Neos Therapeutics, Inc.
Form 10-K
March 18, 2019

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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, 2018**

**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)

**Gerald McLaughlin, 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 every Interactive Data File required to be submitted 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 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, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| Large accelerated filer o | Accelerated filer ý | Non-accelerated filer o | Smaller reporting company ý |
|---|---|---|---|
| | | | Emerging growth company ý |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ý

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, 2018 was $177.9 million.

As of March 11, 2019, there were 49,710,677 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 2019 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, 2019.

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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 anticipated expenses, capital requirements and our needs for additional financings;
- our ability to commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or develop and commercialize any other future product or product candidate;
- our ability to maintain our license for NT0502, to obtain regulatory approval of NT0502 and to otherwise realize the intended benefits of this license;
- the effect of the amendment to our facility agreement with Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. and our ability to satisfy the repayment obligations thereunder;
- the cost or other aspects of the future sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or the timing, cost or other aspects of the commercial launch and future sales of any other future product or product candidate;
- our ability to increase our manufacturing and distribution capabilities for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or any other future product or product candidate;
- the attention deficit hyperactivity disorder patient market size and market adoption of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER by physicians and patients;
- the therapeutic benefits, effectiveness and safety of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or any other future product or product candidate;
- our expectations regarding the commercial supply of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, 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, ("FDA"), approvals, or other regulatory action in the United States and elsewhere, for any future product candidate;
- our expectations regarding federal, state and foreign regulatory requirements;
- our entry into the settlement and licensing agreement with Actavis Laboratories FL, Inc. ("Actavis") the effect of our agreement with Actavis on its Abbreviated New Drug Application ("ANDA") and with the FDA for a generic version of

Adzenys XR-ODT, and the expected timing of the manufacture and marketing of Actavis's generic version of Adzenys XR-ODT under the ANDA;

our entry into the settlement and licensing agreement with Teva Pharmaceuticals USA, Inc. ("Teva") the effect of our agreement with Teva on its ANDA and with the FDA for a generic version of Cotempla XR-ODT, and the expected timing of the manufacture and marketing of Teva's generic version of Cotempla XR-ODT under the ANDA;

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- our product research and development activities, including the timing and progress of our clinical trials, and projected expenditures;
- issuance of patents to us by the U.S. Patent and Trademark Office and other governmental patent agencies;
- our ability to achieve profitability;
- our staffing needs; and
- the additional risks, uncertainties and other factors described under the caption "Risk Factors" in this Annual 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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**NEOS THERAPEUTICS, INC.**
**Annual Report on Form 10-K**
**For the Fiscal Year Ended December 31, 2018**
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## PART I

### ITEM 1. Business

**Overview**

We are a fully-integrated 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, Cotempla XR-ODT and Adzenys ER oral suspension ("Adzenys ER"), for the treatment of attention deficit hyperactivity disorder ("ADHD"). Our products 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. We received approval from the FDA for Cotempla XR-ODT, our methylphenidate XR-ODT for the treatment of ADHD in patients 6 to 17 years old, on June 19, 2017. We initiated an early experience program with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017. Also, we received approval from the FDA for Adzenys ER, our amphetamine extended-release liquid suspension, on September 15, 2017, and launched the commercialization of this product on February 26, 2018. We believe Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER can address an unmet need by providing more patient- and caregiver-friendly dosing options not previously available to patients in the $8.9 billion market for ADHD-indicated medications. In addition to our marketed products, we are developing NT-0400, our preclinical XR-ODT product candidate, for nausea and vomiting, and NT0502, our preclinical product candidate for the treatment of sialorrhea.

Our branded products 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 and Cotempla XR-ODT are the first amphetamine XR-ODT and the first methylphenidate XR-ODT, respectively, for the treatment of ADHD on the market. 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 products. As a result of Abbreviated New Drug Applications ("ANDAs") filed with the FDA for a generic version of Adzenys XR-ODT by Actavis Laboratories FL, Inc. ("Actavis") and for a generic version of Cotempla XR-ODT by Teva Pharmaceuticals USA, Inc. ("Teva") we have entered into a Settlement Agreement and Licensing Agreement with Actavis whereby Actavis is granted the right to manufacture and market its generic version of Adzenys XR-ODT under its ANDA beginning on September 1, 2025, or earlier under certain circumstances, and a Settlement Agreement and Licensing Agreement with Teva whereby Teva is granted the right to manufacture and market its generic version of Cotempla XR-ODT under its ANDA beginning on July 1, 2026, or earlier under certain circumstances. These agreements have been submitted to the applicable governmental agencies.

In 2018, 74.8 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

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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 are focusing on commercialization in the United States using our own commercial infrastructure. We currently have a specialty sales force of approximately 75 representatives targeting the highest-volume prescribers of ADHD medication. We manufacture Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in our current Good 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 cold.

We believe we can apply our XR-ODT and XR liquid suspension technologies that underlie our branded products and our generic Tussionex to other active pharmaceutical ingredients ("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 ("CNS") conditions, such as stroke, Parkinson's disease and Alzheimer's disease often have difficulty swallowing their medication and may benefit from ODT and liquid suspension dosage forms. In 2019, we plan to further evaluate NT-0400, a preclinical product candidate for the treatment of nausea and vomiting to determine its development feasibility. On October 23, 2018, we entered into an Exclusive License Agreement (the "License Agreement") with NeuRx Pharmaceuticals LLC ("NeuRx"), pursuant to which NeuRx granted an exclusive, worldwide royalty-bearing license to us to develop, manufacture, and commercialize certain pharmaceutical products containing NeuRx's proprietary compound designated as NRX 101, referred to by us as NT0502. NT0502 is a new chemical entity and a selective muscarinic receptor antagonist that will utilize our microparticle technology, which is used in the Company's four on-market products. NT0502 will be developed to address the significant unmet medical needs for the treatment of chronic sialorrhea (excessive salivation or drooling) in adult and pediatric patients with neurological conditions including cerebral palsy, Parkinson's disease, mental retardation, and amyotrophic lateral sclerosis (ALS). We intend to utilize the regulatory pathway provided by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (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.

Our total revenues increased to $50.0 million for the year ended December 31, 2018, from $27.1 million for the year ended December 31, 2017 and $10.0 million for the year-ended December 31, 2016, all of which were generated in the United States.

