspension, such as NT-0201, may solve the swallowing issue that undermines compliance with tablet and capsule medication regimens.

OUR PRODUCT CANDIDATES AND CURRENTLY MARKETED PRODUCT

Utilizing our proprietary modified-release drug delivery technology platform, we currently manufacture and market our Adzenys XR-ODT and our generic Tussionex and are developing our two other product candidates. We are developing each of our product candidates to seek FDA approval in

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accordance with Section 505(b)(2). The table below summarizes our pipeline of product candidates and currently marketed products.

Product	Active Drug and Indication	Formulation	Status
Adzenys XR-ODT	Amphetamine for ADHD	XR-ODT	Approved and marketed
Cotempla XR-ODT	Methylphenidate for ADHD	XR-ODT	Resubmitted NDA; June 19, 2017 PDUFA goal date
NT-0201	Amphetamine for ADHD	XR Liquid Suspension	Submitted NDA; September 15, 2017 PDUFA goal date
Generic Tussionex	Hydrocodone and chlorpheniramine for cough and upper respiratory symptoms of a cold	XR Liquid Suspension	Approved and marketed

The 505(b)(2) regulatory approval pathway allows for a potentially streamlined and targeted clinical development program. During the development process, we communicated with the FDA on several occasions and received feedback on our clinical development plans for Adzenys XR-ODT and our two product candidates. In general, our clinical development program for our branded product and two product candidates comprised single-dose clinical pharmacology studies, each designed to evaluate the bioequivalence and bioavailability of these dosage forms under different test conditions. Each product candidate was studied in adult volunteers and children with ADHD. In addition, a clinical efficacy and safety trial in children with ADHD was conducted for Cotempla XR-ODT, our methylphenidate XR-ODT. During each phase of the clinical trials, safety and tolerability were systematically assessed. A summary of each program is presented below. For the purposes of our clinical trials, unless otherwise indicated, we refer to children as individuals ages 6 to 12, adolescents as individuals ages 13 to 17, and adults as individuals 18 and older.

Adzenys XR-ODT: Amphetamine XR-ODT for the treatment of ADHD

We received approval from the U.S. Food and Drug Administration, or FDA, for Adzenys XR-ODT, our amphetamine XR-ODT, on January 27, 2016. We believe Adzenys XR-ODT is the first amphetamine XR-ODT for the treatment of ADHD. Our NDA for Adzenys XR-ODT relies on the efficacy and safety data that formed the basis of FDA approval for the listed drug, Adderall XR, 30 mg, together with bioequivalence, bioavailability and aggregate safety data from our Adzenys XR-ODT clinical program.

Adzenys XR-ODT 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 offer Adzenys XR-ODT in 30-day supply, child-resistant blister packs. We have composition-of-matter patents for Adzenys XR-ODT that are scheduled to expire in 2026 and 2032. These patents are listed in the Orange Book, which we believe will provide additional protection for Adzenys XR-ODT.

Adzenys XR-ODT commercialization

We launched the commercialization of Adzenys XR-ODT on May 16, 2016 and are commercializing this product in the United States with our own infrastructure. We are using a dedicated contract specialty sales force in approximately 125 territories targeting approximately 12,500 physicians who prescribe approximately 40% of all ADHD prescriptions. Through December 2016, we had 30,339 total prescriptions, including 7,444 in December 2016. The number of prescribers of Adzenys XR-ODT continues to grow, and as of December 31, 2016, 4,268 health care providers had written prescriptions for the product. As of the end of 2016, Adzenys XR-ODT was covered by managed care for approximately 83% of commercially-covered lives.

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Adzenys XR-ODT clinical program

The clinical program for Adzenys XR-ODT consisted of five Phase 1 single-dose human pharmacokinetic studies under fasted and/or fed conditions. Four of the five single-dose clinical studies were submitted to the FDA with the original NDA in December 2012. The fifth study was conducted using commercial-scale material, and was included in our resubmission to the FDA. The four original studies were a Phase 1 bioequivalence study versus Adderall XR, 30 mg, in healthy adult volunteers under fasted conditions; a Phase 1 bioavailability study in healthy adult volunteers under both fed and fasted conditions; a Phase 1 study to determine the impact of alcohol on the bioavailability of Adzenys XR-ODT; and a bioavailability study in children with ADHD under fasted conditions.

The data from the pilot-scale bioequivalence study versus Adderall XR, 30 mg, is shown in Figure 1 and shows that Adzenys XR-ODT is bioequivalent to the listed drug, Adderall XR, 30 mg, under fasted conditions.

Figure 1: Bioequivalence Study of Adzenys XR-ODT versus Adderall XR, 30 mg, in Healthy Adult Volunteers under Fasted Conditions

Other key observations from our original clinical program for Adzenys XR-ODT included:

No alcohol dose-dumping: The extended-release properties of Adzenys XR-ODT were maintained in the presence of varying concentrations of alcohol, indicating that Adzenys XR-ODT is a "rugged" formulation that does not cause premature and intentional release of the drug product, or dose-dump, in the presence of alcohol.

Similar exposure rate: Consistent with the listed drug, there was a higher mean amphetamine exposure in children, which decreased with increasing age.

Safety and Tolerability: There were no unexpected adverse events, serious adverse events, deaths or other safety signals. The aggregate data suggested that Adzenys XR-ODT has a similar safety profile to that of the listed drug and is well-tolerated.

Following the receipt of a Complete Response Letter, we received feedback from the FDA on the design of an additional bioequivalence and bioavailability study of Adzenys XR-ODT produced at commercial scale to support the NDA resubmission. This study was designed to compare the pharmacokinetic profile of the commercial-scale product to the listed drug in adult volunteers under fasted conditions; compare the

pilot-scale manufacturing batches to the commercial-scale batches; and

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evaluate the oral bioavailability of Adzenys XR-ODT under fed and fasted conditions in adult volunteers.

The bioequivalence data for the commercial-scale product demonstrated that Adzenys XR-ODT has a similar pharmacokinetic profile to the listed drug under fasted conditions, meeting bioequivalence criteria for key exposure parameters ($AUC_{5-t,}$ C_{max}, AUC_{last}, and AUC_{inf}). The lower 90% confidence interval for early exposure (AUC_{0-5}) of Adzenys XR-ODT produced at commercial scale fell just below the 80% lower criterion when compared to the listed drug. However, the concentration-time profiles for Adzenys XR-ODT produced at commercial scale and pilot scale are virtually identical, as shown in Figure 2, indicating that scale-up of the Adzenys XR-ODT process did not affect the rate and extent of absorption of amphetamine.

Figure 2: Comparison of Adzenys XR-ODT Pilot Scale versus Adzenys XR-ODT Commercial Scale

Our settlement agreement with Shire, the producer of Adderall XR, precludes the possibility of a 30-month stay of approval under the Hatch-Waxman Act.

We have committed to the FDA to conduct the following three trials as a post-marketing requirement after approval of the Adzenys XR-ODT NDA: 1) a single-dose, open-label, randomized pharmacokinetic study of Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets), in male and female children (4 to less than 6 years of age) with ADHD; 2) a randomized, double-blind, placebo-controlled, flexible-dose titration study of Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets), in children ages 4 to 5 years diagnosed with ADHD; and 3) a one year Pediatric Open-Label Safety Study of patients age 4 to 5 years (at the time of entry into the first or second study, or at the time of enrollment if directly enrolled into this study) diagnosed with ADHD treated with Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets). We met with FDA officials in January 2017 to further clarify the design of the protocols required to conduct these studies. We expect to commence with the pharmacokinetics trial in 2017.

Cotempla XR-ODT: Methylphenidate XR-ODT for the treatment of ADHD

We believe our most advanced methylphenidate product candidate, Cotempla XR-ODT, if approved, will be the first methylphenidate XR-ODT for the treatment of ADHD, providing onset-of-effect within one hour and a 12-hour duration. We submitted a 505(b)(2) NDA for Cotempla XR-ODT on January 9, 2015. On October 16, 2015, we received notification from the FDA stating that,

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as part of its ongoing review of our NDA for Cotempla XR-ODT, it had identified deficiencies that precluded discussion of labeling and post marketing requirements or commitments at that time. On November 10, 2015, we announced that we received a Complete Response Letter from the FDA, which requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. The FDA did not raise any safety or efficacy issues with the clinical data previously provided beyond the need for an adequate bridge between the clinical trial material and the to-be-marketed drug product. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. On December 20, 2016, we announced that we had resubmitted an NDA for Cotempla XR-ODT, our methylphenidate XR-ODT, following the completion of a bioequivalence bridging study. We have a PDUFA goal date of June 19, 2017 for Cotempla XR-ODT. Our Cotempla XR-ODT NDA relies on the efficacy and safety data that formed the basis of FDA approval for the listed drug, Metadate CD®, together with bioavailability/bioequivalence data and efficacy/safety data from our Cotempla XR-ODT clinical program. The FDA conducted a cGMP and pre-approval inspection related to our NDA for Cotempla XR-ODT from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. On June 19, 2015, we responded to the FDA and we implemented corrective action related to this observation, and the FDA closed the inspection. Additionally, the FDA has concluded that the trade name Cotempla XR-ODT for our methylphenidate XR-ODT product candidate is provisionally acceptable.

Cotempla XR-ODT 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. We plan to offer Cotempla XR-ODT in 30-day supply, child-resistant blister packs. We have composition-of-matter patents in the U.S. which we expect will provide Cotempla XR-ODT intellectual property protection until 2032. If any of our composition-of-matter patents are also listed in the Orange Book, we believe this will provide additional market protection for Cotempla XR-ODT.

Cotempla XR-ODT Clinical Program

The clinical program for Cotempla XR-ODT consists of four Phase 1 clinical pharmacology studies and a Phase 3 clinical efficacy and safety trial. Three of the clinical pharmacology studies were previously completed. They were single-dose pharmacokinetic studies conducted under fasted and/or fed conditions: a Phase 1 bioequivalence study versus Metadate CD in healthy adult volunteers under fasted conditions; a Phase 1 bioavailability study in healthy adult volunteers under both fed and fasted conditions; and a Phase 1 bioavailability study in children and adolescents with ADHD under fasted conditions. A fourth clinical pharmacology study, which was designed to be a Phase 1 bioequivalence study, demonstrated equivalence between our clinical trial formulation and our to-be-marketed formulation in healthy adult volunteers under fed and fasted conditions and was completed in July 2016. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. On December 20, 2016, we completed the resubmission of our NDA which is a Class 2 resubmission, and with a target six-month PDUFA review period, we have a PDUFA goal date of June 19, 2017. The NDA includes results from our Phase 3 clinical efficacy and safety study that showed a statistically significant improvement in ADHD symptom control compared to placebo across the classroom day. Onset of effect was observed within one hour

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post-dose and persisted through 12 hours. No serious adverse events were reported during the study and the adverse event profile was consistent with the drug's mechanism of action. In addition, data from a pharmacokinetic study in children with ADHD was submitted.

The data from our bioequivalence study versus Metadate CD is presented in Figure 3, and shows that Cotempla XR-ODT has a similar plasma concentration-time profile to the listed product, Metadate CD, with a peak exposure that is about 25% higher. The potential efficacy benefits of this increased maximum exposure, as well as any impact on safety parameters, were evaluated in a clinical efficacy and safety trial.

Figure 3: Bioequivalence Study of Cotempla XR-ODT versus Metadate CD, 60 mg, in Healthy Adult Volunteers under Fasted Conditions

Other key observations from the Cotempla XR-ODT clinical pharmacology program included:

No formulation-related food effect: The pharmacokinetic profile of Cotempla XR-ODT was similar under fed and fasted conditions.

Similar exposure rate: There was higher mean methylphenidate exposure in children, which decreased with increasing age.

Safety and tolerability: There were no unexpected adverse events, serious adverse events, deaths or other safety signals. The aggregate data suggested that Cotempla XR-ODT has a similar safety profile to that of the listed drug and is well-tolerated.

Cotempla XR-ODT Phase 3 classroom efficacy and safety trial

The efficacy, safety and tolerability of Cotempla XR-ODT were evaluated in a multicenter, double-blind, placebo-controlled laboratory classroom trial in 87 children with ADHD. The laboratory classroom was a controlled study environment designed to model the community school classroom setting while allowing detailed assessments of behavior over time by trained observers. The primary efficacy variable was the Swanson, Kotkin, Agler, M-Flynn and Pelham, or SKAMP, Combined Score, a validated rating of attention and behavior, averaged over the test day, with higher scores indicating a higher degree of functional impairment. Time to onset and duration of effect were also evaluated as key secondary endpoints. Additional secondary efficacy endpoints included the Permanent Product Measure of Performance, or PERMP, a ten-minute, level-adjusted math test that measures the child's ability to focus on written schoolwork by determining the number of problems

attempted and the number answered correctly.

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Cotempla XR-ODT met the primary and key secondary efficacy endpoints, showing statistically significant improvement versus placebo on the SKAMP ($p<0.0001$). Statistical significance expresses the probability that the results of a particular study could have occurred purely by chance. Results are said to be statistically significant when the p-value obtained is less than the pre-established significance level, which in this case was $p<0.05$ for the primary efficacy endpoint. The SKAMP-Combined score averaged over the classroom testing day was 25.3 for the placebo group and 14.3 in the Cotempla XR-ODT group indicating greater symptom severity in the placebo group. The least squares mean difference was 11.04. Figure 4 shows SKAMP-Combined Scores for Cotempla XR-ODT versus placebo over the classroom day from our Phase 3 efficacy trial. Time to onset was observed within one hour, with a 12-hour duration of effect.

Figure 4: Change from Baseline in Mean SKAMP Score During the Test Day

Statistically significant improvement versus placebo was also observed on both attempted and correct PERMP scales ($p<0.0001$). Figure 5 shows PERMP scores for Cotempla XR-ODT versus placebo from our Phase 3 classroom efficacy trial. Taken together, the data demonstrate clinically meaningful differences on both the rater-evaluated assessment of attentiveness and behavior and the objective measure of sustained attention.

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Figure 5: Mean Profiles for PERMP Measurements During the Test Day

All of the other secondary endpoints were also statistically significant, indicating a robust effect of the drug, as well as internal consistency in the study results. There was no impact on safety parameters as Cotempla XR-ODT was well-tolerated with no unexpected adverse events, serious adverse events, deaths or other safety signals.

Bridging Study: Bioequivalence Between Clinical Trial Formulation and Commercial Formulation

The objective of this study was to compare the rate of absorption and oral bioavailability of the previously studied clinical trial formulation of Cotempla XR-ODT 60 mg (2 × 30 mg) under fasted conditions to the commercial scale formulation of Cotempla XR-ODT 60 mg (2 × 30 mg) under fasted conditions. Additionally, the rate of absorption and oral bioavailability of the commercial scale formulation of Cotempla XR-ODT 60 mg (2 × 30 mg) under fed and fasted conditions was compared.

The results from the bioequivalence study bridging the clinical trial lot used in the Cotempla XR-ODT clinical trial program and the commercial lot are presented in Figure 6 below. Key findings from this study are:

The clinical trial formulation of Cotempla XR-ODT is bioequivalent to the commercial formulation of Cotempla XR-ODT under fasted conditions.

Peak exposure is decreased slightly (approximately 23%) in the presence of a high-fat meal; however, overall systemic.

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Fig. 6 Bioequivalence Study of Cotempla XR-ODT Clinical vs. Commercial Scale Lot in Healthy Adult Volunteers

Analyte=DMETH+LMETH

Treatment A = Cotempla XR-ODT Commercial Scale Lot (Fed); Treatment B = Cotempla XR-ODT Commercial Scale Lot (Fasted); Treatment C = Cotempla XR-ODT Clinical Scale Lot (Fasted)

Our 505(b)(2) application for Cotempla XR-ODT referenced the FDA's previous findings of safety and effectiveness for Metadate CD. The NDA submission included a Paragraph IV certification notification to UCB, Inc., or UCB, the NDA holder of Metadate CD, in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. UCB has acknowledged that they will not initiate a suit against us, and the 45-day period following Paragraph IV notification has since passed which precludes the possibility of a 30-month stay of approval under the Hatch-Waxman Act.

NT-0201: Amphetamine XR liquid suspension for the treatment of ADHD

In addition to the clinical trial program outlined below, we conducted two additional bioequivalence studies for NT-0201, in support of the NDA: a bridging study of our clinical trial material and our to-be-marketed drug material, which examined the effect of a high-fat meal on the commercial formulation, and a bioequivalence study of the commercial formulation versus Adderall XR 30 mg. We announced on November 17, 2016 that we submitted an NDA for NT-0201. With a 10-month PDUFA review period, we have a PDUFA goal date of November 15, 2017. We are pursuing a Section 505(b)(2) regulatory strategy, which allows us to rely in part on the FDA's findings of safety and efficacy of the listed drug, Adderall XR, together with bioavailability/bioequivalence data for NT-0201 from our own clinical program.

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. We have composition-of-matter patents for NT-0201 that are scheduled to expire in 2032. If NT-0201 receives FDA approval, we expect to list these patents in the Orange Book, which we believe will provide additional market protection for NT-0201.

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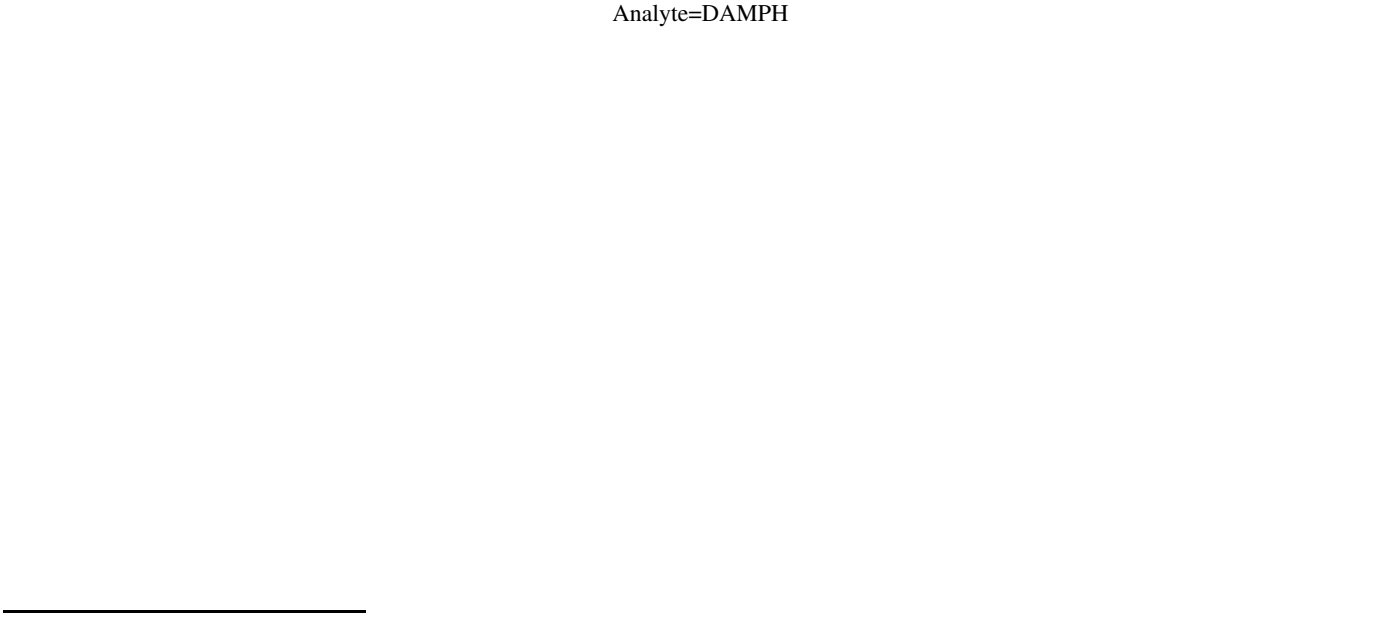
NT-0201 clinical program

The bioavailability/bioequivalence of NT-0201 has been characterized in five Phase 1 clinical studies: a Phase 1 study investigating the bioavailability and bioequivalence of three test formulations of NT-0201 in healthy adults; a Phase 1 study comparing the pharmacokinetic, or PK, profile of the commercial scale formulation of NT-0201 to Adderall XR 30 mg capsules; a Phase 1 food effect study of NT-0201 in healthy adults; a Phase 1 study comparing the commercial scale and clinical trial formulations of NT-0201 under fasted conditions, as well as the effect of food on the PK profile of the commercial scale formulation of NT-0201; and a Phase 1 PK study of NT-0201 in children with ADHD.

The data from our recent bioequivalence study versus Adderall XR is shown in Figure 7 and shows that the commercial scale formulation of NT-0201 is bioequivalent to the listed drug, Adderall XR, 30 mg, under fasted conditions.

Figure 7: Mean *d*-amphetamine Concentration-Time Profiles after Administration of AMP XR OS (Treatment A) and Adderall XR 30 mg (Treatment B)



Treatment A = NT-0201 (30 mg/15 mL); Treatment B = Adderall XR 30 mg capsule

Other key observations from our clinical program for NT-0201 included:

No significant food effects: When administered under fasted and fed conditions, no significant food effects were observed for NT-0201, and the observed food effects of NT-0201 were less than those for the listed drug.

Similar exposure rate: Consistent with the listed drug, there was a higher mean amphetamine exposure in children, which decreased with increasing age.

Safety and Tolerability: There were no unexpected adverse events, serious adverse events, deaths or other safety signals. The aggregate data suggested that NT-0201 has a similar safety profile to that of the listed drug and is well-tolerated.

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We announced on November 17, 2016 that we submitted an NDA for NT-0201. With a targeted 10-month PDUFA review period, we have a PDUFA goal date of November 15, 2017. We included a Paragraph IV certification in the NDA submission, which required a Paragraph IV certification notification to the producer of Adderall XR, Shire Pharmaceuticals, in accordance with the Hatch-Waxman Act. On March 6, 2017, we entered into a license agreement with Shire, pursuant to which Shire granted us a non-exclusive license to certain patents owned by Shire for certain activities with respect to NT-0201. Under the terms of the agreement, we must pay a lump sum, non-refundable license fee of an amount less than $1.0 million due no later than thirty days after receiving regulatory approval by the FDA of our NDA for NT-0201. We will also pay a single digit royalty on net sales of the NT-0201 during the life of the relevant Shire patents. Additionally, the license agreement contains a covenant from Shire not to file a patent infringement suit against us alleging that NT-0201 infringes the Shire patents.