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**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 targeted sales force and commercial infrastructure in the United States to efficiently market Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER as well as any of our other product candidates that we may develop that are FDA approved or any FDA approved products that we in-license.**

We believe that we can effectively commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in the United States with a specialty sales force of approximately 75 representatives. We intend to target the highest volume prescribers for the approved uses to address the unmet need for more patient- and caregiver-friendly dosage forms of the two most prescribed medications in the $8.9 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.

**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 products.

**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 (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

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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 2018, 74.8 million prescriptions for medications with ADHD labeling were written in the United States and generated $8.9 billion in sales. Approximately 91% 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 $2.8 billion and $5.8 billion in sales, respectively, in 2018 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 it 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 54% of ADHD prescriptions. Most of these 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

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extended-release chewable formulation of methylphenidate and Tris Pharmaceuticals launched an extended-release liquid formulation of amphetamine, Dyanavel XR™. In 2017, Quillivant XR had approximately 627,000 prescriptions and gross sales of approximately $193.3 million. Quillivant XR had captured a 0.9% share of the ADHD market in the fourth quarter of 2017 prior to a drug shortage issue at the end of year, which further impacted the Quillivant XR market share in 2018.

We launched commercialization of our amphetamine extended-release ODT, Adzenys XR-ODT, on May 16, 2016, initiated an early experience program with Cotempla XR-ODT with limited product availability on September 5, 2017 and launched this product nationwide on October 2, 2017, and launched Adzenys ER oral suspension on February 26, 2018. In 2018, we shipped 275,476, 211,440 and 1,836 units of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, respectively, generating $26.6 million and $19.0 million in product revenue for of Adzenys XR-ODTand Cotempla XR-ODT, respectively. Our ADHD portfolio captured a 0.62% aggregate share in the fourth quarter of 2018, including Adzenys XR-ODT and Cotempla XR-ODT which captured a 0.36% share and 0.25% share, respectively, of the ADHD market in the fourth quarter of 2018.

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 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 products:

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 two XR-ODT products and an XR liquid suspension product, each of which addresses an unmet need. Adzenys XR-ODT and Cotempla XR-ODT are the first XR-ODT products for the treatment of ADHD. We believe that our XR-ODT products have unique attributes to improve compliance and 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.

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Adzenys ER 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 Adzenys ER, may solve the swallowing issue that undermines compliance with tablet and capsule medication regimens.

**OUR CURRENTLY MARKETED PRODUCTS**

Utilizing our proprietary modified-release drug delivery technology platform, we currently manufacture and market Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and our generic Tussionex. We are in the early stages of discovering and developing future product candidates for which we intend to seek FDA approval in accordance with Section 505(b)(2). The table below summarizes our pipeline of 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 | Approved and marketed |
| Adzenys ER | Amphetamine for ADHD | XR Liquid Suspension | Approved and marketed |
| Generic Tussionex | Hydrocodone and chlorpheniramine for cough and upper respiratory symptoms of a cold | XR Liquid Suspension | Approved and marketed |

In general, our clinical development program for our branded products comprised single-dose clinical pharmacology studies, each designed to evaluate the bioequivalence and bioavailability of these dosage forms under different test conditions. Each product 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 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. In addition, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the "Actavis Agreement") with Actavis Laboratories FL, Inc. ("Actavis") which resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Adzenys XR-ODT. Under the Actavis Agreement, we granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances.

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**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 specialty sales force in approximately 75 territories targeting approximately 6,100 physicians who prescribe approximately 20% of all ADHD prescriptions. During 2018, we had 254,299 total prescriptions. The number of prescribers of Adzenys XR-ODT continues to grow, and during the year ended December 31, 2018, 12,684 health care providers had written prescriptions for the product.

**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.

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*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 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 ($AUC_{5[ib]-t,}$ $C_{max}$, $AUC_{last}$, and $AUC_{inf}$). The lower 90% confidence interval for early exposure ($AUC_{0[ib]-5}$) 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 significantly 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 Pharmaceuticals ("Shire"), the producer of Adderall XR, precluded the possibility of a 30-month stay of approval under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments.

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,

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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 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 commenced the program beginning with the pharmacokinetics trial in 2017, and we expect to complete this pharmacokinetics trial in 2019.

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

We received approval from the FDA for Cotempla XR-ODT, our methylphenidate XR-ODT for the treatment of ADHD in patients 6 to 17 years old, on June 19, 2017. We believe Cotempla XR-ODT is the first methylphenidate XR-ODT for the treatment of ADHD, providing onset-of-effect within one hour and a 12-hour duration. 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.

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 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. These patents are listed in the Orange Book, which we believe will provide additional market protection for Cotempla XR-ODT. Cotempla XR-ODT also has an FDA marketing exclusivity period of three years which bars approval of an ANDA. In addition, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the "Teva Agreement") with Teva Pharmaceuticals USA, Inc. ("Teva") which resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA with the FDA for a generic version of Cotempla XR-ODT. Under the Teva Agreement, we granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances.

**Cotempla XR-ODT commercialization**

We initiated an early experience program with limited product availability for Cotempla XR-ODT on September 5, 2017 before launching this product nationwide on October 2, 2017 and are commercializing this product in the United States with our own infrastructure. We are using the same dedicated contract specialty sales force that we are using for our commercialization of Adzenys XR-ODT, and have sales professionals in approximately 75 territories targeting approximately 6,100 physicians who prescribe approximately 20% of all ADHD prescriptions. During 2018, we had 156,996 total prescriptions. The number of prescribers of Cotempla XR-ODT continues to grow, and during the year ended December 31, 2018, 8,562 health care providers had written prescriptions for the product.

**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

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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. 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 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.

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**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.

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 Hatch-Waxman Amendments. 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 precluded the possibility of a 30-month stay of approval under the Hatch-Waxman Amendments.

We have committed to the FDA to conduct the following three trials as a post-marketing requirement after approval of the Cotempla XR-ODT NDA: 1) a single-dose, open-label, randomized pharmacokinetic study of Cotempla XR-ODT (methylphenidate 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 Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablets), in children ages 4 to 5 years diagnosed with ADHD; and 3) a 6-month Pediatric Open-Label Safety Study of patients age 4 to 5 years (at the time of entry into the second study, or at the time of enrollment if directly enrolled into this study) diagnosed with ADHD treated with Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablets). We commenced with the pharmacokinetics trial in 2018, and we expect to complete this pharmacokinetics trial in 2019.