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. In 2014, approximately 2.1 million prescriptions of Tussionex and related generic products were sold.

Since its launch in September 2013, we have manufactured and utilized our DTRS technology in the production of our generic Tussionex at our facilities in Grand Prairie, Texas. In August 2014, we acquired all commercialization and profit rights to this formulation of the generic Tussionex product from Cornerstone BioPharma, Inc. and Coating Place, Inc. We have an exclusive supply agreement, or Supply Agreement, with Coating Place, Inc., or CPI, which expires in August 2021, 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. Under the terms of the Supply Agreement, we must deliver a 24-month rolling forecast, or Forecast, of our expected product requirements to CPI on a quarterly basis; however, only the first calendar quarter commencing on or after the 90th day after the delivery of a Forecast constitutes a binding purchase commitment with respect to the products listed in such Forecast. In October 2014, we re-launched the product under our own label. 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. We have obtained required state licenses, set up distribution channels and established trade relations in order to commercialize our generic Tussionex.

Commercialization

We are commercializing Adzenys XR-ODT and, if approved, plan to market Cotempla XR-ODT and NT-0201, in the United States using our existing commercial infrastructure. We sell our Adzenys XR-ODT product to drug wholesalers in the United States, and we have obtained required state licenses and set up distribution channels.

In the United States, approximately 12,500 physicians prescribe approximately 40% of all ADHD prescriptions. We are using a specialty sales force of approximately 125 sales representatives primarily targeting the highest-volume prescribers of ADHD medication. The sales force is divided into 13 regions, each managed by a regional sales manager. Furthermore, since our target physicians tend to prescribe both methylphenidate and amphetamine, we intend to leverage our sales force by promoting all three of our ADHD products, after they are approved, to the same audience.

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Our commercialization efforts are focused on delivering the right message for each of our three ADHD products. Data indicates that ADHD-indicated extended-release methylphenidate and extended-release amphetamine products are widely prescribed. Based on this, our messaging can focus on anticipated benefits of our XR-ODT and XR liquid suspension dosage forms. We use multi-channel tactics to reach physicians, payers, patients and patient caregivers with the right frequency to drive behavior. In addition to personal promotion, we intend to reach physicians through medical education, direct marketing, journal advertising and electronic health record communication.

Advocacy groups, patients and caregivers are extremely active and vocal in the ADHD space. The period from initial diagnosis to symptom control is difficult, and caregivers actively seek and pass on useful information. Our direct-to-patient and direct-to-consumer plan is designed to tap into this social group through focused education and advertising, as well as by employing appropriate social media listening and engagement to inform these consumers.

We launched Adzenys XR-ODT, our amphetamine XR-ODT, on May 16, 2016. If approved, we expect to follow with the launch of Cotempla XR-ODT, our methylphenidate XR-ODT, in the fall of 2017. This would allow our sales force time to prepare for a second wave of new prescriptions in the fourth quarter of the year, as follow up from the "back-to-school" dosing period begins and parent-teacher conferences drive new patients to doctors' offices. If approved, our plan is to also launch NT-0201, our amphetamine XR liquid suspension, in the fourth quarter of 2017.

Our proprietary technology platform

We believe that we can apply the XR-ODT and XR liquid suspension technologies that underlie Adzenys XR-ODT, our product candidates and generic Tussionex to other active pharmaceutical ingredients, or APIs. This would allow us to offer more patient- and caregiver-friendly dosage forms, potentially improving compliance rates due to difficulty swallowing and providing other clinical advantages. 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 or improve existing therapies not otherwise available in XR-ODT or XR liquid suspension form.

Our proprietary modified-release drug delivery technology platform, as illustrated below in Figure 8, allows us to produce drug-loaded micro-particles through an ion exchange process that creates new salt forms of existing drug compounds that have been proven safe and effective. By applying a uniform modified-release coating to these drug-loaded micro-particles and avoiding agglomeration, or clumping, we are able to create particle structures that can withstand compression and osmotic forces without rupturing, sloughing or leaking. This allows us to compress the modified-release micro-particles into ODT or suspend them in a liquid formulation without destroying their integrity or causing dose-dumping. By applying different types of coatings, we can modify the drug release characteristics of a micro-particle. Additionally, by mixing combinations of these micro-particles, each of which has its own release profile, we are able to produce complex drug release profiles. These micro-particles are further blended with excipients to form a final drug product, which we incorporate into a patient-friendly dosage form such as an ODT or liquid suspension. We are also able to utilize this technology to achieve tamper-resistant formulations and taste-masking.

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Figure 8: Our Proprietary Modified-Release Drug Delivery Technology Platform

We believe our technology platform is able to deliver a proprietary portfolio of commercially available drugs in highly desirable dosage forms.

Our XR-ODT Technology: Rapidly Disintegrating Ionic Masking

Our Rapidly Disintegrating Ionic Masking, or RDIM, technology utilizes an orally disintegrating, modified-release, taste-masked pharmaceutical composition that can withstand compression forces associated with standard tableting technology, allowing for a drug to be incorporated into the ODT dosage form using ion resin technology. This technology not only provides extended-release and controlled-release properties, it masks the unpleasant taste of the active drug. Flavor and coloring can also be added to the compression blend to further enhance the pharmaceutical elegance of the finished XR-ODT. The finished product is then packaged in blister packs making them extremely portable, child resistant and stable for 24 months. Our RDIM technology is protected by a U.S. patent that is scheduled to expire in 2026.

Although ODT are one of the most preferred solid oral dosage forms in the market, there is currently no approved XR-ODT product for the treatment of ADHD. We expect to have the first XR-ODT dosage form on the market using our patented XR-ODT technology.

Our XR Liquid Suspension Technology: Dynamic Time Release Suspension

Our Dynamic Time Release Suspension, or DTRS, technology encompasses a set of process technologies and know-how to manufacture and test modified-release liquid suspension products that are shelf-stable. By matching the specific gravity, osmotic and ionic characteristics of the drug resin particle to that of the suspension, we are able to obtain shelf-stable liquids with a 24-month shelf life that do not require reconstitution or refrigeration.

XR liquid suspension provides a patient-friendly dosage form for patients who find swallowing an intact tablet or capsule to be difficult, or for whom more precise dose-titration may be preferred or required. Our DTRS technology not only provides for an extended-release, ready-to-use Liquid Suspension but also provides excellent taste-masking of the drug itself. Our DTRS technology is protected by a series of patents and patent applications.

Our Tamper Resistant Technology: Kinetically Controlled Tamper Protection

Ion resin drug products inherently deter some forms of abuse, such as inhalation, smoking and injection; however, the most common form of abuse for many drugs is to induce dose-dumping by crushing, chewing or extraction. Our Kinetically Controlled Tamper Protection, or KCTP, technology is

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designed to prevent abuse by altering the kinetics of the drug product and can be used in conjunction with both our XR-ODT and XR liquid suspension dosage forms. KCTP is designed to discourage common methods of tampering associated with certain classes of medications which can be abused and misused. KCTP utilizes an additional ion resin particle with an aversive agent bound to it. The aversive resin complex is then coated so that it passes through the body without material release. If an attempt is made to tamper with the XR-ODT or XR liquid suspension to cause dose-dumping, the aversive agent will also be released and block or disrupt the properties of the active drug product.

We believe that our KCTP technology may be especially useful for opioid-based pain products or other DEA scheduled drug products for which abuse and dose dumping are known problems. Our KCTP technology is the subject of a patent application and, if granted, this patent will provide protection until 2032.

Our product pipeline potential

Beyond our initial focus on ADHD, our strategy is to apply our proprietary drug delivery technology platform for the development of additional drug candidates where patients may benefit from either XR-ODT or XR liquid suspension dosage forms of existing extended-release medications. Difficulty and inability to swallow tablets and capsules are not limited to ADHD medications. Patients with CNS conditions, such as stroke, Parkinson's disease and Alzheimer's, often have difficulty swallowing their medication and would benefit from ODT and liquid suspension dosage forms.

In addition, our technology can be applied to existing drugs that are currently not optimized for their kinetic delivery. We believe that our technology is capable of overcoming some of the common issues in oral drug delivery, such as high peak to trough ratios, blood level spikes that induce unwanted side effects, wide variations in fed-fasted effect, suboptimal onset of action, suboptimal duration of effect, dose-dumping and single point failures of the delivery system, while providing an oral dosage form that is preferred by patients, caregivers and physicians.

We have an active development pipeline that includes product candidates in complementary therapeutic areas such as psychiatry and neurology, along with additional novel treatment options for ADHD. We have completed feasibility studies on several of these product candidates thus far. We believe several of these product candidates will be synergistic to our existing commercial infrastructure and the others would allow us to expand into adjacent therapeutic categories. We plan to complete feasibility work on several potential product candidates by mid-2017 and then select two to three candidates for further clinical development.

Our screening criteria for future potential product candidates to initially assess technical feasibility include whether the target drug compound can be ionized and bound to a resin micro-particle. We are assessing drug loading efficiency and coating polymers and conducting initial coating work to determine whether the desired release profile can be achieved for a particular drug resin micro-particle.

We are also assessing regulatory criteria to minimize regulatory approval risk. We intend to continue to use the 505(b)(2) regulatory approval pathway in an effort to mitigate approval risk, and also simplify the clinical development program. We intend to address clinical study design, study endpoints and labeling advantages early in the development process so that we can tailor a given clinical program that produces a product candidate with attributes that allow for the optimal strategic positioning, if approved.

Finally, we are evaluating criteria when systematically choosing a potential product candidate for our pipeline. We have looked for product candidates that we believe have a market potential in excess of $50.0 million, a concentrated specialty physician prescribing base, in the case of complementary candidates, and a patent landscape that can be navigated and protected through the lifespan of our potential product candidate.

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We have designed our development process to be targeted and relatively efficient. If we are able to effectively execute our development process, we may be able to initiate clinical trials in approximately 18 months, and submit our NDA in as few as 36 months, after identifying a potential product candidate. We believe we have identified several product candidates that fit our screening criteria and that are attractive candidates for our branded product portfolio.

OUR MANUFACTURING CAPABILITIES

Overview

We lease one manufacturing site in Grand Prairie, Texas that handles the development, production, quality control testing and packaging of our products. This facility has 77,112 square feet of manufacturing and laboratory space, and contains dedicated cGMP manufacturing suites for both XR-ODT and XR liquid suspension. We hold DEA manufacturing and analytical licenses, and maintain storage and use of Schedule II through IV controlled substances. The manufacture of our products is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control. We have operated and maintained these facilities dating back to when we operated as a contract manufacturer by our predecessor corporation, 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, our former Chief Technology officer, 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 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 Adzenys XR-ODT, our generic Tussionex and drug products for our clinical trials. We have also concluded the required annual audit program as prescribed by the Consent Decree. For our most recent annual audit by a cGMP expert in November 2014, the cGMP expert concluded our corrective actions satisfactorily addressed the 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. To date, the consent decree has had no material impact on our current business operations or our ability to pursue approval of our product candidates.

We are currently producing Adzenys XR-ODT and our generic Tussionex for commercial distribution. To date, we have produced Cotempla XR-ODT and NT-0201 for use in our clinical trials and stability studies. We have fully scaled up Cotempla XR-ODT and NT-0201 to commercial batch sizes and have validated all Cotempla XR-ODT processes. We believe that our current facilities have the manufacturing capacity for commercial production of Adzenys XR-ODT and generic Tussionex and potential commercialization of Cotempla XR-ODT and NT-0201 in quantities sufficient to meet what we believe will be our commercial needs, and to accommodate the manufacturing of materials for future clinical trials of other potential product candidates that we may identify for our product pipeline. We believe that maintaining our internal manufacturing capabilities enables us to obtain our products at-cost without manufacturer's margins and to better control supply quality and timing.

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Drug substances

We currently purchase the APIs used in Adzenys XR-ODT and NT-0201 (amphetamine), and Cotempla XR-ODT (methylphenidate), anionic resins, excipients and other materials from third-party providers, on a purchase order basis from manufacturers based outside and within the United States. We anticipate entering into commercial supply agreements with many of these manufacturers at a later date.

Both amphetamine and methylphenidate are classified as controlled substances under U.S. federal law. Adzenys XR-ODT, Cotempla XR-ODT and NT-0201 are classified by the DEA as Schedule II controlled substances, meaning that these drug products have a high potential for abuse and dependence among drugs that are recognized as having an accepted medical use. Consequently, the procurement, manufacturing, shipping, dispensing and storing of our product candidates will be subject to a high degree of regulation, as described in more detail under the caption "Governmental Regulation DEA Regulation" included elsewhere in this Annual Report on Form 10-K.

INTELLECTUAL PROPERTY

Proprietary protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We have been building and continue to build our intellectual property portfolio relating to our ADHD drug candidates, our generic Tussionex and our technology platform. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also intend to rely on trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Patent rights

Our intellectual property portfolio consists of 12 patents and 10 patent applications in the United States, including 2 provisional applications, and 6 patents and 2 patent applications in foreign countries and regions. Our intellectual property strategy emphasizes specific drug products, product groups, and technology platforms. Our patents and patent applications covering specific drug products include claims to the drug products and to methods of using those products. Our patents and patent applications covering technology platforms include claims to methods of making products as well as claims to the products made by those methods. Certain of these patents and patent applications cover more than one product.

Our XR-ODT product Adzenys XR-ODT patent portfolio includes four granted U.S. patents and five pending U.S. non-provisional applications. The issued patents contain pharmaceutical composition-of-matter claims covering controlled-release direct compression ODT with drug-resin particles and, among other things, composition of matter for Adzenys XR-ODT. The composition-of-matter patents are scheduled to expire in 2026 and 2032.

Our XR-ODT product candidate Cotempla XR-ODT patent portfolio includes three granted U.S. patents, including pharmaceutical composition-of-matter claims covering controlled-release direct compression ODT with drug-resin particles and, among other things, composition of matter for

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Cotempla XR-ODT. These patents are scheduled to expire in 2026 and 2032, respectively. This portfolio also includes four other pending U.S. non-provisional applications and one U.S. provisional patent application.

Our XR liquid suspension product candidate NT-0201 patent portfolio contains eight granted U.S. patents and four other pending U.S. non-provisional applications. These patents contain claims directed to, among other things, compositions of matter, as well as methods of preparing liquid controlled-release formulations and for predicting bioequivalence for liquid suspension. The longest-term composition-of-matter patent is scheduled to expire in 2032, and the method patents are scheduled to expire in 2025, 2029 and 2031, respectively.

Our generic Tussionex is covered by six of our granted U.S. patents which include claims directed to, among other things, a composition-of-matter, as well as methods-of-making, and for predicting bioequivalence for liquid suspension. Our generic Tussionex is also covered by one other pending non-provisional applications. The composition-of-matter patent is scheduled to expire in 2031. We expect protection under certain other granted patents and/or a patent granted on the pending application to also extend until 2031.

Upon receiving FDA approval for any of these products, we intend to list both applicable platform patents and relevant specific drug patents in the Orange Book. We own all of the above patents and pending applications.

On July 25, 2016, we received a Paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Adzenys XR-ODT. The certification notice alleges that the four U.S. patents listed in the FDA's Orange Book for Adzenys XR-ODT, one with an expiration date in April 2026 and three with expiration dates in June 2032, will not be infringed by Actavis's proposed product, are invalid and/or are unenforceable. On September 1, 2016, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Actavis that automatically stayed, or barred, the FDA from approving Actavis's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier.

Adzenys XR-ODT and Cotempla XR-ODT are not currently protected by patents outside of the United States and our generic Tussionex and NT-0201 are currently protected by method patents only in the United States, Australia, Canada, China, Mexico and South Africa. As such, competitors may be free to sell products that incorporate the same or similar technologies that are used in our products in countries in which the relevant product does not have patent protection.

Patent life determination depends on the date of filing of the application and other factors as promulgated under the patent laws. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country.

Trade secret and other protection

In addition to patented intellectual property, we also rely on trade secrets and proprietary know-how to protect our technology and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual's relationship with us except in limited circumstances. These agreements generally also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

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Other intellectual property rights

We seek trademark protection in the United States when appropriate. We have filed for trademark protection for the Neos Therapeutics mark, which we use with our pharmaceutical research and development as well as products, as well as trade names that could be used with our potential products. We currently have registered trademarks for Neos Therapeutics in the United States as well as for our DTRS technology.

From time to time, we may find it necessary or prudent to obtain licenses from third party intellectual property holders.

RESEARCH AND DEVELOPMENT

For the years ended December 31, 2016, December 31, 2015 and December 31, 2014, our research and development expenses were $12.2 million, $11.7 million and $10.6 million, respectively.

COMPETITION

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates include ease of administration and convenience of dosing, therapeutic efficacy, safety and tolerability profiles and cost. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Consequently, our competitors may develop modified-release products for the treatment of ADHD or for other indications we may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

Adzenys XR-ODT and our two branded product candidates also face competition from commercially available generic and branded medications currently produced by companies that are promoting products in the ADHD market, including Shire (Vyvanse, Adderall XR, Intuniv), Janssen (Concerta), Eli Lilly (Strattera), Pfizer (Quillivant XR and QuilliChew ER), Concordia (Kapvay), Noven (Daytrana), Novartis (Focalin XR and Ritalin LA), Tris Pharmaceuticals (Dyanavel XR), Rhodes Pharmaceuticals (Aptensio XR) and related generics. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Shire, Noven, Alcobra, Highland Therapeutics, Sunovion and Neurovance. Tris Pharmaceuticals is also working in this space to reformulate existing methylphenidate and amphetamine medications.

The FDA recently issued revised guidance for bioequivalence testing of extended-release methylphenidate, which makes it more difficult to seek approval on the basis of bioequivalence for new generic products. We believe this will result in limited competition for the generic Concerta market and a new branded, extended-release methylphenidate drug with 12-hour duration of effect, such as Cotempla XR-ODT, if approved, would benefit from the lack of competition. In light of these developments, we believe that along with Concerta and Aptensio XR, Cotempla XR-ODT is positioned to be one of only three branded solid oral dosage formulations of extended-release methylphenidate with 12-hour coverage, and its ODT formulation would offer a unique and patient- and caregiver-friendly dosage form. While two additional generic manufacturers launched generic versions of Concerta, Mallinckrodt in 2011 and KUDCO in 2013, both have lost their AB-rating, are now

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BX-rated, and may no longer be substituted for Concerta. This results in a market with a higher barrier to entry.

GOVERNMENT REGULATION

Government authorities in the United States at the federal, state and local levels and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and ultimately approved by the applicable regulatory authority.

U.S. drug development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its' implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approval and maintaining subsequent compliance with applicable federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during product development, the approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, voluntary product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution injunctions, fines, consent decrees, refusals of government contracts, restitution, disgorgement or civil and criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. For a description of a consent decree our predecessor corporation entered into with the FDA and to which we remain subject, see "Our manufacturing capabilities Overview" and "Risk factors Risks related to commercialization."

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

Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. We intend to submit our NDAs under the 505(b)(2) regulatory approval pathway. Development and approval of drugs generally involves the following:

Submission to the FDA of an IND, which must become effective before clinical trials involving humans may begin;

Approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before a trial may be initiated at that site;

Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations and other good clinical practices, or GCPs;

Submission of an NDA to the FDA;

The FDA's decision within 60 days of its receipt of an NDA to accept it for filing and review;

Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMPs and assure that the

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facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

Possible FDA audit of the clinical trial sites that generated the data in support of the NDA; and

FDA review and approval of the NDA.

The nonclinical testing, clinical trials and review process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. The data required to support an NDA are generated in two distinct developmental stages: nonclinical and clinical. The nonclinical development stage generally involves synthesizing the active component, developing the formulation and control procedures and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which may support subsequent clinical testing in humans. In the case of documentation to support a 505(b)(2) NDA, this nonclinical data may be referenced in literature or the FDA's previous findings of safety and efficacy for a listed drug. The sponsor must submit the results of the nonclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans, and must become effective before clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

The clinical stage of development involves the administration of the product candidate to healthy volunteers and patients under the supervision of qualified investigators, generally physicians not employed by or under the sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB for each institution where the trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each subject or his or her legal representative and must monitor the clinical trial until completed.

Clinical trials

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacology, side effect tolerability and safety of the drug.

Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamics information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

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Phase 3 clinical trials generally involve large numbers of patients at multiple sites and are designed to provide the data necessary to demonstrate the product candidate's safety and effectiveness for its intended use, establish its overall benefit/risk relationship, and provide an adequate basis for approval.

By following the 505(b)(2) regulatory approval pathway, the applicant may reduce some of the burdens of developing a full clinical program by relying on investigations not conducted by the applicant and for which the applicant has not obtained a right of reference, such as prior investigations involving the listed drug. In such cases, some clinical trials may not be required or may be otherwise limited.

Post-approval trials, sometimes referred to as Phase 4, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Before approval, progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or the use of the drug raises any safety concerns. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of all trial-related information, and it is possible that data and other information from trials involving drugs that never garner approval could require disclosure in the future.

Concurrent with clinical trials, companies usually develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing it in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate, and, among other things, a drug manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

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NDA and FDA review process

The results of nonclinical studies and clinical trials, together with other detailed information, including extensive information on manufacturing and drug composition and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. FDA approval of an NDA must be obtained before a drug may be legally marketed in the United States.

Under the PDUFA as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2017, the user fee for an application requiring clinical data, such as an NDA, is $2,038,100. Clinical data, as interpreted by the FDA to assess fees under PDUFA, include (1) study reports or literature reports of what are explicitly or implicitly represented by the applicant to be adequate and well-controlled trials for safety or effectiveness or (2) reports of comparative activity (other than bioequivalence and bioavailability studies), immunogenicity, or efficacy, where those reports are necessary to support a claim of comparable clinical effect. The term does not include bioequivalence and bioavailability studies submitted in support of an NDA. NDAs for which clinical data are not required to demonstrate safety and effectiveness are reduced to half of the amount of the prescribed user fee, or $1,019,050 for 2017. PDUFA also imposes an annual product fee for human drugs ($97,750 per product) and an annual establishment fee ($512,200 per establishment) on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including waiver of the application fee for the first application filed by a small business.