**Adzenys ER: Amphetamine XR liquid suspension for the treatment of ADHD**

We received approval from the FDA for Adzenys ER, our amphetamine extended-release liquid suspension, on September 15, 2017. There are currently no post-marketing requirements for this product.

In addition to the clinical trial program outlined below, we conducted two additional bioequivalence studies for Adzenys ER, 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.

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Adzenys ER 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. Adzenys ER is designed to be shelf stable for 24 months, without requiring refrigeration or reconstitution. We have composition-of-matter patents for Adzenys ER that are scheduled to expire in 2032. These patents are listed in the Orange Book, which we believe will provide additional market protection for Adzenys ER.

**Adzenys ER commercialization**

We launched the commercialization of Adzenys ER on February 26, 2018 and are commercializing this product in the United States with our own infrastructure. We are using the same dedicated contract specialty sales force that we are using for our commercialization of Adzenys XR-ODT and Cotempla XR-ODT, and have sales professionals in approximately 75 territories targeting approximately 6,100 physicians who prescribe approximately 20% of all ADHD prescriptions. During 2018, we had 1,658 total prescriptions, and as of December 31, 2018, 414 health care providers had written prescriptions for the product.

**Adzenys ER clinical program**

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

The data from our most recent bioequivalence study versus Adderall XR is shown in Figure 7 and shows that the commercial scale formulation of Adzenys ER 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)**

Analyte=DAMPH

*Treatment A = Adzenys ER (30 mg/15 mL); Treatment B = Adderall XR 30 mg capsule*

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Other key observations from our clinical program for Adzenys ER included:

*No significant food effects:* When administered under fasted and fed conditions, no significant food effects were observed for Adzenys ER, and the observed food effects of Adzenys ER 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 Adzenys ER has a similar safety profile to that of the listed drug and is well-tolerated.

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 Amendments. 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 Adzenys ER. Under the terms of the agreement, we paid 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 Adzenys ER. We will also pay a single digit royalty on net sales of the Adzenys ER 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 Adzenys ER 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.

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 (the "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 90$^{th}$ 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, Cotempla XR-ODT and Adzenys ER, in the United States using our existing commercial infrastructure. We sell our Adzenys XR-ODT, Cotempla XR-ODT

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and Adzenys ER products to drug wholesalers in the United States, and we have obtained required state licenses and set up distribution channels.

In the United States, approximately 6,100 physicians prescribe approximately 20% of all ADHD prescriptions. We are using a specialty sales force of approximately 75 sales representatives primarily targeting the highest-volume prescribers of ADHD medication for the approved uses. The sales force is divided into eight regions, each managed by a regional sales manager. Furthermore, since our target physicians tend to prescribe both methylphenidate and amphetamine, we leverage our sales force by promoting all three of our ADHD products to the same audience.

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. Our messaging focuses on anticipated benefits of our XR-ODT and ER liquid suspension dosage forms with balancing important product safety information. 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 provide useful educational materials and tools to help caregivers and patients successfully manage ADHD treatment.

We launched Adzenys XR-ODT, our amphetamine XR-ODT, on May 16, 2016. We initiated an early experience program with limited product availability for Cotempla XR-ODT, our methylphenidate XR-ODT, on September 5, 2017 before launching this product nationwide on October 2, 2017. We launched Adzenys ER, our amphetamine extended-release liquid suspension, on February 26, 2018.

**Our proprietary technology platform**

We believe that we can apply the XR-ODT and XR liquid suspension technologies that underlie Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER 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 ("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.

ODT are one of the most preferred solid oral dosage forms in the market. We believe Adzenys XR-ODT and Cotempla XR-ODT, using our patented XR-ODT technology, are the first amphetamine XR-ODT and the first methylphenidate XR-ODT, respectively, for the treatment of ADHD on the market.

**Our XR Liquid Suspension Technology: Dynamic Time Release Suspension**

Our Dynamic Time Release Suspension ("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.

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**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 ("KCTP") technology is 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, and gastrointestinal conditions, such as nausea and vomiting, often have difficulty swallowing their medication and would benefit from ODT and liquid suspension dosage forms.

In addition, our technology may be able to be applied to new chemical entities and existing small molecule therapeutics 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 are focused on further advancing the development of our pipeline to diversify our revenue base and sustain our future. Our lead product candidate that will utilize our proprietary drug delivery technology platform is NT0502 or N-desethyloxybutynin. This candidate is a new chemical entity and a selective muscarinic receptor antagonist that will utilize our microparticle technology, which is used in our four on-market products. NT0502 will be developed to potentially address the significant unmet medical needs for the treatment of chronic sialorrhea in adult and pediatric patients with neurological conditions including cerebral palsy, Parkinson's disease, mental retardation, and amyotrophic lateral sclerosis (ALS). N-desethyloxybutynin is the active metabolite of oxybutynin, an approved drug to treat a urological condition and, therefore we believe we can leverage existing preclinical data for the parent molecule in our NT0502 development program.

In the US, more than 1.4 million patients with neurological disease  including those with cerebral palsy, Parkinson's disease, mental retardation, ALS, and other central nervous system disorders  experience sialorrhea due to neuromuscular/sensory dysfunction.1 Anatomic abnormalities and side effects from certain medications including anticonvulsants and antipsychotics can also cause excessive drooling. Sialorrhea can lead to significant physical and psychosocial complications, including perioral chapping, dehydration, infection, foul odor, stigmatization, and increased dependency and level of care, all of which can create an additional burden for these medically complicated patients. Current

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anticholinergic agents are associated with treatment-limiting adverse events and require titration and dosing up to three times per day, presenting complexity and inconvenience to patients and caregivers. Based on the pharmacological profile of NT0502, we expects a potentially improved tolerability profile for this product candidate.

We have completed feasibility studies on several additional potential product candidates thus far, including NT-0400 for nausea and vomiting. We believe several of these potential product candidates will be synergistic to our existing commercial infrastructure and the others would allow us to expand into adjacent therapeutic categories.

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. 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 our currently marketed products. 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.

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 potential 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 and Russ McMahen, our Senior Vice President of Scientific Affairs, who held a similar position at the time with

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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, 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 our generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER for commercial distribution 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 and the FDA closed the matter. 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, Cotempla XR-ODT, Adzenys ER and our generic Tussionex for commercial distribution. We believe that our current facilities have the manufacturing capacity for commercial production of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and generic Tussionex 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.

**Drug substances**

We currently purchase the APIs used in Adzenys XR-ODT and Adzenys ER (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 have entered into commercial supply agreements, with several of these manufacturers, and anticipate entering into commercial supply agreements with additional 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 Adzenys ER 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 products and 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

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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 products, 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 13 patents and 8 patent applications in the United States, including 2 provisional applications, and 3 patents and 2 patent applications in foreign countries and regions, and 1 international (PCT) patent application. 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 five granted U.S. patents and three 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 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 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 international (PCT) patent application.

Our XR liquid suspension product Adzenys ER patent portfolio contains nine granted U.S. patents and three 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.

Both applicable platform patents and relevant specific drug patents for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER are listed in the Orange Book. We own all of the above patents and pending applications.

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On July 25, 2016, we received a Paragraph IV certification from Actavis advising us that Actavis has filed an 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. On October 17, 2017, we entered into the Actavis Agreement with Actavis, which resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we have granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

On October 31, 2017, we received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. ("Teva") advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Cotempla XR-ODT. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva. This case alleged that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Teva's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. On December 21, 2018, we entered into the Teva Agreement with Teva, which resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, we have granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies.

On October 23, 2018, we signed a licensing agreement with NeuRx Pharmaceuticals LLC ("NeuRx") for NRX 101 (now known as NT0502 and formerly known as NT0501), a selective muscarinic receptor antagonist drug candidate for the treatment of sialorrhea. Under the terms of this licensing agreement, we have assumed responsibility for the NeuRx intellectual property portfolio protecting NT0502, currently consisting of two pending U.S. non provisional patent applications. These applications include claims directed to, among other things, methods of treatment and pharmaceutical dosage forms with NT0502. Patents, if granted, from these applications would be expected to expire in 2032.

Adzenys XR-ODT and Cotempla XR-ODT are not currently protected by patents outside of the United States and our generic Tussionex and Adzenys ER are currently protected by method patents only in the United States, Canada and Mexico. 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.

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**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.

**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, Adzenys, Adzenys XR-ODT, Adzenys ER and Cotempla XR-ODT 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, 2018, December 31, 2017 and December 31, 2016, our research and development expenses were $8.5 million, $9.0 million and $12.2 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, Cotempla XR-ODT and Adzenys ER 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, Mydayis), Janssen (Concerta), Pfizer (Quillivant XR and QuilliChew ER), Novartis (Focalin XR and Ritalin LA), Tris Pharmaceuticals (Dyanavel XR), Rhodes Pharmaceuticals (Aptensio XR), Osomotica Pharmaceuticals (Methylphenidate HCl ER 72 mg Tablet) and related generics. On August 9, 2018, Ironshore Pharmaceuticals announced the FDA approval for its ADHD product Jornay PM, a delayed-release and extended-release formulation of methylphenidate, which it expects to commercially launch in the

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first half of 2019. Also, on March 1, 2019, Adlon Therapeutics L.P., as subsidiary of Purdue Pharma L.P., announced that the FDA approved Adhansia XR, its methylphenidate extended release capsule for the treatment of ADHD. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Sunovion, Kem Pharm 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 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 several generic versions of Concerta have recently been approved by the FDA, two additional generic manufacturers launched generic versions of Concerta, Mallinckrodt in 2011 and KUDCO in 2013, both have lost their AB-rating, are now 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, Cotempla XR-ODT or Adzenys ER 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.

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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 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

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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.

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

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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.

**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 Prescription Drug User Fee Act, as amended (the "PDUFA"), 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, 2018, the user fee for an application requiring clinical data, such as an NDA, was $2,421,495, which increased to $2,588,478 for the period beginning October 1, 2018. 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 $1,210,748 through September 30, 2018 and $1,294,239 through September 30, 2019. PDUFA also imposes an annual program fee for human drugs ($304,162 through September 30, 2018, and $309,915 through September 30, 2019, per product up to a maximum of five fees for a fiscal year for prescription drug products identified in a single approved application). 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.

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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.

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.

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**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.

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 agreements 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) NDAs covering Adzenys XR-ODT and Adzenys ER. The agreements with Shire applies solely with respect to Adzenys XR-ODT and Adzenys ER.

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**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 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

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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 and Cotempla 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 for Adzenys XR-ODT. We commenced with the pharmacokinetic trial for Adzenys XR-ODT in 2017. We commenced with the pharmacokinetic trial for Cotempla XR-ODT in 2018, and we expect to complete these pharmacokinetic trials in 2019.

**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 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 products, hydrocodone, 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

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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 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

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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 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, overtly or covertly, 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;

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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 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.

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Additionaly, on January 31, 2019, the Department of Health and Human Services (HHS) and HHS Office of Inspector General (OIG) proposed an amendment to one of the existing Anti-Kickback safe harbors (42 C.F.R. 1001.952(h)) which would prohibit certain pharmaceutical manufacturers from offering rebates to pharmacy benefit managers ("PBMs") in the Medicare Part D and Medicaid managed care programs. The proposed amendment would remove protection for "discounts" from Anti-Kickback enforcement action, and would include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs. At the same time, HHS also proposed to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients, and adds another safe harbor to protect certain administrative fees paid by manufacturers to PBMs. If this proposal is adopted, in whole or in part, it could affect the pricing and reimbursement for any products for which we receive approval in the future.

**EMPLOYEES**

As of December 31, 2018, we employed 215 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."

**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.*

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**RISKS RELATED TO COMMERCIALIZATION**

***We are heavily dependent on the success of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. We have not generated substantial revenues from the sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, any sales revenues from any of our product candidates, if approved, 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, Cotempla XR-ODT, Adzenys ER and, if approved, any other product candidates that we may develop. We have limited experience in generating revenues from our marketed products, having only generated revenues from the sale of our generic Tussionex since we acquired it in 2014, Adzenys XR-ODT, which we commenced commercializing in May 2016, and Cotempla XR-ODT, which we commenced commercializing in September 2017. None of our marketed products have thus far generated substantial product sales revenues. We launched Adzenys ER in February 2018, and as a result have generated minimal sales revenue for this product to date. We have not generated any revenues from product sales of any other product candidates that we may develop and, to date, 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"), Cotempla XR-ODT, our methylphenidate XR-ODT, and Adzenys ER, our amphetamine XR liquid suspension, for the treatment of attention deficit hyperactivity disorder, or ADHD, and any other product candidates that we may identify, develop and obtain approval of. Our ability to successfully commercialize our products and product candidates depends on, among other things, our ability to:

- manufacture commercial quantities of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and, if approved, any other product candidates that we may develop at acceptable cost levels; and

- successfully establish and maintain sales and marketing capabilities to commercialize Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and, if approved, any other product candidates that we may develop.