The FDA reviews submitted NDAs before it accepts them for filing, and may request additional information rather than accepting the applications. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for an NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product to specifications. The FDA may also audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation regarding whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers them carefully when making decisions. NDAs submitted under Section 505(b)(2) are typically not referred to an Advisory Panel for consideration unless new safety information is revealed in the review cycle. The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

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After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA, and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial, and other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than the sponsor interprets the same data.

There is no assurance that the FDA will approve a product candidate for marketing, and the sponsor may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or it may condition approval on changes to the proposed labeling. The FDA also may condition approval on the development of adequate controls and specifications for manufacturing and a commitment to conduct post-marketing testing and surveillance to monitor the potential effects of approved products. For example, the FDA may require Phase 4 trials designed to further assess a drug's safety and efficacy.

The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Section 505(b)(2) regulatory approval pathway

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway for approval of a new drug by allowing the FDA to rely on data not developed by the applicant. Specifically, Section 505(b)(2) permits the submission of an NDA where one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and/or the FDA's findings of safety and effectiveness for an approved drug already on the market. Approval or submission of a 505(b)(2) application, like those for abbreviated new drugs, or ANDAs, may be delayed because of patent and/or exclusivity rights that apply to the previously approved drug.

A 505(b)(2) application may be submitted for a new chemical entity, or NCE, when some part of the data necessary for approval is derived from studies not conducted by or for the applicant and when the applicant has not obtained a right of reference. Such data are typically derived from published studies, rather than FDA's previous findings of safety and effectiveness of a previously approved drug. For changes to a previously approved drug however, an applicant may rely on the FDA's finding of safety and effectiveness of the approved drug, coupled with information needed to support the change from the approved drug, such as new studies conducted by the applicant or published data. When based on an approved drug, the 505(b)(2) drug may be approved for all of the indications permitted for the approved drug, as well as any other indication supported by additional data.

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Section 505(b)(2) applications also may be entitled to marketing exclusivity if supported by appropriate data and information. As discussed in more detail below, three-year new data exclusivity may be granted to the 505(b)(2) application if one or more clinical investigations conducted in support of the application, other than bioavailability/bioequivalence studies, were essential to the approval and conducted or sponsored by the applicant. Five years of marketing exclusivity may be granted if the application is for an NCE, and pediatric exclusivity is likewise available.

Orange Book listing and Paragraph IV certification

For NDA submissions, including those under Section 505(b)(2), applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval, each of the patents listed in the application is published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. Any applicant who subsequently files an ANDA or 505(b)(2) NDA that references a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification.

If an applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the holder of the NDA for the approved drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, the applicant's successful defense of the suit, or expiration of the patent.

Pursuant to our settlement agreement with Shire, we stipulated that Shire's two Orange Book-listed patents covering Adderall XR were valid, enforceable and infringed by our 505(b)(2) NDA covering Adzenys XR-ODT and Adzenys XR-ODT itself. The agreement with Shire applies solely with respect to Adzenys XR-ODT.

Pediatric information

Under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation in which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was signed into law on July 9, 2012, amended the FDCA to require that a sponsor who is planning to submit an NDA for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. The initial PSP must include an outline of the pediatric trial(s) that the sponsor plans to conduct, including objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such information and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials. The FDA and the sponsor must reach an agreement on the PSP, but the sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on

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data collected from nonclinical studies, early phase clinical trials and other clinical development programs.

Post-marketing requirements

Following approval, the company and the new product are subject to continuing regulation by the FDA, which include monitoring and recordkeeping activities, reporting of adverse experiences and complying with promotion and advertising requirements, which include prohibitions on the promotion of the drugs for unapproved, or "off-label" uses. Although physicians may prescribe legally available drugs for off-label treatments, manufacturers may not promote such non-FDA approved uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use on an on-going basis. Further, if there are any modifications to the drug, including changes to indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a supplemental NDA or new NDA, which may require the applicant to develop additional data or conduct additional nonclinical studies or clinical trials.

The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. These regulations require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMPs. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic, unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including voluntary recalls and product seizures.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrections to advertising or communications to doctors and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

As a condition of approval for Adzenys XR-ODT, we committed to three post-marketing requirements to evaluate the pharmacokinetic, efficacy and safety of the product in children ages 4 to 5 years of age. We met with FDA officials in January 2017 to further clarify the design of the protocols required to conduct these studies. We will be commencing with the pharmacokinetic trial in 2017.

U.S. marketing exclusivity

The FDCA provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, for a drug product that contains a previously approved NCE if new clinical investigations, other than bioavailability/bioequivalence studies, were essential to the application's approval (*e.g.*, for new indications, dosages or strengths of an existing drug). This three-year exclusivity for new data covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication. Furthermore, this exclusivity will not delay the submission or approval

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of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States, which, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protections or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with a FDA-issued "Written Request." The FDA issues a written request for pediatric clinical trials before approval of an NDA only where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may produce health benefits in that population.

DEA regulation

Because our products and product candidates are subject to the Controlled Substances Act, or CSA, we must comply with various requirements set forth by that legislation, as amended, its implementing regulations and as enforced by the DEA. The CSA imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls, prescription and order form requirements and restrictions on prescription refills for certain kinds of pharmaceutical products. A principal factor for determining the particular requirements of the CSA applicable to a product, if any, is its actual or potential abuse profile. A product may be listed as a Schedule I, II, III, IV or V controlled substance, with Schedule I presenting the highest perceived risk of abuse and Schedule V presenting the least. For example, Schedule I controlled substances have no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision. The active ingredients in our product, hydrocodone, and product candidates, amphetamine and methylphenidate, are Schedule II controlled substances and under various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. 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. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Because our products are, and our product candidates are expected to be, regulated as Schedule II controlled substances, they will be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for

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individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II controlled substance for use in manufacturing of our product and product candidates. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

In addition to federal scheduling, some drugs may be subject to state-controlled substance regulation and thus more extensive requirements than those determined by the DEA and FDA.

Pharmaceutical coverage, pricing and reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor by payor basis. 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 product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for brand-named prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

As noted above, even if we are able to secure regulatory approval, sales of any of our products may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased, and we expect this sentiment will continue to increase the pressure on drug pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable

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coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other healthcare laws and compliance requirements

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the U.S. Department of Justice, the DEA, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

We also are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states 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, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal health care program;

The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from the federal government or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the health care benefit program through false representations or knowingly and willingly falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for, health care benefits or services;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

The provision under the ACA commonly referred to as the Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations; and

State law equivalents of each of the above federal laws, such as the Anti-Kickback Statute and False Claims Act, and state laws concerning security and privacy of health care information, which may differ in substance and application from state-to-state thereby complicating compliance efforts.

The ACA broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud

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statutes contained within 42 U.S.C. Section 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

As noted above, the federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment from federal programs, including Medicare and Medicaid. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for such violations could include three times the actual damages sustained by the government, mandatory civil penalties between $5,500 and $11,000 for each separate false claim, exclusion from participation in federal healthcare programs, and the potential implication of various federal criminal statutes. Private individuals also have the ability to bring actions under the federal False Claims Act, or *qui tam* actions, and certain states have enacted laws based on the federal False Claims Act.

EMPLOYEES

As of December 31, 2016, we employed 134 full-time employees.

AVAILABLE INFORMATION

Our website address is www.neostx.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Alternatively, these reports may be accessed at the SEC's website at www.sec.gov.

CORPORATE INFORMATION

Our predecessor company was incorporated in Texas on November 30, 1994 as PharmaFab, Inc. and subsequently changed its name to Neostx, Inc. On June 15, 2009, we completed a reorganization pursuant to which substantially all of the capital stock of Neostx, Inc. was acquired by a newly formed Delaware corporation, named Neos Therapeutics, Inc. The remaining capital stock of Neostx, Inc. was acquired by us on June 29, 2015, and Neostx, Inc. was merged with and into Neos Therapeutics, Inc. Our principal executive offices are located at 2940 N. Highway 360, Grand Prairie, Texas, 75050, and our telephone number is (972) 408-1300. We completed our initial public offering of common stock July 2015 and our common stock is listed on the NASDAQ Global Market under the symbol "NEOS."

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Item 1A. Risk factors

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

RISKS RELATED TO COMMERCIALIZATION

We are heavily dependent on the success of Adzenys XR-ODT and our product candidates, Cotempla XR-ODT and NT-0201. We have not generated substantial revenues from the sales of Adzenys XR-ODT or any of our product candidates, and we may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate revenues from sales of Adzenys XR-ODT and, if approved, our product candidates. We have only generated revenues from the sale of our generic Tussionex and contract manufacturing, which contract manufacturing operations were discontinued in 2013 and we only commenced commercializing Adzenys XR-ODT in May 2016 and have not generated substantial revenues from product sales of Adzenys XR-ODT. We have not generated any revenues from product sales of our product candidates and have incurred significant operating losses.

Our ability to generate product revenues is dependent on our ability to successfully commercialize Adzenys XR-ODT, our amphetamine extended-release orally disintegrating tablet ("XR-ODT"), and, if approved, our product candidates, Cotempla XR-ODT, our methylphenidate XR-ODT, and NT-0201, our amphetamine XR liquid suspension, for the treatment of attention deficit hyperactivity disorder, or ADHD, and any other product candidates that we may identify and pursue. Our ability to successfully commercialize Adzenys XR-ODT and our product candidates depends on, among other things, our ability to:

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

We anticipate incurring significant costs associated with commercialization of Adzenys XR-ODT and, if approved, our product candidates. It is possible that we will never have sufficient product sales revenues to achieve profitability.

If our sales and marketing efforts for Adzenys XR-ODT are not successful, and if we are unable to establish and maintain sales and marketing capabilities or enter into agreements with third parties to market and sell our other product candidates, if approved, we may be unable to generate significant revenue.

We have only recently completed building an organization for the sale, marketing and distribution of Adzenys XR-ODT, and there is no guarantee that we will be successful in the commercialization of Adzenys XR-ODT, which we only launched in May 2016. We currently have a limited sales history for Adzenys XR-ODT. Additionally, we may need to build additional sales, marketing and distribution capabilities for Cotempla XR-ODT and NT-0201, if they are approved. We must finish building these capabilities for Cotempla XR-ODT and NT-0201, and/or enter into a marketing collaboration with a third party, in order to commercialize Cotempla XR-ODT and NT-0201, if approved. Although we have

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established a focused, specialty sales and marketing organization of approximately 125 representatives to promote our approved products in the United States, these commercialization capabilities for Adzenys XR-ODT have only been recently established. Establishing and developing our sales force in the United States to market Adzenys XR-ODT was expensive and time-consuming and, if additional such resources are needed for Cotempla XR-ODT and NT-0201, doing so for Cotempla XR-ODT and NT-0201 could similarly be expensive and time consuming and could delay the launch of those products, if approved. We cannot be certain that we will reap the benefits of our commercialization efforts of Adzenys XR-ODT compared to its cost, and there is no guarantee that we will be able to successfully develop this capacity for Cotempla XR-ODT and NT-0201, and even if we do, the cost of establishing and maintaining such an organization may exceed the benefit of doing so. Our prior experience in the marketing, sale and distribution of pharmaceutical products is limited to our generic Tussionex, and we have no prior experience in marketing, sale and distribution of branded pharmaceutical products. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals and in the appropriate numbers, generate sufficient sales leads, provide adequate training to sales and marketing personnel, effectively manage a geographically dispersed sales and marketing team and successfully negotiate with managed care and third-party payors. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

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

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

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

Prescription drug advertising, marketing and promotion are subject to federal, state and foreign regulations, which include requirements for direct-to-consumer advertising, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. In the

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United States, prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure they are marketed only for their approved indications and in accordance with the provisions of the approved label. Any promotion for uses or in patient populations not described in the approved labeling, known as "off-label" promotion, is impermissible and could subject us to enforcement actions and significant penalties for off-label marketing.

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

Moreover, the facilities used by us to manufacture Cotempla XR-ODT and NT-0201 will be subject to pre-approval inspections following our submissions, and, in the case of Cotempla XR-ODT, resubmission of our NDAs to the FDA. For example, the FDA conducted a cGMP and pre-approval inspection related to our NDA for Cotempla XR-ODT from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. We implemented corrective action related to this observation and responded to the FDA, and the FDA closed the inspection. 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;

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

suspend or withdraw regulatory approval;

suspend any ongoing clinical trials;

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

seize the product.

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

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

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

The commercial success of Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201, depends upon attaining market acceptance by physicians, patients, third-party payors and the medical community.

To date, we have expended significant time, resources, and effort on the development of Adzenys XR-ODT, Cotempla XR-ODT and NT-0201, and a substantial majority of our resources are now focused on the commercialization in the United States of Adzenys XR-ODT, which commenced on May 16, 2016, and, if approved, the commercial launches of Cotempla XR-ODT and NT-0201 in the second half of 2017. Accordingly, our ability to generate significant product revenue will depend almost entirely on our ability to successfully commercialize Adzenys XR-ODT and to obtain final marketing approval for and successfully commercialize Cotempla XR-ODT and NT-0201. We may not sell Cotempla XR-ODT or NT-0201 in the United States until the FDA grants final marketing approval and, therefore, our planned commercial launch of Cotempla XR-ODT and NT-0201 in the United States could experience unanticipated delays or problems and may be prohibited altogether.

Our ability to successfully commercialize Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201 will depend on, among other things, our ability to:

establish relationships with third-party suppliers for the active pharmaceutical ingredient ("API"), in Adzenys XR-ODT, Cotempla XR-ODT and NT-0201;

manufacture and produce, through a validated process, sufficiently large quantities and inventory of Adzenys XR-ODT, Cotempla XR-ODT and NT-0201 to permit successful commercialization;

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

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

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

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

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

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

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

In addition, we have begun, and will need to continue, investing substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel to support the commercialization of Adzenys XR-ODT which commenced on May 16, 2016, and, if approved, the planned commercial launch of Cotempla XR-ODT and NT-0201. We have committed and will continue to commit these additional resources prior to obtaining final approval of any of Cotempla XR-ODT or NT-0201 from the FDA. If we are unable to successfully obtain final FDA approval of any of our product candidates or complete these activities, or experience unanticipated delays or problems, our costs could substantially increase and our business, financial condition and results of operations will be adversely affected. In addition, we have certain revenue expectations with respect to the sale of Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201. If we cannot successfully commercialize and achieve those revenue expectations with respect to Adzenys XR-ODT and, if approved, Cotempla XR-ODT and NT-0201, our anticipated revenues and liquidity will be materially adversely impacted.

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

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

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and

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other research institutions. For example, amphetamine XR is currently marketed in the United States by Shire under the brand name Adderall XR and Tris Pharmaceuticals, or Tris, under the brand name Dyanavel XR, a liquid suspension, and methylphenidate is marketed in the United States by Janssen under the brand name Concerta, by Pfizer under the brand name Quillivant XR, a reconstituted liquid suspension, and QuilliChew ER, a chewable formulation, Rhodes Pharmaceuticals under the brand name Aptensio XR, a capsule, and by Novartis under the brand names Focalin XR and Ritalin LA. Further, makers of branded drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Shire, Noven, Alcobra, Highland Therapeutics, Sunovian and Neurovance.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our XR-ODT or XR liquid suspension, or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our products, or the nonclinical studies or clinical trials that support their approval, contain deficiencies or that new regulatory requirements be placed on the product candidate or drug class of the product candidate. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

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

- the ability to commercialize and market any of our products and product candidates that receive regulatory approval;
- the price of our product and product candidates that receive regulatory approval, including in comparison to branded or generic competitors;
- the efficacy and safety of our product and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our product and product candidates that receive regulatory approval;
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other healthcare providers;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicaid and Medicare; and
- the ability to protect intellectual property rights related to our product and product candidates.

If our competitors market products that are more effective, safer or less expensive than our product, if any, or that reach the market sooner than our products, if any, we may enter the market too

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

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

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

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

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

For example, on July 25, 2016, we received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an ANDA with the FDA for a generic version of Adzenys XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Adzenys XR-ODT. On September 1, 2016, we filed a patent infringement suit in federal district court against Actavis and related parties. While our lawsuit automatically stayed, or barred, the FDA from approving Actavis' ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier, such litigation is often time-consuming and costly, and may result in generic competition if our patents are not upheld or if Actavis is found not to infringe our patents. While we intend to vigorously enforce our intellectual property rights relating to Adzenys XR-ODT, we cannot guarantee a favorable outcome of those proceedings and we anticipate incurring increasing amounts of legal fees in the enforcement of such rights.

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

We are subject to extensive regulation in connection with the preparation and manufacture of our products, product candidates and potential product candidates for clinical trials and commercial sale. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMPs and equivalent foreign standards. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products and product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and NT-0201, as well as any of our future potential product candidates, are highly regulated processes and technically complex. We, along with our third-party suppliers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. For instance, because each of Adzenys XR-ODT, Cotempla XR-ODT and NT-0201 is a regulated drug product and subject to DEA regulation, we have had to, and will continue to, need to secure state licenses from each state in which we intend to sell such product allowing us to distribute a regulated drug product in such state.

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

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

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For our approved products, we must comply with the requirements of the Drug Supply Chain Security Act, which outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

For our approved drugs, we must comply with the requirements of the Drug Supply Chain Security Act, including those related to product tracing, verification, and authorized trading partners. Signed into law on November 27, 2013, the Drug Supply Chain Security Act amended the Federal Food, Drug, and Cosmetic Act and is being implemented over a ten-year period. The law's requirements include the ability to quarantine and promptly investigate suspect product, such as potentially counterfeit, diverted or stolen product, to determine if it is illegitimate, and notify our trading partners and FDA of any illegitimate product. By November 27, 2017, we will be required to place a unique product identifier on prescription drug packages. This identifier consists of the National Drug Code, serial number, lot number and expiration date, in the form of a 2-dimensional data matrix barcode that can be easily read electronically. If our drug products fail to bear this unique product identifier, they would be misbranded under the Federal Food, Drug, and Cosmetic Act and our drug products may not be accepted into the supply chain.

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

Our approved NDA for Adzenys XR-ODT, and the NDAs we plan to resubmit for Cotempla XR-ODT and submit for NT-0201, include our proposed manufacturing process for each product candidate. Any change to our manufacturing process, facilities or suppliers could require that we supplement our approved NDA and amend any pending NDA. Also, because of our proprietary processes for manufacturing our product candidates, we cannot immediately transfer manufacturing activities for Adzenys XR-ODT, Cotempla XR-ODT, NT-0201 or our generic Tussionex to an alternate supplier, and a change of facilities would be a time-consuming and costly endeavor. This would also require us to supplement or amend our NDA filings to include the change of manufacturing site.

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

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our products and product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable

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prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of Adzenys XR-ODT, our generic Tussionex and, if approved, our branded product candidates and clinical trials of future potential product candidates, may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

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

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

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

Manufacturers of pharmaceutical products need to comply with cGMP requirements enforced by the FDA through their facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. We may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such products or product candidate or

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successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates. The FDA conducted a cGMP and pre-approval inspection related to our NDA for Cotempla XR-ODT from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. We implemented corrective action related to this observation and responded to the FDA, and the FDA closed the inspection.

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

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

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

Our Grand Prairie facility was formerly operated by our predecessor, PharmaFab, Inc., or PharmaFab. In April 2007, the FDA announced entry of a Consent Decree of Permanent Injunction, or the Consent Decree, against PharmaFab, one of its subsidiaries and two of its officials, including Mark Tengler, a former officer of ours who was, at the time, PharmaFab's president, and Russ McMahen, our Vice President of Scientific Affairs, who held a similar position at the time with PharmaFab, or jointly, the Defendants. The Consent Decree arose out of several perceived cGMP deficiencies related to the manufacture of unapproved drugs or Drug Efficacy Study Implementation ("DESI"), drugs that we no longer manufacture. Pursuant to the Consent Decree, the Defendants were permanently restrained and enjoined from directly or indirectly manufacturing, processing, packing, labeling, holding or distributing any prescription drugs that are not the subject of an NDA or an abbreviated NDA. Among other things, the Consent Decree also granted the FDA the ability to, without prior notice, inspect PharmaFab's place of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of the Consent Decree. The FDA has inspected the Grand Prairie facility several times since the Consent Decree was entered, and we have been able to manufacture and ship our generic Tussionex, Adzenys XR-ODT and drug products for our clinical

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trials. Although we have concluded the annual audit program prescribed by the Consent Decree entered into by our predecessor, our facilities may be inspected by the FDA at any time as a result of the Consent Decree. Although for our most recent annual audit by the cGMP expert in November 2014, the expert concluded that our corrective actions satisfactorily addressed the observations noted in its report, on May 22, 2015, the FDA's Dallas District Office identified three ongoing cGMP deviations in our response to the audit related to batch failure investigations, quality control unit procedures, and in-process specifications. We implemented corrective actions and submitted additional information in our response to the FDA pursuant to the Consent Decree and the FDA closed the matter. Although we may apply for relief from the Consent Decree in the future, there is no guarantee that such relief will be granted or that we will be in compliance with the requirements of the Consent Decree.

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

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

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

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

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

All of our manufacturing capabilities are housed in our sole manufacturing 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

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and manufacture our product candidates or products for some period of time. The inability to manufacture our products and product candidates if our facility or our equipment is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facility and the equipment we use to manufacture our products and product candidates could become damaged and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility or repair or replace our equipment or license or transfer our proprietary technology to a third-party, particularly in light of the requirements for a DEA-registered manufacturing and storage facility like ours. If we are required to change or add a new manufacturer or supplier, the process would likely require prior FDA, DEA and/or equivalent foreign regulatory authority approval, and would be very time consuming. Even in the unlikely event we are able to find a third party with such qualifications to enable us to manufacture our products or product candidates, we may be unable to negotiate commercially reasonable terms.