We have incurred and anticipate continuing to incur significant costs associated with commercialization of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and, if approved, any other product candidates that we may develop. 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, Cotempla XR-ODT and Adzenys ER 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, Cotempla XR-ODT and Adzenys ER, and there is no guarantee that we will be successful in the commercialization of our products. We currently have a limited sales history for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Additionally, we may need to expand or build additional sales, marketing and distribution capabilities for our products. Although we have established a focused, specialty sales and marketing organization of approximately 75 representatives to promote our approved products in the United States, these commercialization capabilities have only been recently established, and we may need to expand our sales force if we decide to undertake additional commercialization activities on our own, which will be costly and time-consuming. We cannot be certain that we will reap the benefits of our commercialization efforts of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER compared to the cost of such efforts. Our prior experience in the marketing, sale and distribution of pharmaceutical products is limited to our generic Tussionex, and,

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before launching the commercialization of Adzenys XR-ODT, we had 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.

In addition, while we realigned our commercial operations in November 2018 to deploy our resources to what we believe are the most appropriate regions and physician targets, there can be no assurances that we will realize the intended benefits of this realignment or that our strategy will improve our operating results. The realignment of our commercialization organization resulted in approximately $1.0 million of severance and employee related costs. In addition, our reduced salesforce may result in fewer prescriptions written for our marketed products, and we may experience difficulty in hiring and retaining qualified sales personnel for our commercial organization in the future.

We also intend to enter into strategic partnerships with third parties to commercialize Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and our product candidates, if approved, 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. Even though we have established an internal sales team, we may be unable to compete successfully against these more established companies.

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

Even after a product is approved, we will remain subject to ongoing FDA, and other regulatory requirements governing, among other things, the production, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved 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 and promotional activities involving the Internet and social media. In the United States, prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure they are marketed only for their approved indications and in accordance with the provisions of the approved label. Any promotion for uses or in

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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. The FDA has also provided guidance on industry-sponsored scientific and educational activities to ensure such activities are not promotional.

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 Adzenys ER. 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 pursuant to the Consent Decree and the FDA closed the matter.

The facilities used by us to manufacture our products and any product candidates that we may develop are subject to inspections, including pre-approval inspections following our submission of any NDAs to the FDA for any product candidates that we may develop. 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, in connection with a general cGMP and pre-approval inspection for Adzenys ER from July 11 to July 25, 2017, we received a Form FDA 483 with one observation related to complaint records failing to document the reason and the individual making the decision not to conduct a complaint investigation. We implemented corrective action related to this observation and responded to the FDA. The FDA conducted a Post-Marketing Adverse Drug Experience Reporting Inspection from June 25 through June 27, 2018. The FDA did not have any findings and did not issue a Form FDA 483. The FDA conducted a complete Six Systems cGMP inspection of our Grand Prairie, Texas facility from September 4, 2018 through September 7, 2018 and did not issue any Form FDA 483s.

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 future product candidates or if it withdraws any such approval in the future for our products, our ability to develop or market any of our products or any product candidates that we may develop 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 prescription drug product

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program fee. 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 Federal Food, Drug and Cosmetic Act (the "FDCA");
- impose restrictions on the marketing or manufacturing of any product or product candidate that we may develop;
- 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 with respect to any product candidate that we may develop; 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, Cotempla XR-ODT and Adzenys ER 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 Adzenys ER, and a substantial majority of our resources are now focused on the commercialization of these products in the United States. Accordingly, our ability to generate significant product revenue will depend almost entirely on our ability to successfully commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER.

Our ability to successfully commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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 Adzenys ER;

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

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

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

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

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

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

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

There are no guarantees that we will be successful in completing these tasks. Successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective. If we are unable to successfully complete these tasks, we may be unable to generate sufficient revenues to sustain and grow our business.

In addition, we 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 ongoing commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. In addition, we have certain revenue expectations with respect to the sale of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. If we cannot successfully commercialize and achieve those revenue expectations with respect to Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, our anticipated revenues and liquidity will be materially adversely impacted.

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

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

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

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by Takeda, following its acquisition of Shire, under the brand names Adderall XR, Vyvanse and Mydayis and by Tris Pharmaceuticals, or Tris, under the brand name Quillivant XR, a reconstituted liquid suspension, QuilliChew ER, a chewable formulation and Dyanavel XR, a liquid suspension, and methylphenidate is marketed in the United States by Janssen under the brand name Concerta, by Rhodes Pharmaceuticals under the brand name Aptensio XR, a capsule, by Osomotica Pharmaceuticals under the name Methylphenidate HCl ER 72 mg Tablet and by Novartis under the brand names Focalin XR and Ritalin LA. On August 9, 2018, Ironshore Pharmaceuticals announced the FDA approval for its ADHD product Jornay PM, a delayed-release and extended-release formulation of methylphenidate, which it expects to commercially launch in the first half of 2019. Also, on March 1, 2019, Adlon Therapeutics L.P., as subsidiary of Purdue Pharma L.P., announced that the FDA approved Adhansia XR, its methylphenidate extended release capsule for the treatment of ADHD. 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 Sunovian, KemPharm 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 products and product candidates that receive regulatory approval, including in comparison to branded or generic competitors;
- the efficacy and safety of our products 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 products 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;

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

***If we are unable to differentiate our products 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 products or product candidates, our ability to successfully commercialize such products 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 products 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 products and product candidates against other drugs, the opportunity for our products 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, Cotempla XR-ODT or Adzenys ER, 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 had filed an 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 alleged 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,

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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.

On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the "Actavis Agreement") with Actavis. This Actavis Agreement resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we have granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

On October 31, 2017, we received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. ("Teva") advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Cotempla XR-ODT. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva. This case alleged that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Teva's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier.

On December 21, 2018, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the "Teva Agreement") with Teva. This Teva Agreement resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, we have granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies.

***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 approved products 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 Adzenys ER is a regulated drug product and subject to the U.S. Drug Enforcement Administration ("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

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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. Additionally, in connection with a general cGMP and pre-approval inspection for Adzenys ER from July 11, 2017 to July 25, 2017, we received a Form FDA 483 with one observation related to complaint records failing to document the reason and the individual making the decision not to conduct a complaint investigation. We implemented corrective action related to this observation and responded to the FDA. The FDA conducted a Post-Marketing Adverse Drug Experience Reporting Inspection from June 25, 2018 through June 27, 2018. The FDA did not have any findings and did not issue a Form FDA 483. The FDA conducted a complete Six Systems cGMP inspection of our Grand Prairie, Texas facility from September 4, 2018 through September 7, 2018 and did not issue any Form FDA 483s. 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.

***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 FSCA 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 the FDA of any illegitimate product. By November 27, 2017, we were required to place a unique product identifier on prescription drug packages, and such requirement will be enforced beginning November 2018. 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

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product identifier, they would be misbranded under the FDCA 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, Adzenys ER and our generic Tussionex, and any disruption in the chain of supply may impact production and sales of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and our generic Tussionex, and cause delays in developing and commercializing our product candidates and currently manufactured and commercialized products.***

Our approved NDAs for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, 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. Also, because of our proprietary processes for manufacturing our product candidates, we cannot immediately transfer manufacturing activities for Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or our generic Tussionex to an alternate supplier, and a change of facilities would be a time-consuming and costly endeavor.

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 products 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 products or product candidates or a decrease in sales of our approved products, 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, 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, Adzenys ER 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 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, Cotempla XR-ODT, Adzenys ER, our generic Tussionex and clinical trials of future potential product candidates, may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

***If we fail to produce our 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, Adzenys ER and our generic Tussionex, we currently rely on single suppliers for raw materials including APIs, which we use to manufacture,

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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, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in quantities that meet their demand. 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 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 development, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our products or 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. In addition, in connection with a general cGMP and pre-approval inspection for Adzenys ER from July 11 to July 25, 2017, we received a Form FDA 483 with one observation related to complaint records failing to document the reason and the individual making the decision not to conduct a complaint investigation. We implemented corrective action related to this observation and responded to the FDA. The FDA conducted a Post-Marketing Adverse Drug Experience Reporting Inspection from June 25, 2018 through June 27, 2018. The FDA did not have any findings and did not issue a Form FDA 483. The FDA conducted a complete Six Systems cGMP

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inspection of our Grand Prairie, Texas facility from September 4, 2018 through September 7, 2018 and did not issue any Form FDA 483s.

***If we fail to manufacture Adzenys XR-ODT, Cotempla XR-ODT or Adzenys ER 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 these products or our product candidates, if approved, 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, Cotempla XR-ODT and Adzenys ER we have installed specialized processing equipment in our Grand Prairie, Texas facilities, which we believe will produce sufficient quantities of our products for commercialization. We purchase raw materials and components from various suppliers in order to manufacture Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. 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 Adzenys ER, and may not be able to meet our customers' demands for our products.

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 products. 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 Senior 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, Cotempla XR-ODT and Adzenys ER for commercial distribution and drug products for our clinical 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

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Consent Decree and the FDA closed the matter. On June 20, 2018, we wrote to the Department of Justice and the FDA and explained we wished to move the court for relief from the Consent Decree, and asked the FDA to recognize the appropriateness of this request and not oppose the motion. Although we may apply for relief from the Consent Decree, 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 our approved products to meet market demand for such products on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of Adzenys XR-ODT, Cotempla XR-ODT or Adzenys ER, 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, Cotempla XR-ODT and Adzenys ER 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, Cotempla XR-ODT and Adzenys ER. 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 product candidates, if approved, 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 manufacturing facility becomes damaged or inoperable or we are required to vacate our facility, our ability to manufacture Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, our generic Tussionex or future potential product candidates for clinical development, may be jeopardized. Our inability to continue manufacturing adequate supplies of our products 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 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

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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, Adzenys ER or our generic Tussionex at our Grand Prairie, Texas facility could result in a disruption in the supply of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, or our generic Tussionex to physicians and pharmacies, which would adversely affect our ability to generate revenues.

***If other forms of our products and product candidates are approved and successfully commercialized by other third parties, especially if approved before we can successfully commercialize our products and product candidates, our business would be materially harmed.***

Other third parties may seek approval to manufacture and market their own versions of product candidates in our product pipeline 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 our product candidates and, as a result, we may never achieve significant market share for these products. 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's product candidate, 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 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. Some state and local governments also require manufacturers to operate a drug stewardship program that collects, secures, transports and safely disposes of unwanted drugs.

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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 or result in other legal action. For example, we are the target of a lawsuit filed in December 2017 by the County of Harris, Texas, against us and other alleged manufacturers, promoters, sellers and distributers of opioid pharmaceutical products.

***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" or "ACA"), 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 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.

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Despite initiatives to invalidate the Affordable Care Act, the U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018, the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017 and again on July 18, 2018. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In 2019, Congress may consider other legislation to repeal and replace elements of the Affordable Care Act, and litigation and legislation over the Affordable Care Act are likely to continue, with unpredictable and uncertain results. Changes to the Affordable Care Act or other existing health care regulations could significantly impact our business and the pharmaceutical industry. Although it is too early to determine the effect of legal challenges, pending legislation, and executive action on 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.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.

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The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Right to Try Act of 2018 provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. Individual states in the United States have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We anticipate pricing scrutiny 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.

CMS may also develop new payment and delivery models, such as bundled payment models. CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization (PA) and step therapy (ST) for six protected classes of drugs and, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" as well as add a definition of "price concession" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business.

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

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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.