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

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

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

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

Amphetamine, methylphenidate and hydrocodone are listed by the DEA as a Schedule II controlled substance under the Controlled Substances Act ("CSA"). The DEA classifies substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, distribution and physician prescription procedures. For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. In addition to federal scheduling, some drugs may be subject to state-controlled substance laws and regulations and more extensive requirements than those

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determined by the DEA and FDA. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may schedule products separately. While some states automatically schedule a drug when the DEA does so, other states require additional state rulemaking or legislative action, which could delay commercialization.

Entities must register annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, including those for thefts or losses of any controlled substances, and to obtain authorization to destroy any controlled substances.

Registered entities also must follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Security requirements vary by controlled substance schedule with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration. The DEA also has a production and procurement quota system that controls and limits the availability and production of Schedule I or II controlled substances. If we or any of our suppliers of raw materials that are DEA-classified as Schedule I or II controlled substances are unable to receive any quota or a sufficient quota to meet demand for our products, if any, our business would be negatively impacted.

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

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

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

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

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

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

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

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

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

The new presidential administration has indicated that enacting changes to the Affordable Care Act is a legislative priority, and has discussed repealing and replacing the Affordable Care Act or amending the Affordable Care Act. We do not know at this time what implications such changes, if enacted, would have on the Affordable Care Act's current requirements or on our future business. Changes to the Affordable Care Act or other existing health care regulations could significantly impact our business and the pharmaceutical industry.

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

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

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

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In

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addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

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

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

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

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

For our product and any product candidates that obtain regulatory approval and are marketed in the United States, our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to health information privacy

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and security regulation by U.S. federal and state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

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

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

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

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

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

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

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

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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 face even greater risks upon any commercialization by us of our products and product candidates. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products.

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

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

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

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

Our business and future success are substantially dependent on our ability to timely obtain regulatory approval for and commercialize our product candidates, Cotempla XR-ODT and NT-0201, for the treatment of ADHD, and any other product candidates that we may identify and pursue. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. Satisfaction of regulatory requirements can be protracted, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. For example, on November 10, 2015, we announced that we received a Complete Response Letter from the FDA for our NDA for Cotempla XR-ODT. We will need to satisfactorily address the deficiencies the FDA identified or may identify in the future in order to obtain the FDA's approval of our NDA. We cannot predict whether we will obtain regulatory approval to commercialize our product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any delay or setback in the regulatory approval or commercialization of any of these product candidates could adversely affect our business.

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

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

- could determine that we cannot rely on the 505(b)(2) regulatory approval pathway for Cotempla XR-ODT, NT-0201 or any other product candidate that we may identify and develop;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate safety and effectiveness of any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the safety risks outweigh clinical and other benefits of our product candidates;
- may require us to conduct additional bioequivalence studies to demonstrate that the proposed commercial product is bioequivalent to the batch used in clinical trials;
- may disagree with our trial design or our interpretation of data from nonclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we inappropriately relied on a certain listed drug or drugs for our 505(b)(2) NDA or that approval of our applications for Cotempla XR-ODT, NT-0201 or any other product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the API used in our product candidates;
- may identify deficiencies in our own manufacturing processes or our proposed scale-up of the manufacturing processes or facilities for the production of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

For example, on October 16, 2015, we received notification from the FDA stating that, as part of its ongoing review of our NDA for Cotempla XR-ODT, it had identified deficiencies that precluded discussion of labeling and post marketing requirements or commitments at that time. On November 10, 2015, we announced that we received a Complete Response Letter from the FDA, which requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. On July 28, 2016, we announced that we had completed the

bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. On December 20, 2016, we announced that we had resubmitted an NDA for Cotempla XR-ODT, our methylphenidate XR-ODT, following the completion of a bioequivalence bridging study. We have a PDUFA goal date of June 19, 2017 for Cotempla XR-ODT. However, if we are unable to satisfactorily address the agency's concerns, the FDA could deny approval of our NDA for Cotempla XR-ODT.

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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.

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 Annual Report on Form 10-K. 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 have been and 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

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referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

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

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

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

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

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

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our reputation may suffer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

lack of adequate funding to continue the clinical trial.

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

Positive results in nonclinical studies and clinical trials of any of our product candidates may not be predictive of similar results in future clinical trials. Also, interim results during a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from any completed nonclinical studies and clinical trials for any of our product candidates may not be predictive of the results we may obtain in later stage trials. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products. For example, On November 10, 2015, we announced that we received a Complete Response Letter from the FDA, which requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. Although results in this study

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confirmed results from earlier studies, results from our previous clinical trials may not be predictive of similar results in any future bridging studies.

RISKS RELATED TO OUR BUSINESS AND FINANCIAL POSITION

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

Our company has limited operating history commercializing branded products. To date, we have focused primarily on developing Adzenys XR-ODT and our product candidates, Cotempla XR-ODT and NT-0201. Adzenys XR-ODT requires substantial additional resources as we implement commercialization strategies and begin generating revenue from product sales. In addition, our product candidates will require substantial additional resources before we will be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales, if approved. There can be no assurance that any of our product candidates will ever achieve regulatory approval or generate any revenue. We do not anticipate generating substantial revenue from sales of Adzenys XR-ODT, or any revenue from sales of Cotempla XR-ODT, NT-0201 or any of our other product candidates in the near term, if ever. We have incurred significant net losses of $83.3 million for the year ended December 31, 2016, and $30.8 million and $20.8 million for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $200.1 million. We have devoted most of our financial resources to implementation of our commercialization strategies, 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 operate a specialty sales force and commercialization infrastructure. Our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to the clinical trials we have already completed. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

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

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

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

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

- the costs of establishing and operating sales, marketing, distribution and commercial manufacturing capabilities for Adzenys XR-ODT and, if approved, Cotempla XR-ODT, NT-0201 and any other potential product candidates;
- our ability to successfully commercialize Adzenys XR-ODT and, if approved, to successfully launch Cotempla XR-ODT and NT-0201, and to continue to increase the level of sales in the marketplace;
- the timing of any regulatory approvals of Cotempla XR-ODT and NT-0201;
- the rate of progress and cost of our trials and other product development programs for our other potential product candidates;
- the costs and timing of in-licensing additional product candidates or acquiring other complementary technologies, assets or companies;
- the actions of our competitors and their success in selling competitive product offerings; and
- the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

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

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

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

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

On May 11, 2016, we entered into a $60 million senior secured credit facility with Deerfield as lender. Approximately $33 million of the proceeds was used to repay the existing senior and subordinated debt that was otherwise payable in 2016 and 2017. Principal on the new debt is due in three equal annual installments beginning in May 2019 and continuing through May 2022, with a final payment of principal, interest and all other obligations under the facility due on May 11, 2022. Interest is due quarterly beginning in June 2016, at a rate of 12.95% per year. All obligations under our credit facility are secured by substantially all of our existing property and assets subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing

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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 December 31, 2016, we had an accumulated deficit of $200.1. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to develop and seek marketing approval for our product candidates. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our credit facility with Deerfield. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations, finance our operations, our research and development efforts and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail or eliminate one or more of our programs.

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

Our quarterly operating results may fluctuate significantly.

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

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

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

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

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

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

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

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

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. At the end of 2015, a significant deficiency was noted with regards to Information Technology General Controls, or ITGC. Based on implementation of a SOX compliance program during 2016, the deficiency was remediated. We have established an annual SOX Risk Assessment and Control Effectiveness Test Cycle that is designed to timely identify deficiencies to management for remediation to comply with Section 404 of the Sarbanes-Oxley Act. We may discover additional deficiencies in our internal controls over financial reporting, including those identified through testing conducted by us in connection with Section 404 of the Sarbanes-Oxley Act. Such deficiencies may be deemed to be significant deficiencies or material weaknesses that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further remedial action. Failures of internal controls could also cause

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investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

Due to legal standards relating to patentability, validity, enforceability and scope of claim, patents covering pharmaceutical and biotechnology inventions involve complex legal, scientific and factual questions. Formulation of drug products such as ours with complex release profiles is an area of intense research, publishing and patenting, which limits the scope of any new patent applications. As a result, our ability to obtain, maintain and enforce patents is uncertain and any rights under any existing patents, or any patents we might obtain or license, may not provide us with sufficient protection for our products and product candidates to afford a commercial advantage against competitive products or processes. The patent applications that we own may fail to result in issued patents in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge their

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patentability, validity (e.g., by discovering previously unidentified prior art, or a patent-barring event such as a prior public disclosure, use, sale or offer for sale of the invention), enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. For example, U.S. patents may be challenged by third parties via *inter partes* review, post grant review, derivation or interference proceedings at the USPTO, and European patents may be challenged via an opposition proceeding at the European Patent Office. Furthermore, if we were to assert our patent rights against a competitor, the competitor could challenge the validity and/or enforceability of the asserted patent rights. Although a granted U.S. patent is entitled to a statutory presumption of validity, its issuance is not conclusive as to its validity or its enforceability, and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products.

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

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

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

For example, on July 25, 2016, we received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an ANDA with the FDA for a generic version of Adzenys XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Adzenys XR-ODT. A paragraph IV certification is a certification by a generic applicant that in the opinion of that applicant, the patent(s) listed in the Orange Book for a branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product. On September 1, 2016, we filed a patent infringement suit in federal district court against Actavis and related parties. While such lawsuit automatically stayed, or barred, the FDA from approving Actavis' ANDA for 30 months or until a district court decision that is adverse to the asserted patents, such litigation is often time-consuming and costly and its outcome would be unpredictable. We

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intend to vigorously enforce our intellectual property rights relating to Adzenys XR-ODT, and we anticipate incurring increasing amounts of legal fees in the enforcement of such rights. We would expect to face generic competition for our Adzenys XR-ODT product if such patents are not upheld or if Actavis is found not to infringe such patents. The resulting loss of exclusivity would impact pricing and our sales of Adzenys XR-ODT, which could have a material adverse impact on our business.

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

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

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

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

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

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to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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non-refundable license fee no later than thirty days after receiving such approval and are required to pay a single-digit royalty on net sales of Adzenys XR-ODT during the life of Shire's patents. In addition, on January 26, 2017, we sent a letter to Shire, notifying Shire that we have made a Paragraph IV certification to the FDA that in our opinion and to the best of our knowledge, the patents owned by Shire that purportedly cover our NT-0201 product candidate are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of NT-0201. On March 6, 2017, we entered into a license agreement with Shire, pursuant to which Shire granted us a non-exclusive license to certain patents owned by Shire for certain activities with respect to NT-0201. Under the terms of the agreement, we must pay a lump sum, non-refundable license fee of an amount less than $1.0 million due no later than thirty days after receiving regulatory approval by the FDA of our NDA for NT-0201. We will also pay a single digit royalty on net sales of the NT-0201 during the life of the relevant Shire patents. Additionally, the license agreement contains a covenant from Shire not to file a patent infringement suit against us alleging that NT-0201 infringes the Shire patents.

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

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

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

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

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

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or

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defending against such claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATED TO OUR COMMON STOCK

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

The trading price of our common stock is likely to be volatile. Since shares of our common stock were sold in our initial public offering ("IPO"), in July 2015 at a price of $15.00 per share, our stock price has ranged from $4.85 to $28.99, through March 10, 2017. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

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

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

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

additions or departures of key scientific or management personnel;

changes in the market valuations of similar companies;

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

trading volume of our common stock.

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

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

As of December 31, 2016, our executive officers, directors, 5% or greater stockholders and their affiliates, including shares purchased in the IPO by members of that group and their affiliated entities, beneficially own approximately 53% of our outstanding voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. Shares held by our affiliates will be subject to volume limitations and other conditions pursuant to Rule 144 of the Securities Act. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period also became eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

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

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

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in the Annual Report on Form 10-K and our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) in 2020, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior March 31st, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

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

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

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

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

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

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

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

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limiting the removal of directors by the stockholders;

creating a classified board of directors;

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

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

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

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

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

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

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our corporate headquarters are located in Grand Prairie, Texas, where we lease approximately 97,282 square feet of office, laboratory and manufacturing space. Our lease expires on December 31, 2024, with an option to extend. We believe our current office, laboratory and manufacturing space is sufficient to meet our needs until the expiration of the lease. In addition, we executed a 60-month lease for 6,078 square feet of office space in Blue Bell, Pennsylvania for our commercial operations which commenced on May 1, 2016 and which has an option to extend for 60 months. We may seek to negotiate new leases or evaluate additional or alternate space to accommodate operations relating to commercialization. We believe that appropriate alternative space is readily available on commercially reasonable terms.

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ITEM 3. Legal Proceedings

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

On July 25, 2016, we received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Adzenys XR-ODT. On September 1, 2016, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Actavis, Inc. This case alleges that Actavis infringed our Adzenys XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Adzenys XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Actavis's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. We intend to vigorously enforce our intellectual property rights relating to Adzenys XR-ODT. We cannot predict the timing or outcome of these proceedings.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for our Common Stock

Our common stock has been listed on the NASDAQ Global Market under the symbol "NEOS" since July 23, 2015. Prior to that date, there was no public trading market for our common stock. Our initial public offering was priced at $15.00 per share on July 22, 2015. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

	High	Low
Third Quarter (from July 23, 2015 to September 30, 2015)	$ 28.99	$ 16.12
Fourth Quarter (from October 1, 2015 to December 31, 2015)	$ 21.70	$ 11.53
First Quarter (from January 1, 2016 to March 31, 2016)	$ 7.57	$ 15.20
Second Quarter (from April 1, 2016 to June 30, 2016)	$ 7.15	$ 11.40
Third Quarter (from July 1, 2016 to September 30, 2016)	$ 6.33	$ 9.99
Fourth Quarter (from October 1, 2016 to December 31, 2016)	$ 9.23	$ 5.30

On December 30, 2016, the last trading day of 2016, the last reported sale price of our common stock on the NASDAQ Global Market was $5.85 per share. As of March 10, 2017, there were 22,560,635 shares of common stock outstanding, held by approximately 81 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

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Dividends

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 Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, 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.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is included in Item 11 of Part III of this Annual Report on Form 10-K.

Performance Graph

The following stock performance graph illustrates a comparison of the total cumulative stockholder return on our common stock to two indices; the NASDAQ Composite Index and the NASDAQ Biotechnology Index since July 23, 2015, which is the date our common stock first began trading on the NASDAQ Global Market. The graph assumes an initial investment of $100 at the initial public offering price to the public for Neos stock of $15 on July 23, 2015 or at June 30, 2015 if invested in the indices, and all dividends, if any, were reinvested. No cash dividends have been declared or paid on our common stock. Stockholder return over the indicated period should not be considered indicative of future stockholder returns.

COMPARISON OF 17 MONTH CUMULATIVE TOTAL RETURN*

Amoung Neos Therapeutics, Inc., the NASDAQ Composite Index
and the NASDAQ Biotechnology Index

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Recent Sales of Unregistered Securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

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

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

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Shares purchased in the fourth quarter of 2016 are as follows:

Period	Total Number of Shares Purchased(1)	Average Price Paid per Share
October 1 - 31, 2016	9,709	$ 6.37
November 1 - 30, 2016		
December 1 - 31, 2016		
Total	9,709	$ 6.37

(1) Represents shares withheld to satisfy tax withholding amounts due from an employee related to the vesting of restricted stock.

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ITEM 6. Selected Consolidated Financial Data

The following selected consolidated statements of operations data for the years ended December 31, 2016, 2015, and 2014, and the balance sheet data as of December 31, 2016 and 2015 are derived from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected historical financial data for the year ended December 31, 2013 and as of December 31, 2014 and December 31, 2013 have been derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. You should read this data together with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K and the information under the caption "Item 7. 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.

Consolidated Statements of Operations Data:

	Year ended December 31,			
	2016	**2015**	**2014**	**2013**
	(in thousands, except per share data)			
Total Revenue(1)	$ 9,154	$ 3,792	$ 758	$ 1,044
Cost of Goods Sold	11,437	5,929	3,391	2,534
Research and Development	12,207	11,691	10,574	9,974
Selling and Marketing Expenses(1)	49,291	5,672	229	153
General and Administrative Expenses	12,625	7,078	5,036	5,471
Interest and Other Expense (Income)	6,927	4,203	2,377	1,512
Net Loss from Continuing Operations(1)	$ (83,333)	$ (30,781)	$ (20,849)	$ (18,600)
Loss from Discontinued Operations				(437)
Net Loss(1)	$ (83,333)	$ (30,781)	$ (20,849)	$ (19,037)
Preferred Stock Accretion to Redemption Value		(1,169)	(1,118)	(1,227)
Preferred Stock Dividends		(1,221)	(2,185)	(2,185)
Net Loss Attributable to Common Stock	$ (83,333)	$ (33,171)	$ (24,152)	$ (22,449)
Net Loss per Share B*asic and Diluted(2)*	$ (5.19)	$ (4.38)	$ (27.56)	$ (28.45)
Shares Used to Compute Net Loss per Share *Basic and Diluted(2)*	16,052,390	7,581,881	876,318	788,964

(1) We began marketing Adzenys XR-ODT on May 16, 2016, and has determined that at this time it cannot reliably estimate expected returns of the product at the time of shipment to wholesalers. Accordingly, we defer recognition of revenue and related cost of goods sold on product shipments of Adzenys XR-ODT until the right of return no longer exists, which occurs at the earlier of the time Adzenys XR-ODT units are dispensed through patient prescriptions or expiration of the right of return. Thus, the amounts included in Total Revenue and Net Loss from Continuing Operations for Adzenys XR-ODT reflect only patient prescriptions dispensed to date. Also, the Selling and Marketing Expenses and Net Loss amounts in 2016 reflect the sales and marketing expenses associated with the commercialization of Adzenys XR-ODT.

(2)

See Note 3 to the notes to our audited financial statements included elsewhere in this Annual Report on Form 10-K for an explanation of the calculations of our basic and diluted net loss per common share.

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Consolidated Balance Sheet Data:

	December 31,			
	2016	2015	2014	2013
	(in thousands)			
Cash and Cash Equivalents	$ 24,352	$ 90,763	$ 13,343	$ 11,947
Short-Term Investments	15,430		3,000	7,497
Working Capital	33,624	82,306	13,380	14,303
Total Assets	80,142	122,510	45,230	41,878
Long Term Debt, net of Current Portion(1)	58,599	26,271	23,121	16,454
Warrant Liability(2)			1,789	
Redeemable Convertible Preferred Stock(3)			90,149	70,836
Stockholders' Equity (Deficit)	(1,548)	78,374	(78,782)	(54,844)

1) On May 11, 2016, we entered into a $60 million senior secured credit facility ("Facility") with Deerfield Private Design Fund III, L.P. ($66^{2}/_{3}$% of loan) and Deerfield Special Situations Fund, L.P. ($33^{1}/_{3}$% of Loan) ("Deerfield"), as lenders. See Note 11 to the notes to our audited financial statements included elsewhere in this Annual Report on Form 10-K for further details.

(2) Upon closing the IPO, the warrants issued in conjunction with the Series C preferred stock financing were exchanged in a cashless exercise for 947,185 shares of Series C preferred stock which converted into 78,926 shares of our common stock. The remaining Series C warrants issued with the senior debt to purchase 170,000 pre-split shares of Series C preferred stock, or the Hercules Warrants, were converted into warrants to purchase 70,833 shares of our common stock and the warrant liability was reclassified to Additional Paid in Capital within Stockholders' Equity (Deficit).

(3) On the closing of the IPO, all outstanding shares of redeemable preferred stock converted into 9,217,983 shares of common stock and all remaining outstanding Series C warrants issued in conjunction with purchases of Series C preferred stock were net exercised at the IPO price for 78,926 shares of common stock. Upon the closing of our IPO, all of the shares of our redeemable convertible preferred stock were retired and cancelled and shall not be reissued as shares of such series, and all rights and preferences of those shares of redeemable convertible preferred stock were cancelled, including the right to receive undeclared accumulated dividends.

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ITEM 7. 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 "Item 6. Selected Consolidated Financial Data" and the consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K. 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 "Item 1A. Risk Factors" or in other parts of this Annual Report on Form 10-K.

OVERVIEW

We are a pharmaceutical company focused on developing, manufacturing and commercializing products utilizing our proprietary modified-release drug delivery technology platform, which we have already used to develop Adzenys XR-ODT and our two product candidates for the treatment of attention deficit hyperactivity disorder ("ADHD"). Our product and product candidates are extended-release ("XR"), medications in patient-friendly, orally disintegrating tablets ("ODT"), or liquid suspension dosage forms. Our proprietary modified-release drug delivery platform has enabled us to create novel, extended-release ODT and liquid suspension dosage forms. We received approval from the U.S. Food and Drug Administration ("FDA"), for Adzenys XR-ODT, our amphetamine XR-ODT, on January 27, 2016 and launched the commercialization of this product on May 16, 2016.

On November 10, 2015, we announced that we received a Complete Response Letter from the FDA in its review of our New Drug Application, or NDA, for Cotempla XR-ODT, which required us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. Cotempla XR-ODT is the provisionally accepted trade name of our methylphenidate XR-ODT. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. We resubmitted an NDA for Cotempla XR-ODT on December 20, 2016 and have a Prescription Drug User Fee Act, or PDUFA, goal date of June 19, 2017.

In addition, on November 17, 2016, we submitted an NDA for NT-0201, our amphetamine XR liquid suspension for which we have a PDUFA goal date of September 15, 2017. Pending FDA approval, we plan to launch Cotempla XR-ODT and NT-0201 in the fall of 2017.

We believe Adzenys XR-ODT is and, if approved, Cotempla XR-ODT will be the first amphetamine XR-ODT and the first methylphenidate XR-ODT, respectively, for the treatment of ADHD on the market. On July 25, 2016, we received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Adzenys XR-ODT. On September 1, 2016, we filed a patent infringement lawsuit in federal district court against Actavis. This case alleges that Actavis infringed our Adzenys XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Adzenys XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Actavis's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. We intend to vigorously enforce our intellectual property rights relating to Adzenys XR-ODT. We are unable to predict the timing or outcome of these proceedings at this time. We anticipate incurring increasing amounts of legal fees in the enforcement of our intellectual property rights.

We are commercializing Adzenys XR-ODT and plan to commercialize our product candidates in the United States using our own commercial infrastructure. We are manufacturing Adzenys XR-ODT, and, if approved, intend to manufacture Cotempla XR-ODT and NT-0201 in our current Good

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Manufacturing Practice ("cGMP") and U.S. Drug Enforcement Administration ("DEA")-registered manufacturing facilities, thereby obtaining our products at cost without manufacturer's margins and better controlling supply quality and timing. We also currently use these facilities to manufacture our generic equivalent to the branded product, Tussionex, an XR liquid suspension of hydrocodone and chlorpheniramine indicated for the relief of cough and upper respiratory symptoms of a cold.

Our predecessor company was incorporated in Texas on November 30, 1994 as PharmaFab, Inc. and subsequently changed its name to Neostx, Inc. On June 15, 2009, we completed a reorganization pursuant to which substantially all of the capital stock of Neostx, Inc. was acquired by a newly formed Delaware corporation, named Neos Therapeutics, Inc. The remaining capital stock of Neostx, Inc. was acquired by us on June 29, 2015, and Neostx, Inc. was merged with and into Neos Therapeutics, Inc. Historically, we were primarily engaged in the development and contract manufacturing of unapproved or Drug Efficacy Study Implementation ("DESI"), pharmaceuticals and, to a lesser extent, nutraceuticals for third parties. The unapproved or DESI pharmaceuticals contract business was discontinued in 2007, and the manufacture of nutraceuticals for third parties was discontinued in March 2013.

Since our reorganization in 2009, we have devoted substantially all of our resources to funding our manufacturing operations and to our product candidates which consist of implementation of our commercialization strategies, research and development activities, clinical trials for our product candidates, the general and administrative support of these operations and intellectual property protection and maintenance. Prior to our initial public offering of our common stock in July 2015, we funded our operations principally through private placements of our common stock, redeemable convertible preferred stock, bank and other lender financings and through payments received under collaborative arrangements.

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

We have incurred significant losses in each year since our reorganization in 2009. Our net losses were $83.3 million, $30.8 million and $20.8 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016 and December 31, 2015, we had an accumulated deficit of approximately $200.1 million and $116.8 million, respectively. We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

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

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On July 28, 2015, we closed our initial public offering ("IPO"), whereby we sold 5,520,000 shares of common stock, at a public offering price of $15.00 per share, which includes 720,000 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the IPO price on July 23, 2015. The net proceeds from our IPO, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $75.0 million. The securities described above were offered by us pursuant to a registration statement on Form S-1 declared effective by the SEC on July 22, 2015.

On May 11, 2016, we entered into a $60 million senior secured credit facility ("Facility") with Deerfield Private Design Fund III, L.P. ($66^{2}/_{3}$% of loan) and Deerfield Special Situations Fund, L.P. ($33^{1}/_{3}$% of Loan) ("Deerfield"), as lenders. Approximately $33 million of the proceeds was used to prepay the existing senior and subordinated debt (the "Note") that was otherwise payable in 2016 and 2017. Principal on the new debt is due in three equal annual installments beginning in May 2019 and continuing through May 2021, with a final payment of principal, interest and all other obligations under the facility due May 11, 2022. Interest is due quarterly beginning in June 2016, at a rate of 12.95% per year. We have an option to defer payment of each of the first four interest payments until June 1, 2017. We exercised the option to defer the first three interest payments during the year ended December 31, 2016 and exercised the option to defer the fourth interest payment due March 1, 2017 on February 6, 2017, adding such amounts to the outstanding loan principal until they are paid on June 1, 2017.

On August 1, 2016, we filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale by us of up to an aggregate of $125.0 million of our common stock, preferred stock, debt securities, warrants and/or units (the "Shelf"). We simultaneously entered into a Sales Agreement with Cowen and Company, LLC, as sales agent, to provide for the offering, issuance and sale by us of up to $40.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf (the "ATM Facility"). The Shelf was declared effective by the SEC on August 12, 2016. Pursuant to the Shelf, the Company closed an underwritten public offering of 5,000,000 shares of its common stock at a public offering price of $5.00 per share, before underwriting discounts and commissions, on February 8, 2017. In addition, on February 17, 2017, the underwriters elected to exercise their option in full to purchase up to an additional 750,000 shares of common stock at the $5.00 per share public offering price, less underwriting discounts and commissions. The net proceeds to the Company from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company were approximately $26.8 million. During the year ended December 31, 2016, we did not make any sales under our ATM Facility.

We may continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funds will be available on terms favorable to us, if at all, or that we will be able to successfully commercialize our product candidates. In addition, we may not be profitable even if we succeed in commercializing Adzenys XR-ODT and, if approved, any of our product candidates.

FINANCIAL OPERATIONS OVERVIEW

Revenue

Our revenue is generated primarily from product sales of our generic Tussionex recorded on a net sales basis. We launched commercialization of Adzenys XR-ODT on May 16, 2016. We sell our products to drug wholesalers in the United States. We have also established indirect contracts with drug, food and mass retailers that order and receive our generic Tussionex product through wholesalers. As a result of our acquisition of all of the rights to commercialize and derive future profits from the Tussionex ANDA, and the commercial launch of Adzenys XR-ODT, we expect our future revenue to increase from historical levels.

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

We expect the number of prescriptions filled for Adzenys XR-ODT to continue to increase in 2017 and in subsequent years. Data from IMS shows 1,050 prescriptions reported for the period from the May 16, 2016 launch date through June 30, 2016, 8,959 prescriptions filled during the three months ended September 30, 2016 and 20,330 prescriptions filled during the three months ended December 31, 2016, for a total of 30,339 total prescriptions. Monthly prescriptions filled have continued to increase since the launch. These prescriptions generated $8.2 million in gross sales in 2016, of which $5.5 million was in the fourth quarter of 2016. We captured a 0.1% share of the ADHD market in the fourth quarter of 2016.

In the future, we will seek to generate additional revenue from product sales of Adzenys XR-ODT and, if approved, our two late-stage branded product candidates. We do not expect to generate any significant revenue unless or until we commercialize our product candidates. We have little Adzenys XR-ODT sales history and have determined that at this time we cannot reliably estimate expected returns of the product at the time of shipment to wholesalers. Accordingly, we defer recognition of revenue on product shipments of Adzenys XR-ODT until the right of return no longer exists, which occurs at the earlier of the time Adzenys XR-ODT units are dispensed through patient prescriptions or expiration of the right of return. We calculate patient prescriptions of Adzenys XR-ODT dispensed using an analysis of third-party information. If we fail to successfully market Adzenys XR-ODT or to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our inability to generate future revenue from product sales may adversely affect our results of operations and financial position.

Research and development

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

- expenses, including salaries and benefits, which includes share-based compensation expense, of employees engaged in research and development activities;
- expenses incurred under third party agreements with contract research organizations ("CROs"), and investigative sites that conducted our clinical trials and a portion of our pre-clinical activities;
- cost of raw materials, as well as manufacturing cost of our materials used in clinical trials and other development testing;
- cost of facilities, depreciation and other allocated expenses;
- fees paid to regulatory authorities for review and approval of our product candidates; and
- expenses associated with obtaining and maintaining patents.

Direct development expenses associated with our research and development activities are allocated to our product candidates. Indirect costs related to our research and development activities that are not allocated to a product candidate are included in "Other Research and Development Activities" in the table below.

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Prior to 2016, the largest component of our total operating expenses has 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:

	December 31,		
	2016	2015	2014
	(in thousands)		
NT-0102 Cotempla XR-ODT	$ 1,613	$ 3,232	$ 1,641
NT-0201 Amphetamine Liquid	2,403	237	822
NT-0202 Adzenys XR- ODT	650	330	762
Other Research and Development Activities(1)	7,541	7,892	7,349
	$ 12,207	$ 11,691	$ 10,574

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

During the third quarter of 2016, we reclassified our approved product and facility regulatory fees out of research and development expense and into cost of sales commensurate with the commercial launch of Adzenys XR-ODT. We have reclassified all such applicable regulatory fees for prior quarters and prior years out of research and development expense and into cost of goods sold in accordance with this approach.

We expect that our research and development expenses will fluctuate over time as we seek regulatory approval of our two ADHD product candidates and explore new product candidates, but will decrease as a percentage of revenue if Adzenys XR-ODT is commercially successful or any of our product candidates are approved and commercially successful. We expect to fund our research and development expenses from our current cash and cash equivalents, a portion of the net proceeds from our public offerings of common stock and debt financing and revenues, if any, from Adzenys XR-ODT and, if approved, our product candidates.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

On October 16, 2015, we received notification from the FDA stating that, as part of its ongoing review of our NDA for Cotempla XR-ODT, it had identified deficiencies that precluded discussion of labeling and post marketing requirements or commitments at that time. On November 10, 2015, we announced that we received a Complete Response Letter from the FDA, which requires us to conduct a bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. On July 28, 2016, we announced that we had completed the bridging study demonstrating that the Cotempla XR-ODT to-be-marketed drug product met all of the primary and secondary endpoints for establishing bioequivalence under fasted conditions. We resubmitted an NDA for Cotempla XR-ODT on December 20, 2016 and have received a PDUFA goal date of June 19, 2017, and we submitted an NDA for NT-0201, our amphetamine XR liquid suspension, on November 17, 2016 which has a PDUFA goal date of September 15, 2017. Any further actions required by the FDA may result in further research and development expenses. For additional information

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regarding the FDA review process, including the Prescription Drug User Fee Act, see "Government Regulation NDA and FDA review process."

Selling and marketing

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

We believe that our selling and marketing expenses may continue at these levels with the continuing commercialization of Adzenys XR-ODT and, if approved, the commercial launch of our product candidates, particularly as we move to a business model in which we commercialize our own products in the United States.

General and administrative

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation expense, for our employees in executive, finance and human resources functions. Other general and administrative expenses include facility-related costs not otherwise included in research and development expenses or cost of goods sold, and professional fees for business development, accounting, tax and legal services. Beginning in July 2016, we began recording stock compensation expense in the same income statement line as the cash compensation of the employee with the associated stock option in accordance with Staff Accounting Bulletin Topic 14 due to the increased number and amount of stock options and option compensation. We have reclassified all prior quarters' and prior years' amounts that relate to personnel not classified as general and administrative employees out of general and administrative expense to the appropriate income statement line in accordance with this approach.

We anticipate that our general and administrative expenses will increase due to increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services, director and officer insurance premiums and investor relations costs, as well as accounting and compliance costs to support the commercialization of Adzenys XR-ODT and, if approved, our product candidates. In addition, as a result of our Paragraph IV litigation that we commenced against Actavis in September 2016, we have incurred and anticipate incurring increasing amounts of legal fees in the enforcement of our intellectual property rights.

Interest expense, net

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 which was repaid in May 2016 with the proceeds from the new Facility and the capitalized leases resulting from the sale-leaseback transactions of our existing and newly-acquired property and equipment. We amortize debt issuance costs over the life of the notes which are reported as interest expense in our consolidated statements of operations. An additional element of interest expense is the loss on debt extinguishment incurred upon prepaying the Loan and Security Agreement with Hercules ("LSA") and the Note, which consisted of a prepayment charge, payment of legal fees on behalf of the lender and writing off unamortized end-of-term fees and unamortized debt discount.

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Other income (expense), net

Other income and expense to date has primarily consisted of amortization of the net gain recorded on the sale-leaseback of our property and equipment. These sale-leaseback financings occurred in five separate transactions, each with a 42-month lease term. The gains on the transactions are being recognized on a straight-line basis over the respective 42-month lease term (see Note 7 to the notes to our audited financial statements included elsewhere in this Annual Report on Form 10-K). Other income and expense also includes changes resulting from the remeasurement of the fair values of our earnout liability and our warrant liabilities through the effective date of the IPO, July 22, 2015. Due to the increasing amount of interest income and gains on sales of securities, we have reclassified such interest earned, accretion and gains on our cash and cash equivalents and short-term investments to other income, net. The primary objective of our investment policy is liquidity and capital preservation.

RESULTS OF OPERATIONS

Year ended December 31, 2016 compared to the year ended December 31, 2015

Revenues

The following table summarizes our revenues for the year ended December 31, 2016 and 2015:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(in thousands)			
Product	$ 9,154	$ 3,792	$ 5,362	141.4%

Total product revenues were $9.2 million for the year ended December 31, 2016, an increase of $5.4 million or 141.4% from the $3.8 million for the year ended December 31, 2015. Net sales of our generic Tussionex increased approximately $2.5 million to $6.3 million from the $3.8 million for the year ended December 31, 2015 due to increased sales volume. Also included in product revenues for the period from May 16, 2016 through year end 2016 were $2.9 million of net sales of dispensed patient prescriptions of our Adzenys XR-ODT which was launched May 16, 2016.

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

Cost of goods sold

The following table summarizes our cost of goods sold for the year ended December 31, 2016 and 2015:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(in thousands)			
Cost of Goods Sold	$ 11,437	$ 5,929	$ 5,508	92.9%

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The total cost of goods sold was $11.4 million for the year ended December 31, 2016, an increase of $5.5 million or 92.9%, from the $5.9 million for the year ended December 31, 2015. This increase was primarily due to a $1.9 million increase in product costs, a $0.7 million increase in labor costs and a $1.0 million increase in other production costs associated with the increased unit sales of our generic Tussionex and initial sales of Adzenys XR-ODT. Other cost of goods sold also increased, principally due to a $1.5 million accrual of the product and facility regulatory fees for Adzenys XR-ODT, $0.3 million of increased services of outside firms including outside lab testing, a $0.3 million increase in third party logistics provider ("3PL") freight and service fees and $0.2 million of increased lab and manufacturing supplies. These increases were partially offset by a $0.3 million decrease in facility costs and a $0.1 million decrease in depreciation due to capitalized depreciation costs associated with the Adzenys XR-ODT inventory build.

Research and development expenses

The following table summarizes our research and development expenses for year ended December 31, 2016 and 2015:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(in thousands)			
Research & Development Expenses	$ 12,207	$ 11,691	$ 516	4.4%

Research and development expenses were $12.2 million for the year ended December 31, 2016, an increase of approximately $0.5 million or 4.4%, from the $11.7 million for the year ended December 31, 2015. This increase was primarily due to a $2.5 million increase in professional services principally for clinical studies for our product candidates, partially offset by a $1.3 million net decrease in regulatory fees as the $2.3 million FDA filing fee for the NDA for Cotempla XR-ODT submitted in 2015 was partially offset by the $1.0 million FDA filing fee for the NDA for NT-0201 in 2016, a $0.4 million decrease in depreciation expense as certain capital lease assets became fully depreciated in July 2016, a $0.2 million decrease in services of outside firms and a $0.1 million decrease in facility and related costs due principally to reduced equipment repairs.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the year ended December 31, 2016 and 2015:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(in thousands)			
Sales and Marketing	$ 49,291	$ 5,672	$ 43,619	769.0%

The total selling and marketing expenses were $49.3 million for the year ended December 31, 2016, an increase of approximately $43.6 million or 769.0%, from the $5.7 million for the year ended December 31, 2015. Commercial sales organization salesforce and sales support costs increased $18.5 million in support of the launch of Adzenys XR-ODT. Selling and marketing professional services associated with the launch of Adzenys XR-ODT, exclusive of commercial sales organization costs, increased by $19.3 million due to advertising agency, marketing materials, commercial team training and other meeting costs, managed care, pharmacy and patient assistance program management, purchases of sales data, convention costs and public relations costs incurred in 2016. Additionally, salary and compensation expense increased $4.6 million and recruiting fees increased $0.1 million for

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the build out of our sales and marketing management. Selling and marketing travel and entertainment expenses increased $0.9 million and the marketing office facility cost increased $0.2 million.

General and administrative expenses

The following table summarizes our general and administrative expenses for the year ended December 31, 2016 and 2015:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(in thousands)			
General and Administrative	$ 12,625	$ 7,078	$ 5,547	78.4%

The total general and administrative expenses were $12.6 million for the year ended December 31, 2016, an increase of $5.5 million or 78.4%, from the $7.1 million for the year ended December 31, 2015. Salary and compensation expense increased $2.7 million in the year ended December 31, 2016, primarily due a $1.3 million increase in compensation related to share-based payments and a $1.4 million increase, principally due to the addition of personnel for administrative and compliance functions. Also, professional fees increased $2.1 million in 2016 primarily for legal, public filing, SOX compliance, business development and information technology services. In addition, general and administrative expenses increased by $0.4 million in 2016 for a full year of the public company directors and officers insurance policy premium, $0.1 million for board of directors fees and expenses, $0.1 million for facility costs and $0.1 million for depreciation.

Interest expense

The following table summarizes interest expense for the year ended December 31, 2016 and 2015:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(in thousands)			
Interest Expense	$ (6,937)	$ (3,721)	$ (3,216)	86.4%
Loss on Debt Extinguishment	(1,187)		(1,187)	N/A
Total	$ (8,124)	$ (3,721)	$ (4,403)	118.3%

The total interest expense was $8.1 million for the year ended December 31, 2016, an increase of $4.4 million or 118.3%, from the $3.7 million for the year ended December 31, 2015. Of this increase, the early prepayment of the LSA resulted in a $1.2 million loss on debt extinguishment due to recording the $0.2 million LSA prepayment charge, writing off the $0.5 million of unamortized LSA end of term charge and the $0.5 million of unamortized LSA loan discount. Additionally, interest on senior debt was $3.8 million higher due to the increased balance of debt. These increases were partially offset by a $0.3 million reduction in capital lease interest due to the reduced capital lease balances resulting from ongoing lease payments and $0.3 million lower interest on the subordinated debt due to the prepayment of the $5.9 million of principal and $1.3 million of interest on the 10% Note.

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Other income (expense), net

The following table summarizes our other income (expense) for the year ended December 31, 2016 and 2015:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2016	2015		
	(in thousands)			
Other income, net	$ 1,215	$ 831	$ 384	46.2%
Change in fair value of earnout and warrant liabilities	(18)	(1,313)	1,295	(98.6)%
Total	$ 1,197	$ (482)	$ 1,679	(348.3)%

Other income, net was $1.2 million of net income for the year ended December 31, 2016, an absolute increase of $1.7 million or 348.3%, from the $0.5 million of net expense for the year ended December 31, 2015. The 2016 other income, net included $0.5 million of amortization of the gain on the sale-leasebacks, $0.4 million gain on the auction sale of certain fully depreciated property and equipment, and $0.3 million of investment accretion and interest income. The $0.5 million of net expense in 2015 was primarily due to $1.3 million 2015 year-to-date net expense effect of the remeasurements of the fair values of the warrant and earnout liabilities, which was partially offset by the $0.8 million amortization of the gain on the sale-leasebacks. In 2016, as a result of our IPO, the warrants are no longer being revalued at each balance sheet date (see Note 2 W*arrants* in the notes to our financial statements).

Year ended December 31, 2015 compared to the year ended December 31, 2014

Revenues

The following table summarizes our revenues for the year ended December 31, 2015 and 2014:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Product	$ 3,792	$ 316	$ 3,476	1,100%
Manufacturing		113	(113)	(100)%
Profit Sharing		169	(169)	(100)%
Development		160	(160)	(100)%
	$ 3,792	$ 758	$ 3,034	400.3%

Total revenues were $3.8 million for the year ended December 31, 2015, an increase of $3.0 million or 400.3%, from the $0.8 million for the year ended December 31, 2014. All $3.8 million of product revenue in the year ended December 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 manufacturing and profit sharing revenues decreased by $0.3 million due to the termination of our development and manufacturing agreement in August 2014. In addition, the $0.2 million decrease in development revenues for the year ended December 31, 2015 was due to reduced development work related to our generic Tussionex. The $0.3 million of product revenue for the year ended December 31, 2014 included reserves we established for the estimated returns of our generic Tussionex outstanding at the wholesalers as of the October 6, 2014 effective date of the August 26, 2014 DEA reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance. This ruling had the effect of requiring unsold product to either be relabeled or returned.

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Cost of goods sold

The following table summarizes our cost of goods sold for the year ended December 31, 2015 and 2014:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Cost of Goods Sold	$ 5,929	$ 3,391	$ 2,538	74.8%

The total cost of goods sold was $5.9 million for the year ended December 31, 2015, an increase of $2.5 million or 74.8%, from the $3.4 million for the year ended December 31, 2014. This increase was primarily due to $1.0 million increase in raw material costs due to the increased sales of Tussionex, $0.7 million of amortization of the intangibles resulting from the acquisition of the rights to commercialize and derive future profits from Tussionex ANDA, a $0.5 million increase in other cost of goods sold, principally due to personnel for lab testing of products, distribution costs and freight incurred for the shipment of our generic Tussionex and audits of suppliers in 2015, a $0.2 million reclassification of regulatory fees from research and development expense and a $0.1 million reclassification of stock-based compensation expense from general and administrative expense.

Research and development expenses

The following table summarizes our research and development expenses for the year ended December 31, 2015 and 2014:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Research & Development Expenses	$ 11,691	$ 10,574	$ 1,117	10.6%

Research and development expenses were $11.7 million for the year ended December 31, 2015, an increase of $1.1 million, or 10.6%, from the $10.6 million for the year ended December 31, 2014. This increase was primarily due to a $2.3 million FDA filing fee for the NDA for Cotempla XR-ODT submitted in January 2015, a $0.6 million increase in research and development materials, equipment, outside lab testing and other costs, a $0.5 million increase in medical affairs spending related to our ADHD product candidates, and a $0.3 million increase due to salaries and benefits and reclassified stock compensation expense for additional research and development personnel. These increases were offset by a $2.0 million decrease in clinical expense, primarily as a result of the completion of our classroom study of Cotempla XR-ODT and the completion of clinical trials for Adzenys XR-ODT and NT-0201 in 2014 and a $0.6 million decrease in consulting firm services related to the preparation of our prior NDA submissions.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the year ended December 31, 2015 and 2014:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Sales and Marketing	$ 5,672	$ 229	$ 5,443	2,376.9%

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Selling and marketing expenses were $5.7 million for the year ended December 31, 2015, an increase of $5.5 million or 2,376.9%, from the $0.2 million for the year ended December 31, 2014. Selling and marketing professional services increased by $3.8 million due to the pre-commercialization advertising agency and sales organization management costs, market research, managed care research, public relations, sales force planning, recruiting fees and corporate communications expenses incurred in 2015 for Adzenys XR-ODT and Cotempla XR-ODT. Salary and compensation expense increased $1.5 million due to the addition of personnel as part of pre-commercialization efforts for our product candidates and trade sales support for our generic Tussionex and the reclassification of stock-based compensation expense. In addition, selling and marketing travel expenses increased $0.2 million related to these pre-commercialization activities.