***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

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

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

Successful sales of our products 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

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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, Cotempla XR-ODT and Adzenys ER 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, healthcare providers 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, healthcare providers, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to health information privacy and security regulation by U.S. federal and state governments and foreign jurisdictions in which we conduct our business. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below:

The federal Anti-Kickback Statute, makes it illegal for any person, including a prescription drug or biologic manufacturer (or a party on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward referrals, either the referral of an individual, or the purchase, recommendation, order or prescription of a particular item, drug or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. Violations of this law are punishable by up to five years in prison, criminal fines, administrative

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civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

The federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and the potential implication of various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and 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 product and any future product candidates, are subject to scrutiny under this law.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors, or falsifying, concealing or covering up a material fact, or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items, or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose, among other things, specified requirements on covered entities and their business associates, relating to the privacy, and security of individually identifiable health information, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties applicable to business associates, and gave state attorneys general new authority to file civil actions for damage or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act which imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program for certain payments and other "transfers of value" provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. Such laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. Some states, such as California, Massachusetts and Vermont, mandate

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implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians. State and foreign laws also govern the privacy and security of health information in certain circumstances. Such data privacy and security laws may differ from one another in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

On January 31, 2019, the Department of Health and Human Services (HHS) and HHS Office of Inspector General (OIG) proposed an amendment to one of the existing Anti-Kickback safe harbors (42 C.F.R. 1001.952(h)) which would prohibit certain pharmaceutical manufacturers from offering rebates to pharmacy benefit managers ("PBMs") in the Medicare Part D and Medicaid managed care programs. The proposed amendment would remove protection for "discounts" from Anti-Kickback enforcement action, and would include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs. At the same time, HHS also proposed to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients, and adds another safe harbor to protect certain administrative fees paid by manufacturers to PBMs. If this proposal is adopted, in whole or in part, it could affect the pricing and reimbursement for any products for which we receive approval in the future.

In addition, regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the E.U. adopted a new regulation governing data practices and privacy called the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company established in the E.U. as well as to those outside the E.U. if they collect and use personal data in connection with the offering goods or services to individuals in the E.U. or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we operate in.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do 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 related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, disgorgement, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws 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 similar actions, penalties and sanctions. Efforts to ensure that our business arrangements comply with applicable healthcare laws and regulations, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

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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 related to the commercialization of our products and upon any commercialization by us of our future products and, if approved, our product candidates, such as claims related to opioid abuse. For example, on March 7, 2018, we received a citation advising us that the County of Harris Texas filed a lawsuit on December 13, 2017 against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. 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, in particular, our opioid-based product, due to their status as controlled substances.

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

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

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

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of

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such efforts. For example, we may fail to realize the anticipated benefits of the license of NT0502, our in-licensed product candidate, and there is no assurance that we will be able to maintain the license for NT0502 on commercially reasonable terms or at all. 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.

***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 any future 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 any future product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs;

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- 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.

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 future product candidates in our product pipeline. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, 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).

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

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

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

Under the Hatch-Waxman Amendments, 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 products 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 products or product candidates may produce undesirable side effects or adverse reactions or events. Although our products 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 products 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 products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, institutional review boards, or 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.

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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
- 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

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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.

***We are heavily dependent on the success of our product candidates. We cannot give any assurance that we will receive regulatory approval for our 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 any 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. 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.

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

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

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining IRB approval to conduct a clinical trial at a prospective site;
- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;
- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- difficulties maintaining contact with subjects after treatment, which results in incomplete data;
- receipt by a competitor of marketing approval for a product targeting an indication that our product targets;
- 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.

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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.

**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. Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER require substantial resources as we implement commercialization strategies to seek to begin generating substantial 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 substantial revenue or revenue at all. We do not anticipate generating substantial revenue from sales of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or any of our other product candidates, if approved in the near term, if ever. We have incurred significant net losses of $51.7 million, $65.8 million and $82.8 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $317.0 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,

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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, Cotempla XR-ODT and Adzenys ER, we may need to obtain additional capital through equity offerings, debt financing, payments under new or existing licensing and research and development collaboration agreements, or any combination thereof, in order to become cash flow positive and to develop and commercialize additional product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

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

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

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

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

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***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 $60.0 million senior secured credit facility with Deerfield as lender. On November 5, 2018, we amended the facility and prepaid $7.5 million otherwise due in May 2019, and currently have a balance of $52.5 million of senior secured credit. $7.5 million in principal on the debt is due in May 2019, $15.0 million is due in each of May 2020 and May 2021, and a final payment of principal, interest and all other obligations under the facility due on May 11, 2022. Interest is due quarterly 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 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, 2018, we had an accumulated deficit of $317.0 million. Although we have strategies and plans to achieve profitability through revenue growth, we expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to market our approved products and 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.

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***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:

- our ability to establish and maintain 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 delays in regulatory review and approval of our product candidates;
- any intellectual property infringement lawsuit in which we may become involved; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carry-forwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. We have in the past and 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. In addition, pursuant to the Tax Cuts and Jobs Act of 2017, we may not carry back net operating losses to prior years and we may not use net operating losses generated in 2018 and later to reduce our taxable income in any year by more than 80%. Net operating losses generated prior to 2018 are available to fully offset future taxable income. These new rules apply regardless of the occurrence of an "ownership change."

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***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. 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 of 2002 (or the "SOX 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 SOX 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 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.***

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from such cyber attacks, including 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

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information, we could suffer reputational harm or face litigation or adverse regulatory action 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, Cotempla XR-ODT or Adzenys ER 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, Cotempla XR-ODT and Adzenys ER, 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 or license may fail to result in issued patents in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge their patentability, validity (e.g., by discovering previously unidentified prior art, or a patent-barring event such as a prior public disclosure, use, sale or offer for sale of the invention), enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. For example, we are aware that certain patent rights that are in-licensed for NT0502 may be limited by prior art, which may reduce or eliminate the scope of coverage for this product candidate. In addition, 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

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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 advising us that Actavis has filed an 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 alleged 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.

On October 17, 2017, we entered into the Actavis Agreement with Actavis. This Actavis Agreement resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we have granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies. There can be no assurance that the Actavis Agreement will be approved by such agencies. In addition, there can be no assurance that we would not face future litigation regarding Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or any future product candidates.

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For example, on October 31, 2017, we received a paragraph IV certification from Teva advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Cotempla 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 December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva. This case alleged that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Teva's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier.

On December 21, 2018, we entered into the Teva Agreement with Teva. This Teva Agreement resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, we have granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies. There can be no assurance that the Teva Agreement will be approved by such agencies. In addition, there can be no assurance that we would not face future litigation regarding Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or any future product candidates.

Such litigation is often time-consuming and costly and its outcome would be unpredictable; however, we intend to vigorously enforce our intellectual property rights relating to our products. We would expect to face generic competition for our products if such patents are not upheld or if a filer of a Paragraph IV certification is found not to infringe such patents. The resulting loss of exclusivity would impact pricing and our sales of our products, 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.