General and administrative expenses

The following table summarizes our general and administrative expenses for the year ended December 31, 2015 and 2014:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
General and Administrative	$ 7,078	$ 5,036	$ 2,042	40.5%

General and administrative expenses were $7.0 million for the year ended December 31, 2015, an increase of $2.0 million or 40.5%, from the $5.0 million for the year ended December 31, 2014. Salary and compensation expense increased $1.0 million in the year ended December 31, 2015 primarily due a $0.6 million increase in compensation related to share-based payments after the reclassification of such expense to the appropriate department's expense and a $0.4 million increase in 2015 due to the restructuring of the executive team and the addition of contract labor during 2015 and 2014 to bring on additional industry experience in support of our IPO. In addition, general and administrative expenses increased by $0.3 million for directors and officers insurance policy premium for the period following the IPO effective date and $0.2 million for board of directors fees and expenses. Also, Professional Fees included the following offsetting variances: an increase of $1.1 million related to services provided by consultants primarily for audit, tax, business development, financial reporting, computer services, recruiting, compensation review, financial analysis and government pricing, offset by a $0.6 million decrease in legal fees resulting from the termination and settlement of litigation related to the Paragraph IV certification of Adzenys XR-ODT in July 2014.

Interest expense

The following table summarizes interest expense for the year ended December 31, 2015 and 2014:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Interest Expense	$ (3,721)	$ (2,520)	$ (1,201)	47.7%
Loss on Debt Extinguishment		(445)	445	N/A
Total	$ (3,721)	$ (2,965)	$ (756)	25.5%

The total interest expense was $3.7 million for the year ended December 31, 2015, an increase of $0.7 million or 25.5% from the $3.0 million for the year ended December 31, 2014. The interest on senior debt increased by $0.9 million due to the increased senior debt balance in 2015. This increase

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was offset by a $0.2 million reduction in capital lease interest due the reduced capital lease balances resulting from ongoing lease payments.

Other income (expense), net

The following table summarizes our other income (expense) for the year ended December 31, 2015 and 2014:

	Year Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2015	2014		
	(in thousands)			
Other income, net	$ 831	$ 837	$ (6)	(0.7)%
Change in fair value of earnout and warrant liabilities	(1,313)	(249)	(1,064)	427.3%
Total	$ (482)	$ 588	$ (1,070)	(182.0)%

Other expense was $0.5 million for the year ended December 31, 2015, a decrease of $1.1 million or 182.0%, from the $0.6 million of other income for the year ended December 31, 2014. This change was due to the $1.7 million year-to-date effect of the remeasurements of the fair value of the warrant liabilities due to the increased weighting assigned to the IPO scenario in the PWERM valuation model which was partially offset by a $0.6 million decrease in the fair value of the earnout liability, which resulted primarily from new information regarding the projected impact of the DEA's reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance and a review of the projected launch dates of Adzenys XR-ODT and our two ADHD product candidates

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

Since our reorganization in 2009 until our IPO, we have financed our operations primarily through private placements of common stock and redeemable convertible preferred stock and bank and other lender financing.

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

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On July 28, 2015, we closed our IPO whereby we sold 5,520,000 shares of our common stock, at a public offering price of $15.00 per share, which includes 720,000 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the IPO price. We received aggregate net proceeds of $75.0 million from the offering, after deducting underwriting discounts and commissions of $5.8 million and offering expenses of approximately $2.0 million.

On May 11, 2016, we entered into a $60 million senior secured credit facility ("Facility") with Deerfield as lender. Principal on the new Facility is due in three equal annual installments beginning in May 2019 and continuing through May 2021, with a final payment of principal, interest and all other obligations under the facility due May 11, 2022. Interest is due quarterly beginning in June 2016, at a rate of 12.95% per year. We have an option to defer payment of each of the first four interest payments until June 1, 2017. We exercised the option to defer the first three interest payments during the year ended December 31, 2016 and exercised the option to defer the fourth interest payment due March 1, 2017 on February 6, 2017, adding such amounts to the outstanding loan principal until they are paid on June 1, 2017. Borrowings under the Facility are collateralized by substantially all of our assets, except the assets under capital lease, and we will maintain cash on deposit of not less than $5 million. In connection with the Facility, we paid a $1,350,000 yield enhancement fee to Deerfield and approximately $0.2 million of legal fees. Approximately $33 million of the $60 million Facility proceeds was used to prepay the existing $24.3 million principal and $0.1 million of accrued interest related to the LSA, the $1.1 million LSA end of term fee, an LSA prepayment charge of $243,000 and the $5.9 million of principal and $1.3 million of interest on the 10% Note, which were otherwise payable in 2016 and 2017.

On August 1, 2016, we filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale by us of up to an aggregate of $125.0 million of our common stock, preferred stock, debt securities, warrants and/or units. We simultaneously entered into a Sales Agreement with Cowen and Company, LLC, as sales agent, to provide for the offering, issuance and sale by us of up to $40.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf. The Shelf was declared effective by the SEC on August 12, 2016. Pursuant to the Shelf, the Company closed an underwritten public offering of 5,000,000 shares of its common stock at a public offering price of $5.00 per share, before underwriting discounts and commissions, on February 8, 2017. In addition, on February 17, 2017, the underwriters elected to exercise their option in full to purchase up to an additional 750,000 shares of common stock at the $5.00 per share public offering price, less underwriting discounts and commissions. The net proceeds to the Company from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company were approximately $26.8 million. During the year ended December 31, 2016, we did not make any sales under our ATM Facility.

As of December 31, 2016, we had $24.4 million in cash and cash equivalents and $15.4 million in short-term investments. Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity. Accordingly, our cash equivalents are invested primarily in money market funds which are currently providing only a minimal return.

We believe that our existing cash and cash equivalents and short-term investments, taken together with the net proceeds which we received from our public offering of common stock completed in February 2017, will be sufficient to fund our operations for at least the next 12 months after filing this report on Form 10-K.

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Cash flows

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

	Year Ended December 31,		Increase (Decrease)	Year Ended December 31,		Increase (Decrease)
	2016	2015		2015	2014	
	(in thousands)					
Net Cash (used in) provided by:						
Net Cash used in operating activities	$ (70,646)	$ (25,867)	$ (44,779)	$ (25,867)	$ (17,390)	$ (8,477)
Net Cash (used in) provided by investing activities	(19,322)	1,977	$ (21,299)	1,977	(2,125)	$ 4,102
Net Cash provided by financing activities	23,557	101,310	$ (77,753)	101,310	20,911	$ 80,399
Net increase (decrease) in cash and cash equivalents	$ (66,411)	$ 77,420	$ (143,831)	$ 77,420	$ 1,396	$ 76,024

Cash used in operating activities

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

Net cash used in operating activities was $70.7 million and $25.9 million for the years ended December 31, 2016 and 2015, respectively. The $44.8 million increase in net cash used from operating activities was due to the $52.5 million increase in our net losses, as discussed above, partially offset by a $5.7 million increase in noncash items and a $2.0 million increase in the provision of cash from working capital changes. The increase in noncash items was principally due to a $4.2 million of deferred interest on the Facility and the Note, a $2.3 million increase in share-based compensation expense, the $0.9 million loss on debt extinguishment related to unamortized debt discount, partially offset by the $1.3 million decrease in the change in the fair value of the warrant and earnout liabilities since 2015 and a net $0.4 million decrease in all other noncash items. The increase in provision of cash from working capital changes primarily resulted from a $1.3 million decrease in accounts receivable as customers made payments to bring their accounts current, a $1.1 million increase in accrued expenses and accounts payable due to the timing of vendor invoicing and costs related to sales of Adzenys XR-ODT which are deferred until the revenue associated with those fees is recognized and a $3.7 million increase in deferred revenue related to Adzenys XR-ODT, partially offset by increased cash usage from a $2.8 million increase in inventories in anticipation of forecasted increased sales of our generic Tussionex and Adzenys XR-ODT and a $1.3 million increase in deferred contract sales organization fees for advance payments including a net increase in other assets.

Net cash used in operating activities was $25.9 million and $17.4 million for the years ended December 31, 2015 and 2014, respectively. The $8.5 million increase in net cash used from operating activities was primarily due to the $9.9 million increase in our net losses, as discussed above, and a $1.3 million increase in the usage of cash from working capital changes, partially offset by a $2.7 million increase in noncash items. The increase in usage of cash from working capital changes resulted primarily from a $4.0 million increase in cash usage for accounts receivable associated with increased sales of our generic Tussionex and a $0.6 million increase in cash usage for other assets due to the timing of customer and vendor payments, partially offset by a net $2.2 million increase in accounts payable and accrued expenses due to the timing of vendor invoicing and payments and a

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$1.1 million decrease in cash used for inventories due to the initial inventory buildup in 2014 after the Tussionex ANDA acquisition. The decrease in noncash items was principally due to the changes in the fair value of the warrant and earnout liabilities in 2015, an increase in share-based compensation expense and an increase in the amortization of costs to acquire all of the rights to commercialize and derive future profits from Tussionex ANDA in August 2014.

Cash (used) provided by in investing activities

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

Net cash used by investing activities was $19.3 million for the year ended December 31, 2016 primarily due to the $66.1 million purchase of short-term investments partially offset by the $50.8 million sales of short-term investments, $3.5 million of capital expenditures principally for equipment and systems to be used in the production and testing of Adzenys XR-ODT and, if approved, our other product candidates and a new ERP system and $0.5 million for fees related to a license associated with the commercialization of Adzenys XR-ODT. Net cash provided by investing activities of $2.0 million for the year ended December 31, 2015 was primarily due to the net sale of $3.0 million of short-term investments, partially offset by a $1.0 million of capital expenditures in 2015 primarily in association with the expansion of our controlled substances vault.

Net cash provided by investing activities was $2.0 million for the year ended December 31, 2015 as compared to net cash used in investing activities of $2.1 million for the year ended December 31, 2014, which resulted from the net sale of $3.0 million and $4.5 million, respectively, of short-term investments, offset by a $0.7 million increase in 2015 capital expenditures, primarily in association with the expansion of our controlled substances vault and a $6.3 million cash outflow in 2014 for the acquisition all of the rights to commercialize and derive future profits from Tussionex ANDA in August 2014.

Cash provided by financing activities

Net cash provided by financing activities of $23.6 million in the year ended December 31, 2016 primarily resulted from proceeds of $60.0 million from the issuance of notes to Deerfield, partially offset by a $1.4 yield enhancement fee paid to Deerfield and $0.2 million of legal fees, the full repayment of the $25.0 million of principal and a $1.1 million end of term charge payment under the LSA, a $7.3 million of principal and interest payment under the 10% Note, and $1.9 million of principal payments under the sales leasebacks partially offset by $0.4 million of proceeds from the sale of related equipment.

Net cash provided by financing activities of $101.3 million in the year ended December 31, 2015 primarily resulted from net cash proceeds of $77.0 million from our IPO reduced by $2.0 million of cash public offering costs; $13.0 million, net of issuance costs, received from the sale of 2,624,936 shares of our Series C preferred stock and the issuance of Series C warrants for 1,197,218 shares of Series C preferred stock; proceeds of $10.0 million from additional drawdowns under our notes to our senior lender; $5.0 million from the exercise of 1,000,000 of Series C warrants and $0.1 million from the exercise of stock options, partially offset by $1.6 million of principal payments under the sales leasebacks and $0.2 million of payments made to purchase treasury stock.

Net cash provided by financing activities of $20.9 million in the year ended December 31, 2014 was related to proceeds of $17.4 million, net of issuance costs, received from the sale of 3,486,521 shares of our Series C preferred stock; proceeds of $15.0 million from the issuance of notes to our new lender, partially offset by full repayment of the $10.0 million in principal under the previous term loan and

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$0.6 million of deferred financing costs; and $0.8 million from the sale-leaseback of equipment, partially offset by principal payments under the sales-leasebacks.

Credit facilities

On May 11, 2016, we entered into a $60 million senior secured credit facility ("Facility") with Deerfield Private Design Fund III, L.P. (66$^{2}/_{3}$% of loan) and Deerfield Special Situations Fund, L.P. (33$^{1}/_{3}$% of Loan) ("Deerfield"), as lenders. Approximately $33 million of the proceeds was used to repay the existing $24.3 million principal and $0.1 million of accrued interest related to the LSA, the $1.1 million LSA end of term fee, an LSA prepayment charge of $243,000 and the $5.9 million of principal and $1.3 million of interest on the 10% amended and restated subordinated note (the "Note") that was issued by us to Essex Capital Corporation ("Essex") which was to mature in March 2017, which were otherwise payable in 2016 and 2017. Principal on the new facility is due in three equal annual installments beginning in May 2019 and continuing through May 2021, with a final payment of principal, interest and all other obligations under the facility due May 11, 2022. Interest is due quarterly beginning in June 2016, at a rate of 12.95% per year. We have an option to defer payment of each of the first four interest payments until June 1, 2017. As of December 31, 2016, we had exercised the option to defer the first three interest payments and exercised the option to defer the fourth interest payment due March 1, 2017 on February 6, 2017, adding such amounts to the outstanding loan principal until they are paid on June 1, 2017. Borrowings under the Facility are collateralized by substantially all of our assets, except the assets under capital lease, and we will maintain cash on deposit of not less than $5 million. In connection with the Facility, we paid a $1,350,000 yield enhancement fee to Deerfield and approximately $0.2 million in legal fees.

The Facility, also contains certain customary nonfinancial covenants, including limitations on our ability to transfer assets, engage in a change of control, merge or acquire with or into another entity, incur additional indebtedness and distribute assets to shareholders. Upon an event of default, the lender may declare all outstanding obligations accrued under the Facility to be immediately due and payable, and exercise its security interests and other rights. As of December 31, 2016, we were in compliance with the covenants under the Facility.

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

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

The LSA, as amended, also contained certain financial and nonfinancial covenants, including limitations on our ability to transfer assets, engage in a change of control, merge or acquire with or into another entity, incur additional indebtedness, repurchase or redeem stock or other equity interest

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

We had a Note in the aggregate principal amount of $5.9 million that was issued by us to Essex which was to mature in March 2017. Interest was to be accrued and added to the principal balance until such time as we achieved positive EBITDA for three consecutive months. The $5.9 million Note and the related $1.3 million of accrued interest were repaid on May 11, 2016 with proceeds from the Facility as mentioned above. On July 19, 2014, the interest rate on the Note was reduced to 6% for the period from July 19, 2014 through June 28, 2015 pursuant to an amendment to the Note entered into as consideration for the $128,000 payment made by us to Essex as part of the Settlement and Release of Claims Agreement with Essex and a third party. This agreement resolved certain issues and disputes whereby Essex paid $256,000 to the third party, we paid Essex $128,000 and Essex agreed to reduce the interest rate on the Note from 10% to 6% for the July 2014 through June 2015 period. The third party released both Essex and us from any and all claims.

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

Capital resources and funding requirements

We may continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funds will be available on terms favorable to us, if at all, or that we will be able to successfully commercialize Adzenys XR-ODT or our product candidates. In addition, we may not be profitable even if we succeed in commercializing Adzenys XR-ODT or any of our product candidates. We expect to continue to incur operating losses over the next several years as we seek regulatory approval for our product candidates and build commercial infrastructure to support sales and marketing of Adzenys XR-ODT or our product candidates. We believe that our existing cash and cash equivalents will be sufficient to fund our anticipated operating requirements for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, resulting in the use of our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital required to become profitable. Our future funding requirements will depend on many factors, including:

- the costs and timing involved in obtaining regulatory approvals for our product candidates;
- the timing and number of product candidates for which we obtain regulatory approval;
- the costs of developing our anticipated sales, marketing and distribution capabilities;
- the market acceptance of our products and product candidates, if approved, and related success in commercializing and generating sales from our products and product candidates, if approved by the regulatory authorities;
- the costs of our manufacturing capabilities to support our commercialization activities, including any costs associated with adding new capabilities;

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- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

- the number and characteristics of new product candidates that we pursue; and

- our ability to hire qualified employees at salary levels consistent with our estimates to support our growth and development, including additional general and administrative personnel as a result of becoming a public company, and sales and marketing personnel as we evolve into a commercial organization.

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

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements, as well as reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to the notes to our audited financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

Revenue is generated from product sales, recorded on a net sales basis in consideration of product returns, rebates and wholesaler chargebacks, each of which is described in more detail below. Product revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; price to the buyer is fixed and determinable; and collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if the price to the buyer is

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substantially fixed or determinable at the date of sale, the buyer has paid for the product, or the buyer is obligated to pay for the product and the obligation is not contingent on resale of the product, the buyer's obligation to pay would not be changed in the event of theft or physical destruction or damage of the product, the buyer acquiring the product for resale has economic substance apart from that provided by us, we do not have significant obligations for future performance to directly bring about resale of the product by the buyer and the amount of future returns can be reasonably estimated.

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

We sell our generic Tussionex and Adzenys XR-ODT to a limited number of pharmaceutical wholesalers. Pharmaceutical wholesalers buy drug products directly from manufacturers. Title to the product passes upon delivery to the wholesalers, when the risks and rewards of ownership are assumed by the wholesaler. These wholesalers then resell the product to retail customers such as food, drug and mass merchandisers.

Net product sales

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

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The following table presents our gross to net sales deductions for our generic Tussionex since we acquired the rights to the Tussionex ANDA on August 28, 2014 and began to derive revenue directly from sales made by us:

	Chargebacks	Cash Discounts	Sales Offers	Wholesaler Fees	Returns	Government Rebates	Total Gross to Net Sales Deductions
				(in thousands)			
Balance at December 31, 2013	$	$	$	$	$	$	$
Provision, net	202	18		122	212	9	563
Payments / credits	(12)	(4)		(5)			(21)
Balance at December 31, 2014	190	14		117	212	9	542
Provision, net	5,359	194		914	242	103	6,812
Payments / credits	(4,609)	(109)		(670)	(25)	(2)	(5,415)
Balance at December 31, 2015	940	99		361	429	110	1,939
Provision, net	10,504	388		1,756	491	(48)	13,091
Payments / credits	(10,665)	(376)		(2,068)	(36)	(24)	(13,169)
Balance at December 31, 2016	$ 779	$ 111	$	$ 49	$ 884	$ 38	$ 1,861

Total items deducted from gross product sales were $13,091, $6,812 and $563, or 67.8%, 64.2% and 54.1% as a percentage of gross product sales, for the years ended December 31, 2016, 2015 and 2014, respectively. The increase in the gross to net sales deduction percentage resulted from a higher proportion of the sales being made to a major pharmacy chain that receives volume pricing concessions.

The following table presents our gross to net sales deductions for our Adzenys XR-ODT which we launched commercially on May 16, 2016:

	Chargebacks	Cash Discounts	Sales Offers	Wholesaler Fees	Returns	Government Rebates	Total Gross to Net Sales Deductions
				(in thousands)			
Balance at December 31, 2015	$	$	$	$	$	$	$
Provision, net		384	3,746	1,082		444	5,656
Payments / credits		(311)	(3,746)	(766)		(444)	(5,267)
Due to (paid to) third party and deferred until sales recognized		(13)		144		383	514
Balance at December 31, 2016	$	$ 60	$ (3,746)	$ 460	$	$ 383	$ 903

Total items deducted from gross product sales were $5,267, or 64.3% as a percentage of gross product sales, for the year ended December 31, 2016, due principally to the sales offers being made to penetrate the ADHD market.

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Savings offers

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

Product returns

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

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

Rebates

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

Wholesaler Chargebacks

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

Inventories

Inventories are stated at the lower of cost (first in, first out) or market and have been reduced by an allowance for excess and obsolete inventories. Cost elements include material, labor and manufacturing overhead. Inventories consist of raw materials, work in process, finished goods and deferred cost of goods sold. The cost of sales associated with the deferred product revenues are recorded as deferred costs of goods sold that are released from inventory into cost of goods sold as the deferred revenue is recognized into revenue.

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Until objective and persuasive evidence exists that regulatory approval has been received and future economic benefit is probable, pre-launch inventories are expensed into research and development. Manufacturing costs for the production of Adzenys XR-ODT incurred after the January 27, 2016 FDA approval date are being capitalized into inventory.

Research and development expenses

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

Share-based compensation expense

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

We calculated the fair value of share-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the input of subjective assumptions, including stock price volatility and the expected life of stock options. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost. As a formerly private company, we do not have sufficient history to estimate the volatility of our common stock price or the expected life of our options. We have not paid and do not anticipate paying cash dividends. Therefore, the expected dividend rate is assumed to be 0%. The expected stock price volatility for stock option awards was based on the historical volatility of a representative peer group of comparable companies' selected using publicly available industry and market capitalization data. The risk-free rate was based on the U.S. Treasury yield curve in effect commensurate with the expected life assumption. The average expected life of stock options was determined according to the "simplified method" as described in Staff Accounting Bulletin 110, which

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is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate was determined by reference to implied yields available from five-year U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. We estimate forfeitures based on our historical analysis of actual stock option forfeitures. We estimate the fair value of all stock option awards on the grant date by applying the Black-Scholes option pricing valuation model. Given the absence of an active market for our common stock prior to our IPO, our board of directors was required to estimate the fair value of our common stock at the time of each option grant primarily based upon valuations performed by a third party valuation firm. After the closing of our IPO, our board of directors has determined the fair value of each share of underlying common stock based on the closing price of our common stock as reported by the NASDAQ Global Market on the date of grant.

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

Intangible assets

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

CONTRACTUAL COMMITMENTS AND OBLIGATIONS

The following table reflects a summary of our estimates of future material contractual obligations as of December 31, 2016. Future events could cause actual payments to differ from these estimates.

	Total	< 1 Yr	1 - 3 Yrs.	3 - 5 Yrs	Thereafter
			(In thousands)		
Deerfield senior secured facility	$ 95,832	$ 12,646	$ 29,655	$ 37,662	$ 15,869
Capital leases for equipment	473	473			
Earnout liability	232				232
Texas facility operating lease	8,094	955	1,912	2,010	3,217
Pennsylvania office space lease	656	146	302	208	
	$ 105,287	$ 14,220	$ 31,869	$ 39,880	$ 19,318

We had borrowed all $60.0 million under the Deerfield Facility as of December 31, 2016. The payments above are inclusive of related interest amounts as of December 31, 2016.

In addition to the commitments shown above, in response to a lawsuit brought against us by Shire LLC ("Shire"), for infringement of certain of Shire's patents, we entered into a settlement agreement and an associated license agreement with Shire for a non-exclusive license to certain patents for certain activities with respect to our NDA No. 204326 for an extended-release orally disintegrating amphetamine Polistirex tablet in July 2014. Under the terms of the license agreement, after receiving regulatory approval by the FDA of our NDA for Adzenys XR-ODT, in the first quarter of 2016, we paid a lump sum, non-refundable license fee of an amount less than $1.0 million. This license fee was capitalized and is being amortized over the life of the longest associated patent. We are paying a single digit royalty on net sales of Adzenys XR-ODT during the life of the patents.

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On March 6, 2017, after our NDA submission for NT-0201 requiring a Paragraph IV certification notification to the producer of Adderall XR, Shire Pharmaceuticals, in accordance with the Hatch-Waxman Act, we entered into a license agreement with Shire. Pursuant to this agreement, Shire granted us a non-exclusive license to certain patents owned by Shire for certain activities with respect to NT-0201. Under the terms of the agreement, we must pay a lump sum, non-refundable license fee of an amount less than $1.0 million due no later than thirty days after receiving regulatory approval by the FDA of our NDA for NT-0201. We will also pay a single digit royalty on net sales of the NT-0201 during the life of the relevant Shire patents.

Due to the uncertainty of when the NT-0201 license fee and the royalty payments for Adzenys XR-ODT and NT-0201 will be made and the amount of such royalty payments, they are not presented in the table above. The license fee will be recorded as an intangible asset and amortized over the term of the license. The royalties will be recorded as cost of goods sold in the same period as the net sales upon which they are calculated.

OFF-BALANCE SHEET ARRANGEMENTS

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

RECENT ACCOUNTING PRONOUNCEMENTS

In August 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This ASU was designed to reduce the diversity in practice of how the eight specified items are presented and classified in the statement of cash flows, including debt prepayment or debt extinguishment costs. The amendments are effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those years. We believe the amendments will not have a significant effect on our ongoing financial reporting as we have classified our debt prepayment and debt extinguishment costs, in the Consolidated Statements of Cash Flows in accordance with the amendments.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation Stock Compensation Improvements to Employee Share-Based Payment Accounting (Topic 718)*. For public companies, areas of accounting for share-based payment that this ASU was designed to simplify include: the income tax consequences, the accounting policy for forfeitures, the classification of awards as either equity or liabilities and the classification on the statement of cash flows. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2016, including interim periods within those years. The adoption of this standard is not expected to have a material impact on our business, financial position, results of operations or liquidity.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and 2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019, including interim periods within those years. The new standard must be adopted using a modified retrospective transition and requires application of the new

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guidance at the beginning of the earliest comparative period presented. We are evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory Simplifying the Measurement of Inventory (Topic 330).* The amendments in this ASU require an entity to measure inventory that is not measured using the last-in, first-out (LIFO) or retail inventory methods at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, including interim periods within those years. We do not believe that this ASU will have a significant effect on our ongoing financial reporting as valuing inventory at the lower of cost or net realizable value approximates the current policy of valuing inventory at the lower of cost or market.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. This ASU is for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We have performed the review required by this ASU and we believe that we presently have sufficient liquidity to continue to operate for the next twelve months from our filing date.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). The guidance replaces transaction-and industry-specific revenue recognition guidance under current U.S. GAAP with a principles-based approach for determining revenue recognition. The new guidance requires an entity to recognize the amount of revenue based on the value of transferred goods or services to customers. There are also additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB delayed the effective date to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. In addition, in March and April 2016, the FASB issued new guidance intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. Both amendments permit the use of either a retrospective or cumulative effect transition method and are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, with early application permitted. We have limited sales history for our branded product that may not allow for reliable estimates of expected returns of the product at the time of shipment to wholesalers. We are assessing other market data and the impact of this new standard on our financial statements and we have not yet selected a transition method.

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

ITEM 7A. Qualitative and Quantitative Disclosures About Market Risk

Market risk

We are exposed to market risk related to changes in interest rates as it impacts our interest income. As of December 31, 2016, we had cash and cash equivalents of $24.4 million and short-term

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investments of $15.4 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates as our cash equivalents are invested in interest-bearing money market funds. The goals of our investment policy are liquidity and capital preservation to fund our operations. Due to the short-term duration and low risk profile of our cash equivalents portfolio, a 10% change in interest rates would not have a material effect on interest income we recognize or the fair market value of our investments. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates.

Interest risk

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

JOBS ACT

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

ITEM 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officer and effected by the company's board of preparation of financial statements for external purposes in accordance with GAAP and directors, management and other personnel, to provide reasonable assurance regarding the

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reliability of financial reporting and the includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company's assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our principal executive and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2016, based on criteria for effective internal control over financial reporting established in Internal Control Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2016, based on those criteria.

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***Other Information***

None.

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PART III

ITEM 10. *Directors, Executive Officers and Corporate Governance*

Except as set forth below, information required by this item will be included under the captions *Elections of Directors, Information Regarding the Board of Directors and Corporate Governance, Executive Compensation and Other Information,* and *Section 16(a) Beneficial Ownership Reporting Compliance* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2015 (the "Proxy Statement") pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website, which is located at www.neostx.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website, or in a current report on Form 8-K as may be required by law or applicable NASDAQ rules.

ITEM 11. *Executive Compensation*

We maintain an employee compensation program and benefit plans in which our executive officers are participants. Copies of these plans and programs are set forth or incorporated by reference as Exhibits to this report. The information required by this item will be included in our Proxy Statement under the caption *Executive Compensation and Other* and is incorporated herein by reference.

ITEM 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

Information required by this item will be included under the captions *Security Ownership of Certain Beneficial Owners and Management* and *Executive Compensation* contained in our Proxy Statement and is incorporated herein by reference.

ITEM 13. *Certain Relationships and Related Party Transactions, and Director Independence*

Information required by this item will be included under the captions *Certain Relationships and Related Transactions* and *Information Regarding the Board of Directors* contained in our Proxy Statement and is incorporated herein by reference.

ITEM 14. *Principal Accounting Fees and Services*

Information required by this item will be included under the captions *Selection of Independent Registered Public Accounting Firm* contained in our Proxy Statement and is incorporated herein by reference.

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PART IV

ITEM 15. ***Exhibits and Financial Statement Schedules***

(a)

Documents filed as part of this report:

(1)

Financial Statements. The following financial statements of Neos Therapeutics, Inc., together with the report thereon of RSM US LLP, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K, are included on pages **F-2** through **F-41**, as follows:

(2)

Financial Statement Schedule.

Schedule II Valuation and Qualifying Accounts

(3)

The exhibits required by Items 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits and are incorporated herein.

ITEM 16. ***Form of 10-K Summary***

None.

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Neos Therapeutics, Inc.

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Neos Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Neos Therapeutics, Inc. and Subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. Our audits also included the financial statement schedule of Neos Therapeutics, Inc. and Subsidiaries listed in Item 15(a). These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Neos Therapeutics, Inc. and Subsidiaries as of December 31, 2016, and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ RSM US LLP

New York, New York
March 15, 2017

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Neos Therapeutics, Inc. and Subsidiaries

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)	December 31, 2016	2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 24,352	$ 90,763
Short-term investments	15,430	
Accounts receivable, net of allowances for chargebacks and cash discounts of $950 and $1,039, respectively	6,135	3,903
Inventories	5,767	2,520
Deferred contract sales organization fees	720	
Other current assets	2,865	1,058
Total current assets	55,269	98,244
Property and equipment, net	7,076	5,124
Intangible assets, net	15,579	16,672
Other assets	2,218	2,470
Total assets	$ 80,142	$ 122,510
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 7,798	$ 4,824
Accrued expenses	5,264	3,141
Deferred revenue	3,662	
Current portion of long-term debt	4,921	7,973
Total current liabilities	21,645	15,938
Long-Term Liabilities:		
Long-term debt, net of current portion	58,599	26,271
Earnout liability	232	214
Deferred gain on leaseback	40	547
Deferred rent	1,174	1,166
Total long-term liabilities	60,045	28,198
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at December 31, 2016 and December 31, 2015		
Common stock, $0.001 par value, 100,000,000 authorized at December 31, 2016 and December 31, 2015; 16,079,902 and 16,060,996 issued and outstanding, respectively, at December 31, 2016; 16,025,155 and 16,015,958 issued and outstanding, respectively, at December 31, 2015	16	16
Treasury stock, at cost, 18,906 shares at December 31, 2016; 9,197 shares at December 31, 2015	(232)	(171)
Additional paid-in capital	198,787	195,314
Accumulated deficit	(200,118)	(116,785)
Accumulated other comprehensive loss	(1)	
Total stockholders' equity (deficit)	(1,548)	78,374

Total liabilities and stockholders' equity (deficit)	$	80,142	$	122,510

See notes to consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Year Ended December 31, 2016	2015	2014
Revenues:			
Product	$ 9,154	$ 3,792	$ 316
Manufacturing			113
Profit sharing			169
Development			160
	9,154	3,792	758
Cost of Goods Sold	11,437	5,929	3,391
Gross loss	(2,283)	(2,137)	(2,633)
Research and development	12,207	11,691	10,574
Selling and marketing expenses	49,291	5,672	229
General and administrative expenses	12,625	7,078	5,036
Loss from operations	(76,406)	(26,578)	(18,472)
Interest expense	(6,937)	(3,721)	(2,520)
Loss on debt extinguishment	(1,187)		(445)
Other income, net	1,215	831	837
Change in fair value of earnout and warrant liabilities	(18)	(1,313)	(249)
Net loss	(83,333)	(30,781)	(20,849)
Preferred stock accretion to redemption value		(1,169)	(1,118)
Preferred stock dividends		(1,221)	(2,185)
Net loss attributable to common stock	$ (83,333)	$ (33,171)	$ (24,152)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	16,052,390	7,581,881	876,318
Net loss per share of common stock, basic and diluted:	$ (5.19)	$ (4.38)	$ (27.56)

See notes to consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)	Year Ended December 31, 2016	2015	2014
Net loss	$ (83,333)	$ (30,781)	$ (20,849)
Other comprehensive loss:			
Net unrealized gain on short-term investments	2		
Reclassification of gains included in net loss	(3)		
Total other comprehensive loss	$ (1)	$	$
Comprehensive loss	$ (83,334)	$ (30,781)	$ (20,849)

See notes to consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except shares)	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Treasury Stock Shares	Treasury Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
Balance, December 31, 2013		$	925,451	$ 1	(55,905)	$	$ 4,617	$ (59,462)	$	$ (54,844)
Proceeds from exercise of options and warrants			13,408				4			4
Share-based compensation expense							210			210
Series B Preferred Stock accretion to redemption value								(352)		(352)
Series B-1 Preferred Stock accretion to redemption value								(679)		(679)
Series B-1 accrued dividend								(2,185)		(2,185)
Series C Preferred Stock accretion to redemption value								(87)		(87)
Net loss								(20,849)		(20,849)
Balance, December 31, 2014		$	938,859	$ 1	(55,905)	$	$ 4,831	$ (83,614)	$	$ (78,782)
Proceeds from exercise of options and warrants			325,292				75			75
Share-based compensation expense							1,181			1,181
Cancellation of treasury stock			(55,905)		55,905					
Purchase of treasury stock					(9,197)	(171)				(171)
Series B Preferred Stock accretion to redemption value								(192)		(192)
Series B-1 Preferred Stock accretion to redemption value								(370)		(370)
Series B-1 accrued dividend								(1,221)		(1,221)
Series C Preferred Stock accretion to redemption value								(607)		(607)
Conversion of Redeemable Preferred Stock			9,217,983	9			110,767			110,776
Cashless exercise of Series C warrants issued with Series C financing			78,926				2,842			2,842
Reclassification of Series C warrants issued with senior debt							611			611
Net proceeds from issuance of common stock in IPO			5,520,000	6			75,007			75,013
Net loss								(30,781)		(30,781)
Balance, December 31, 2015		$	16,025,155	$ 16	(9,197)	$ (171)	$ 195,314	$ (116,785)	$	$ 78,374
Proceeds from exercise of options and warrants			54,747				13			13
Share-based compensation expense							3,460			3,460
Purchase of treasury stock					(9,709)	(61)				(61)
Net unrealized loss on investments									(1)	(1)
Net loss								(83,333)		(83,333)
Balance, December 31, 2016		$	16,079,902	$ 16	(18,906)	$ (232)	$ 198,787	$ (200,118)	$ (1)	$ (1,548)

See notes to consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Year Ended December 31, 2016	2015	2014
Cash Flows From Operating Activities:			
Net loss	$ (83,333)	$ (30,781)	$ (20,849)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation expense	3,460	1,181	210
Depreciation and amortization of property and equipment	1,598	1,724	1,645
Amortization of intangible assets	1,593	1,495	1,037
Changes in fair value of warrant and earnout liabilities	18	1,313	249
Amortization of patents	69	23	31
Amortization of senior debt fees	406	576	182
Amortization of short-term investment purchase discounts	(156)		
Deferred interest on debt	4,738	548	511
Loss on debt extinguishment	942		445
Gain on sale of equipment	(922)	(831)	(824)
Change in deferred rent	8	(23)	41
Realized gain on sale of short-term investments	(3)		
Provision for bad debts			(264)
Changes in operating assets and liabilities:			
Accounts receivable	(2,232)	(3,536)	417
Inventories	(3,247)	(489)	(1,612)
Deferred contract sales organization fees	(720)		
Other current assets	(1,807)	(794)	(167)
Other assets	183	(266)	(231)
Accounts payable	2,974	3,567	284
Accrued expenses	2,123	426	1,505
Deferred revenue	3,662		
Net cash used in operating activities	(70,646)	(25,867)	(17,390)
Cash Flows From Investing Activities:			
Purchases of short-term investments	(66,088)		
Sales and maturities of short-term investments	50,816	3,000	4,497
Capital expenditures	(3,550)	(1,023)	(339)
Intangible asset acquisition	(500)		(6,283)
Net cash provided by (used in) investing activities	(19,322)	1,977	(2,125)
Cash Flows From Financing Activities:			
Proceeds from Deerfield debt note, net of fees	58,419		
Proceeds from senior debt note		10,000	15,000
Prepayment of senior debt and fee	(26,063)		
Proceeds from sale of equipment	415		795
Net proceeds from issuance of stock	13	18,122	17,350
Net proceeds from initial public offering, net of underwriting discounts, commissions and offering costs		75,013	
Payments made on borrowings	(9,166)	(1,654)	(11,671)
Payments made to purchase treasury stock	(61)	(171)	
Deferred financing costs			(563)
Net cash provided by financing activities	23,557	101,310	20,911
Increase (decrease) in cash and cash equivalents	(66,411)	77,420	1,396
Cash and Cash Equivalents:			
Beginning	90,763	13,343	11,947
Ending	$ 24,352	$ 90,763	$ 13,343

Noncash Investing and Financing Activities:			
Earnout liability incurred in connection with intangible asset acquisition	$	$	$ 589
Issuance of stock warrants	$	$ 2,131	$ 1,707
Exercise of Series C warrants for Series C Preferred Stock	$	$ 2,322	$
Cashless exercise of Series C warrants from Series C financing in IPO closing	$	$ 2,842	$
Conversion of Redeemable Preferred Stocks into Common Stock	$	$ 110,776	$
Reclassification of Series C warrants issued with senior debt upon IPO closing	$	$ 611	$
Preferred stock accretion	$	$ 1,169	$ 1,118
Preferred stock dividend	$	$ 1,221	$ 2,185
Supplemental Cash Flow Information:			
Interest paid	$ 2,857	$ 2,524	$ 1,793

See notes to consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and nature of operations

Neos Therapeutics, Inc., a Delaware corporation, and its subsidiaries (the "Company") is a fully integrated pharmaceutical company. The Company has developed a broad, proprietary modified-release drug delivery technology that enables the manufacture of single and multiple ingredient extended-release pharmaceuticals in patient- and caregiver-friendly orally disintegrating tablet and liquid suspension dosage forms. The Company has a pipeline of extended-release pharmaceuticals including one approved product and two proprietary product candidates in late stage development for the treatment of attention deficit hyperactivity disorder ("ADHD"). Adzenys XR-ODT was approved by the US Food and Drug Administration, or FDA, on January 27, 2016. In addition, the Company manufactures and markets a generic Tussionex (hydrocodone and chlorpheniramine) ("generic Tussionex") extended-release liquid suspension for the treatment of cough and upper respiratory symptoms of a cold. These products are developed and manufactured using the Company's proprietary and patented modified-release drug delivery technology. The Company's predecessor company was incorporated in Texas on November 30, 1994 as PharmaFab, Inc. and subsequently changed its name to Neostx, Inc. On June 15, 2009, the Company completed a reorganization pursuant to which substantially all of the capital stock of Neostx, Inc. was acquired by a newly formed Delaware corporation, named Neos Therapeutics, Inc. The remaining capital stock of Neostx, Inc. was acquired by the Company on June 29, 2015. Historically, the Company was primarily engaged in the development and contract manufacturing of unapproved or Drug Efficacy Study Indication ("DESI"), pharmaceuticals and, to a lesser extent, nutraceuticals for third parties. The unapproved or DESI pharmaceuticals contract business was discontinued in 2007 and the manufacturing of nutraceuticals for third parties was discontinued in March 2013.

On August 28, 2014, the Company completed an acquisition of all of the rights to the Tussionex Abbreviated New Drug Application ("Tussionex ANDA"), which included the rights to produce, develop, market and sell, as well as all the profits from such selling activities, the Company's generic Tussionex, which the Company previously owned the rights to manufacture, but which was marketed and sold by the generic drug division of Cornerstone Biopharma, Inc. ("Cornerstone"). These rights were acquired from the collaboration of the Company, Cornerstone and Coating Place, Inc. ("CPI"), a supplier of the resins for the product (see Note 9). Prior to the acquisition, the Company, Cornerstone and CPI shared profits generated by the sale and manufacture of the product under a development and manufacturing agreement with those companies.

On July 28, 2015, the Company closed its initial public offering ("IPO") whereby the Company sold 5,520,000 shares of common stock, at a public offering price of $15.00 per share, which includes 720,000 shares of common stock resulting from the underwriters' exercise of their over-allotment option at the IPO price on July 23, 2015. Proceeds from the Company's IPO, net of underwriting discounts and commissions and other offering costs, were $75.0 million.

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

Between June 30, 2015 and July 27, 2015, the Company issued a total of 1,000,000 shares of its Series C redeemable convertible preferred stock ("Series C") to several existing investors upon the exercise of warrants to purchase Series C preferred stock ("Series C warrants") held by those investors at an exercise price of $5.00 per share, for an aggregate exercise price of $5.0 million. On the IPO

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Organization and nature of operations (Continued)

closing date, all outstanding shares of redeemable preferred stock converted into 9,217,983 shares of common stock and all remaining outstanding Series C warrants issued in conjunction with purchases of Series C were net exercised at the IPO price for 78,926 shares of common stock. Upon the closing of the Company's IPO, all of the shares of the Company's redeemable convertible preferred stock ("Preferred Shares") were retired and cancelled and shall not be reissued as shares of such series, and all rights and preferences of those Preferred Shares were cancelled including the right to receive undeclared accumulated dividends. These transactions produced a significant increase in the number of shares outstanding which will impact the year-over-year comparability of the Company's loss per share calculations. Additionally, in connection with the closing of the IPO, the Company amended and restated its certificate of incorporation to increase the number of authorized shares of common stock to 100,000,000 and to authorize 5,000,000 shares of undesignated preferred stock.

Note 2. Summary of significant accounting policies

Basis of Presentation: The consolidated financial statements are presented in accordance with accounting principles generally accepted in the United States of America, or GAAP, and with the rules and regulations of the Securities and Exchange Commission, or SEC.

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

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

Short-term investments: Short-term investments consist of debt securities that have original maturities greater than three months but less than or equal to one year and are classified as available-for-sale securities. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive loss, which is a separate component of stockholders' equity. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in other income (expense) in the consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income are recognized in other income when earned. The cost of securities sold is calculated using the specific

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

identification method. The Company places all investments with government agencies, or corporate institutions whose debt is rated as investment grade. The Company classifies all available-for-sale marketable securities with maturities greater than one year from the balance sheet date, if any, as non-current assets.

Allowance for doubtful accounts: The allowance for doubtful accounts is maintained at a level considered adequate to provide for losses that can be reasonably anticipated. Management determines the adequacy of the allowance based on reviews of individual accounts, historical losses, existing economic conditions and estimates based on management's judgments in specific matters. Accounts are written off as they are deemed uncollectible based on periodic review of the accounts. There is no allowance for doubtful accounts at December 31, 2016 or December 31, 2015, as management believes that all receivables are fully collectible.

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

Inventories: Inventories are stated at the lower of cost (first in, first out) or market and have been reduced by an allowance for excess and obsolete inventories. Cost elements include material, labor and manufacturing overhead. Inventories consist of raw materials, work in process, finished goods and deferred cost of goods sold. The cost of sales associated with the deferred product revenues are recorded as deferred costs of goods sold that are released from inventory into cost of goods sold as the deferred revenue is recognized into revenue.

Until objective and persuasive evidence exists that regulatory approval has been received and future economic benefit is probable, pre-launch inventories are expensed into research and development. Manufacturing costs for the production of Adzenys XR-ODT incurred after the January 27, 2016 FDA approval date are being capitalized into inventory.

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

Property and equipment: Property and equipment is recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to ten years. Leasehold improvements are amortized using the straight-line method over the shorter of the respective lease term or the estimated useful lives of the assets.

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

Impairment of long-lived assets: Long-lived assets such as property and equipment and intangibles subject to amortization are evaluated for impairment whenever events or changes in circumstances

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

indicate that the carrying value of an asset group may not be recoverable. Such assets are also evaluated for impairment in light of the Company's continuing losses. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than the carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. No impairment charges were recorded for the years ended December 31, 2016, 2015 or 2014.

Patent costs: The Company estimates that the patents it has filed have a future beneficial value. Therefore, costs associated with filing for its patents are capitalized. Once the patent is approved and commercial revenue realized, the costs associated with the patent are amortized over the useful life of the patent. If the patent is not approved, the costs will be expensed.

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

The Company sells its generic Tussionex to a limited number of pharmaceutical wholesalers. Pharmaceutical wholesalers buy drug products directly from manufacturers. Title to the product passes upon delivery to the wholesalers, when the risks and rewards of ownership are assumed by the wholesaler (freight on board destination). These wholesalers then resell the product to retail customers such as food, drug and mass merchandisers.

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

The Company's manufacturing, profit sharing and development revenue ended in 2014 as the Company has terminated the Company's development and manufacturing agreement. As a result of the Company's acquisition of the rights to commercialize and derive future profits from the Tussionex ANDA, the Company will utilize its manufacturing capability to derive revenue directly from sales made by the Company, rather than through the Company's commercial partner.

Net product sales

Net product sales for the Company's products represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments include savings offers, prompt payment discounts,

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

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

Savings offers

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

Product returns

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

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

Rebates

The Company's products are subject to commercial managed care and government-managed Medicare and Medicaid programs whereby discounts and rebates are provided to participating state governments. Estimated rebates payable under such programs are recorded as a reduction of revenue

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

at the time revenues are recorded. Calculations related to these rebate accruals are estimated based on information from third-party providers. Historical trend of such rebates will be continually monitored and may result in future adjustments to such estimates.

Wholesaler Chargebacks

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

Manufacturing

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

Profit sharing

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

Development revenue

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

Distribution expenses: Costs invoiced to the Company by its third party logistics firm are classified as cost of goods sold in the consolidated statements of operations.

Shipping and handling costs: Amounts billed to customers for shipping and handling fees for the delivery of goods are classified as cost of goods sold in the consolidated statements of operations.

Advertising costs: Advertising costs are comprised of print and electronic media placements that are expensed as incurred. The Company recognized advertising costs of $7.4 million during the year ended December 31, 2016. There were no advertising costs incurred during the years ended December 31, 2015 and 2014.

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

Research and development costs: Research and development costs are charged to operations when incurred, include salaries and benefits, facilities costs, overhead costs, raw materials, laboratory and clinical supplies, clinical trial costs, contract services, fees paid to regulatory authorities for review and approval of the Company's product candidates and other related costs, and are included in research and development in the consolidated statements of operations. During the third quarter of 2016, the Company reclassified its approved product and facility regulatory fees out of research and development expense and into cost of sales commensurate with the commercial launch of Adzenys XR-ODT. The Company has reclassified all such applicable regulatory fees for prior quarters and prior years out of research and development expense and into cost of goods sold in accordance with this approach.

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

Management evaluates the Company's tax positions in accordance with guidance on accounting for uncertainty in income taxes. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not that the position will be sustained upon examination. As of December 31, 2016 and 2015, the Company has unrecognized tax benefits associated with uncertain tax positions in the consolidated financial statements. These uncertain tax positions were netted against net operating losses (NOL's) with no separate reserve for uncertain tax positions required.

Deferred tax assets should be reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized. In evaluating the objective evidence that historical results provide, we consider that three years of cumulative operating losses was significant negative evidence outweighing projections for future taxable income. Therefore, management has determined that it is more likely than not that the deferred tax assets will not be realized. Accordingly, the Company has recorded a valuation allowance to reduce deferred tax assets to zero.

Paragraph IV Litigation Costs: Legal costs incurred by the Company in the enforcement of the Company's intellectual property rights are charged to expense as incurred.

Warrants: The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on the Company's balance sheet at their fair value on the date of issuance and prior to completion of the Company's IPO were revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense) in the statements of operations. The Company estimates the fair value of its derivative liabilities using third party valuation analysis that utilizes option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for expected volatility, expected life, yield, and risk-free interest rate. Prior to the closing of the IPO, the Company's Series C warrants were determined to be derivative liabilities and they were revalued at each subsequent balance sheet date. Upon closing the IPO, the warrants issued in conjunction with the Series C financing were exchanged in a cashless exercise for 947,185 shares of Series C which converted into 78,926 shares of the Company's common stock. The remaining Series C warrants issued with the senior debt to purchase 170,000 pre-split shares of Series C ("Hercules Warrants") were converted into warrants to purchase 70,833 shares of the Company's

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

common stock and the warrant liability was reclassified to Additional Paid in Capital within Stockholders' Equity (Deficit).

Share-based compensation: Share-based compensation awards, including grants of employee stock options and restricted stock and modifications to existing stock options, are recognized in the consolidated statement of operations based on their fair values. Compensation expense related to awards to employees is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. The fair value of the Company's stock-based awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends. Due to the previous lack of a public market for the trading of its common stock and a lack of company-specific historical and implied volatility data, the Company has, prior to the IPO, historically utilized third party valuation analyses to determine the fair value. After the closing of the Company's IPO, the Company's board of directors has determined the fair value of each share of underlying common stock based on the closing price of the Company's common stock as reported by the NASDAQ Global Market on the date of grant. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest. Beginning in July 2016, the Company began recording stock compensation expense in the same income statement line as the cash compensation of the employee with the option in accordance with Staff Accounting Bulletin Topic 14 due to the increased number and amount of options and option compensation. The Company has reclassified all prior periods' amounts out of general and administrative expense to the appropriate income statement line in accordance with this approach.

Use of estimates: The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates.

Concentration of credit risk: Accounts receivable subjects the Company to concentrations of credit risk. Thirteen customers accounted for all the revenue and deferred revenue in the year ended December 31, 2016 and accounts receivable at December 31, 2016 were due from eleven customers. Two customers accounted for 82% of the net revenue for the year ended December 31, 2016, and three customers accounted for 98% of the accounts receivable at December 31, 2016. Four and two customers accounted for substantially all revenue in the years ended December 31, 2015 and 2014, respectively. Accounts receivable at December 31, 2015 were due from three customers.

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

Liquidity: During 2016, 2015 and 2014, the Company produced operating losses and used cash to fund operations. Management intends to achieve profitability through revenue growth from pharmaceutical products developed with its extended-release technologies. The Company does not anticipate it will be profitable until after the successful commercialization of its approved product, Adzenys XR-ODT, or one or more of its ADHD product candidates. Management believes that its existing cash and cash equivalents and short-term investments, taken together with the net proceeds which the Company received from its public offering of common stock completed in February 2017, will be sufficient to fund the Company's operations for at least the next 12 months after the filing of this Annual Report on Form 10-K.

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

Application of revised accounting standards: In April 2012, the Jumpstart Our Business Startups Act (the "JOBS Act"), was enacted in the United States. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. In 2015, the Company irrevocably elected not to avail itself of this extended transition period and, as a result, will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Recent accounting pronouncements:

In August 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This ASU was designed to reduce the diversity in practice of how the eight specified items are presented and classified in the statement of cash flows, including debt prepayment or debt extinguishment costs. The amendments are effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those years. The Company believes the amendments will not have a significant effect on its ongoing financial reporting as the Company has classified its debt prepayment and debt extinguishment costs, in the Consolidated Statements of Cash Flows in accordance with the amendments.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation Stock Compensation Improvements to Employee Share-Based Payment Accounting (Topic 718)*. For public companies, areas of accounting for share-based payment that this ASU was designed to simplify include: the income tax consequences, the accounting policy for forfeitures, the classification of awards as either equity or liabilities and the classification on the statement of cash flows. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2016, including interim periods within those years. The adoption of this standard is not expected to have a material impact on the Company's business, financial position, results of operations or liquidity.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and 2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019, including interim periods within those years. The new standard must be adopted using a modified retrospective transition and requires application of the new guidance at the beginning of the earliest comparative period presented. The Company is evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory Simplifying the Measurement of Inventory (Topic 330).* The amendments in this ASU require an entity to measure inventory that is not measured using the last-in, first-out (LIFO) or retail inventory methods at the lower of cost and net

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of significant accounting policies (Continued)

realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, including interim periods within those years. The Company does not believe that this ASU will have a significant effect on its ongoing financial reporting as valuing inventory at the lower of cost or net realizable value approximates the current policy of valuing inventory at the lower of cost or market.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. This ASU is for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company has performed the review required by this ASU and believes the Company presently has sufficient liquidity to continue to operate for the next twelve months from its filing date.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). The guidance replaces transaction-and industry-specific revenue recognition guidance under current U.S. GAAP with a principles-based approach for determining revenue recognition. The new guidance requires an entity to recognize the amount of revenue based on the value of transferred goods or services to customers. There are also additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB delayed the effective date to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. In addition, in March and April 2016, the FASB issued new guidance intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. Both amendments permit the use of either a retrospective or cumulative effect transition method and are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, with early application permitted. The Company has limited sales history for its branded product that may not allow for reliable estimates of expected returns of the product at the time of shipment to wholesalers. The Company is assessing other market data and the impact of this new standard on its financial statements and has not yet selected a transition method.

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

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

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 3. Net loss per share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. Potentially dilutive securities, which include redeemable convertible preferred stock, warrants, and outstanding stock options under the stock option plan, have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following potentially dilutive securities were excluded from consideration in the computation of diluted net loss per share of common stock for the periods presented because including them would have been anti-dilutive:

	December 31,		
	2016	**2015**	**2014**
Series A Redeemable Convertible Preferred Stock (as converted)			487,494
Series B Redeemable Convertible Preferred Stock (as converted)			1,297,100
Series B-1 Redeemable Convertible Preferred Stock (as converted)			2,275,733
Series C Redeemable Convertible Preferred Stock (as converted)			3,647,274
Series C Redeemable Convertible Preferred Stock Warrants (as converted)	70,833	70,833	383,316
Common Stock Warrants		50,158	337,133
Stock options	2,107,344	1,352,283	511,775

Note 4. Fair value of financial instruments

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

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Fair value of financial instruments (Continued)

Financial assets recorded at fair value on the Company's consolidated balance sheets are categorized as follows:

Level 1: Unadjusted quoted prices for identical assets in an active market.

Level 2: Quoted prices in markets that are not active or inputs that are observable either directly or indirectly for substantially the full-term of the asset. Level 2 inputs include the following:

- Quoted prices for similar assets in active markets.
- Quoted prices for identical or similar assets in nonactive markets.
- Inputs other than quoted market prices that are observable.
- Inputs that are derived principally from or corroborated by observable market data through correlation or other means.

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

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

	Fair Value as of December 31, 2016			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash and cash equivalents	$ 17,917	$ 6,435	$	$ 24,352
Short-term investments		15,430		15,430
Earnout liability			232	232
	$ 17,917	$ 21,865	$ 232	$ 40,014

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

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

Beginning in February 2016, the Company's Level 2 assets include commercial paper and corporate bonds with maturities of less than 90 days less whose values are considered to approximate fair value at December 31, 2016 and 2015 due to the short-term nature of the instruments and/or the current

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Fair value of financial instruments (Continued)

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

The Company's cash and cash equivalents and short-term investments had quoted prices at December 31, 2016 as shown below:

	December 31, 2016		
	Amortized Cost	Unrealized Loss	Market Value
	(in thousands)		
Bank deposits and money market funds	$ 17,917	$	$ 17,917
Financial and corporate debt securities	21,866	(1)	21,865
	$ 39,783	$ (1)	$ 39,782

Level 3 liabilities include the fair values of the earnout liability.

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

	Initial Valuation Earnout Liability	December 31, 2014 Earnout Liability	December 31, 2015 Earnout Liability	December 31, 2016 Earnout Liability
	(Dollars in thousands)			
Date of Valuation	**8/28/2014**	**12/31/2014**	**12/31/2015**	**12/31/2016**
Valuation Method	Monte Carlo	Monte Carlo	Monte Carlo	Monte Carlo
Volatility (annual)	50%	50%	50%	50%
Risk-free rate (annual)	.03% - 3.56%	.15% - 3.21%	.56% - 3.31%	.74% - 3.42%
Time period from valuation until end of earnout	.1708 - 9.8417	.5 - 9.5	.5 - 9.5	.5 - 9.5
Earnout Target 1	$13,700	$13,700	$13,700	$13,700
Earnout Target 2	$18,200	$18,200	$18,200	$18,200
Discount rate	8.03% - 10.51%	7.96% - 11.03%	8.11% - 10.86%	12.02% - 14.70%
Fair value of liability at valuation date	$589	$756	$214	$232

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Fair value of financial instruments (Continued)

The methodologies and significant inputs used in the determination of the fair value of the Hercules Warrants through July 22. 2015 were as follows:

	Series C Warrants Issued With March 28, 2014 Senior Debt	Series C Warrants Issued With September 25, 2014 Senior Debt	Revalue Series C Warrants Issued with Senior Debt at December 31, 2014	Revalue Series C Warrants Issued with Senior Debt at July 22, 2015
	(Dollars in thousands, except $5 and $12 Exercise Prices)			
Date of Valuation	3/28/2014	9/25/2014	**12/31/2014**	**7/22/2015**
Valuation Method	Black-Scholes-Merton	PWERM and Black-Scholes-Merton	PWERM and Option Pricing	Black-Scholes-Merton Option-Pricing
Dividend yield (per share)	0	0	0	0
Exercise price	$5	$5	$5	$12
Volatility (annual)	60%	60%	60%	60%
Risk-free rate (annual)	0.34%	2.03%	.25% - 2.47%	1.78%
Contractual term (years)	1.76	5.76	1 - 5	5
Number of warrants	60,000	110,000	170,000	70,833
Fair value of liability at valuation date	$124	$248	$454	$611

As the Hercules Warrants converted into warrants for common stock effective on July 22, 2015 with the IPO, with a term of five years from the IPO date, it was determined that the Black-Scholes-Merton Option-Pricing model would provide a better indication of the fair value as it was designed to calculate the value of a put or call option over time.

The methodologies and significant inputs used in the determination of the fair value of the Series C warrants issued with the Series C through July 22, 2015 were as follows:

	Initial Valuation of December 31, 2014 Warrants Issued With Series C Redeemable Preferred Stock	Initial Valuation of January 2015 Warrants Issued With Series C Redeemable Preferred Stock	Initial Valuation of February 2015 Warrants Issued With Series C Redeemable Preferred Stock	Revalue All Warrants Issued With Series C Redeemable Preferred Stock at July 22, 2015
	(Dollars in thousands, except $5 and $12 Exercise Prices)			
Date of Valuation	**12/31/2014**	**1/31/2015**	**2/28/2015**	**7/22/2015**
Valuation Method	PWERM and Option Pricing	PWERM and Option Pricing	PWERM and Option Pricing	Intrinsic Value
Dividend yield (per share)	0	0	0	0
Exercise price	$5	$5	$5	$12
Volatility (annual)	60%	60%	60%	
Risk-free rate (annual)	.25% - 2.47%	.25% - 2.47%	.25% - 2.47%	
Contractual term (years)	1 - 5	1 - 5	1 - 5	
Number of warrants	749,967	590,906	606,312	1,347,185
Fair value of liability at valuation date	$1,335	$1,052	$1,079	$4,042

Significant changes to these assumptions in the preceding valuation tables would result in increases/decreases to the fair value of the earnout liability.

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Fair value of financial instruments (Continued)

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

	Earnout Liability	Series C Warrants Issued With Senior Debt	Series C Warrants Issued With Series C Redeemable Preferred Stock Financing
		(in thousands)	
Balance at December 31, 2014	$ 756	$ 454	$ 1,335
Additions during the period			2,131
Changes in fair value	(542)	157	1,698
Warrants exercised			(2,322)
Cashless warrant exercise due to IPO			(2,842)
Conversion to common stock warrant		(611)	
Balance at December 31, 2015	$ 214	$	$
Change in fair value	18		
Balance at December 31, 2016	$ 232		

Upon closing the IPO, the warrants issued in conjunction with the Series C financing were exchanged in a cashless exercise for 947,185 shares of Series C which converted into 78,926 shares of the Company's common stock. The remaining Series C warrants issued with the senior debt to purchase 170,000 pre-split shares of Series C ("Hercules Warrants") were converted into warrants to purchase 70,833 shares of the Company's common stock and the warrant liability was reclassified to Additional Paid in Capital within Stockholders' Equity (Deficit).

The 2015 reductions in fair value of the earnout liability shown above resulted from new information regarding the projected impact of the DEA's reclassification of Tussionex from a Schedule III controlled substance to a Schedule II controlled substance and a review of the launch dates of the Company's approved product, Adzenys XR-ODT, and its two ADHD product candidates. The 2015 increases in the fair value of the Series C warrants were due to the increased weighting of the IPO scenario in the PWERM model.

Note 5. Inventories

Inventories at the indicated dates consist of the following:

	December 31,	
	2016	2015
	(in thousands)	
Raw materials	$ 1,672	$ 1,211
Work in progress	2,546	175
Finished goods	2,060	1,189
Deferred cost of goods sold	225	
Inventory at cost	6,503	2,575
Inventory reserve	(736)	(55)

	$ 5,767	$ 2,520

The deferred cost of goods sold relates to Adzenys XR-ODT and will be recognized when associated revenue is recognized.

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 6. Property and equipment

Property and equipment, net at the indicated dates consists of the following:

	December 31,	
	2016	2015
	(in thousands)	
Assets under capital lease	$ 1,793	$ 6,241
Leasehold improvements	3,757	3,497
Manufacturing, packaging and lab equipment	4,376	874
Office furniture and equipment	1,788	314
Assets under construction	2,066	244
	13,780	11,170
Accumulated depreciation and amortization (including $762 and $3,684 at December 31, 2016 and 2015, respectively, applicable to capital leases)	(6,704)	(6,046)
	$ 7,076	$ 5,124

Depreciation and amortization expense related to property and equipment was $1,598,000, $1,724,000 and $1,645,000 for the years ended December 31, 2016, 2015 and 2014, respectively. Depreciation and amortization expense is recorded in cost of goods sold, research and development, or general and administrative expenses in the accompanying consolidated statements of operations. As noted in Note 7, the Company sold and leased back a substantial portion of its operating assets in a series of capital lease transactions.

On October 20, 2016, the Company utilized a third party auctioneer to conduct an auction of certain fully-depreciated equipment assets, resulting in net proceeds of approximately $415,000 which were paid during the fourth quarter of 2016 and were recorded as a gain on sale and included in other income (loss) in the Company's consolidated statement of operations.

Included in the total of assets under capital lease as of December 31, 2016 and December 31, 2015, are certain manufacturing, packaging and lab equipment that are temporarily idle as a result of the cessation of contract manufacturing. The cost of these assets was $811,000 and $1,699,000, and the accumulated depreciation of these assets was $811,000 and $1,396,000 at December 31, 2016 and December 31, 2015, respectively.

Note 7. Sale-leaseback transaction

The Company accounts for the sale and leaseback transactions discussed below as capital leases under the provisions of Accounting Standards Codification ("ASC") Topic 840-40, *Leases Sale Leaseback Transactions*. Accordingly, the leased assets are recorded in property and equipment and the capitalized lease obligations are included in long-term liabilities at the present value of the future lease payments in accordance with the terms of the lease (see Note 11 for further details). Lease payments are applied using the effective interest rate inherent in the leases. Depreciation of the property and equipment is included within depreciation and amortization in the consolidated statements of operations and consolidated statements of cash flows.

In 2012, the Company negotiated financing arrangements with a related party which provided for the sale-leaseback of up to $6.5 million of the Company's property and equipment with a bargain

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Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Sale-leaseback transaction (Continued)

purchase option at the end of the respective lease. These financing arrangements were executed in five separate tranches that occurred in February, July and November 2013, and March 2014.

In the aggregate, the Company sold groups of assets for $795,000 and $5.5 million, which resulted in a net gains of approximately $116,000 and $2.7 million, in the years ended December 31, 2014 and 2013, respectively, and executed capital leases for these assets with repurchase options at the end of each respective lease term. Gains on the transactions are recognized on a straight-line basis over each respective 42-month lease term. The two February 2013 leases for a total of $3.5 million of assets expired in July 2016 and the related $2.6 million gain was fully amortized at that time and the $385,000 lease buy-out option liability was fully satisfied. The July 2013 lease for a total of $1.0 million of assets expired in December 2016 and the related $0.1 million loss had been recorded at inception of the lease and the $100,000 lease buy-out option liability was fully satisfied. For the years ended December 31, 2016, 2015 and 2014 approximately $507,000, $831,000 and $824,000, respectively, of the net gain was recognized in other income on the consolidated statements of operations.

	Leases 1 & 2 February 2013	Lease 3 July 2013	Lease 4 November 2013	Lease 5 March 2014	Total
			(in thousands)		
Carrying value at December 31, 2014	$ 1,613	$ 792	$ 839	$ 710	$ 3,954
Assets retired in 2015	(28)		(2)		(30)
2015 Amortization	(969)	(143)	(141)	(114)	(1,367)
Carrying value at December 31, 2015	$ 616	$ 649	$ 696	$ 596	$ 2,557
2016 Amortization	(616)	(143)	(147)	(114)	(1,020)
Transfer to property and equipment at end of lease		(506)			(506)
Carrying value at December 31, 2016	$	$	$ 549	$ 482	$ 1,031

Note 8. Intangible assets

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

	December 31, 2016	2015
	(in thousands)	
Proprietary modified-release drug delivery technology	$ 15,600	$ 15,600
Tussionex ANDA	4,829	4,829
CPI profit sharing	2,043	2,043
Other	784	284
	23,256	22,756
Accumulated amortization	(7,677)	(6,084)
	$ 15,579	$ 16,672