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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 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 our and their approved products 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

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30 months provides added incentive to litigate over Orange Book patents, but suits involving non-Orange Book patents are also common in the ADHD space. There have been multiple patent litigations involving nearly all of the medications for treatment of ADHD. This trend may continue and, as a result, we may become party to legal matters and claims arising in the ordinary course of business.

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

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

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- third parties bringing claims against us may have more resources than us to litigate claims against us;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- 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

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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 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 (the "2014 License Agreement") with Shire for certain of Shire's patents with respect to our Adzenys XR-ODT NDA. Under the terms of the 2014 License Agreement, upon obtaining FDA approval of our Adzenys XR-ODT NDA, we were required to pay a lump-sum, 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 Adzenys ER are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Adzenys ER. On March 6, 2017, we entered into a License Agreement (the "2017 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 Adzenys ER. Under the terms of the 2017 License Agreement, we were required to pay a lump sum, non-refundable license fee no later than thirty days after receiving regulatory approval and are required to pay a single digit royalty on net sales of the Adzenys ER during the life of the relevant Shire patents. Additionally, each of the 2014 License Agreement and 2017 License Agreement contains a covenant from Shire not to file a patent infringement suit against us alleging that Adzenys XR-ODT or Adzenys ER, respectively, 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.

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***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 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 $1.40 to $28.99, through March 11, 2019. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to successfully execute our commercialization strategy with respect to Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, or any other approved potential product candidate in the future;
- 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;
- 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 products and product candidates;

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inability to manufacture adequate amounts of product supply or obtain adequate amounts of components of our product supply for our products, 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, Adzenys ER 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, or perceptions regarding unsolicited public acquisition proposals of our company;

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

additions or departures of key scientific or management personnel;

changes in the market valuations of similar companies;

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

trading volume of our common stock.

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

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

As of December 31, 2018, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned approximately 35% 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

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conditions pursuant to Rule 144 of the Securities Act. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock. On November 5, 2018, we amended a $60.0 million senior secured credit facility with Deerfield as lender, pursuant to which we were afforded the right, subject to the terms and conditions of the facility and certain other limitations, to make interest and principal payments owed to Deerfield through the issuance of our common stock, and provided Deerfield with a right, subject to the terms and conditions of the facility and the amended and restated convertible notes issued under the facility and certain other limitations, to convert principal under the amended and restated convertible notes into our common stock, subject to a floor of 95% of $10.00 per share.

***Potential uncertainty resulting from unsolicited acquisition proposals and related matters may adversely affect our business.***

In the past we have received, and in the future we may receive, unsolicited proposals to acquire our company or our assets. For example, in June 2017 and in October 2017, the Board of Directors received an unsolicited non-binding proposal for the acquisition of all of our stock. The review and consideration of acquisition proposals and related matters could require the expenditure of significant management time and personnel resources. Such proposals may also create uncertainty for our employees, customers and vendors. Any such uncertainty could make it more difficult for us to retain key employees and hire new talent, and could cause our customers and vendors to not enter into new arrangements with us or to terminate existing arrangements. Additionally, we and members of our Board of Directors could be subject to future lawsuits related to unsolicited proposals to acquire us. Any such future lawsuits could become time consuming and expensive.

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the SOX Act and reduced disclosure obligations

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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 $1.07 billion (as inflation-adjusted by the SEC from time to time), 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 June 30st, 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 SOX 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;
- 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

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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 lawsuits 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 advising us that Actavis has filed an 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. alleging 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.

On October 17, 2017, we entered into the Actavis Agreement with Actavis, which resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

On October 31, 2017, we received a paragraph IV certification from Teva advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT. We have new product exclusivity for a three-year period from the date of approval for Cotempla XR-ODT. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva alleging that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Teva's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier.

On December 21, 2018, we entered into the Teva Agreement with Teva, which resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, we granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Agreement has been submitted to the applicable governmental agencies.

On March 7, 2018, we received a citation advising us that the County of Harris Texas (the "County") filed a lawsuit on December 13, 2017 against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through this lawsuit, the County seeks to recoup as damages some of the expenses it allegedly has incurred to combat opioid use and addiction. The County also seeks punitive damages, disgorgement of profits and attorneys' fees. While we believe that the lawsuit is without merit and intend to vigorously defend against it, we are not able to predict at this time whether this proceeding will have a material impact on our results of operations.

**ITEM 4. Mine Safety Disclosures**

Not applicable.

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## 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. Our initial public offering was priced at $15.00 per share on July 22, 2015. On December 31, 2018, the last trading day of 2018, the last reported sale price of our common stock on the NASDAQ Global Market was $1.65 per share. As of March 11, 2019, there were 49,710,677 shares of common stock outstanding, held by approximately 62 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.

### 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 12 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

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common stock. Stockholder return over the indicated period should not be considered indicative of future stockholder returns.

**Recent Sales of Unregistered Securities**

On November 5, 2018, we amended a $60.0 million senior secured credit facility with Deerfield as lender, pursuant to which we were afforded the right, subject to the terms and conditions of the facility and certain other limitations, to make interest and principal payments owed to Deerfield through the issuance of our common stock, and provided Deerfield with a right, subject to the terms and conditions of the facility and the amended and restated convertible notes issued under the facility and certain other limitations, to convert principal under the amended and restated convertible notes into our common stock, subject to a floor of 95% of $10.00 per share.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

There was no share purchase in the year ended December 31, 2018.

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**ITEM 6. Selected Consolidated Financial Data**

*The following selected consolidated statements of operations data for the years ended December 31, 2018, 2017, and 2016, and the balance sheet data as of December 31, 2018 and 2017 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, 2015 and 2014 and as of December 31, 2016, 2015 and 2014 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, | | | | |
|---|---|---|---|---|---|
| | **2018** | **2017** | **2016** | **2015** | **2014** |
| | (in thousands, except per share data) | | | | |
| Total Revenue(1) | $ 49,988 | $ 27,132 | $ 10,033 | $ 3,792 | $ 758 |
| Cost of Goods Sold | 26,928 | 14,030 | 11,734 | 5,929 | 3,391 |
| Research and Development Expenses | 8,508 | 8,957 | 12,207 | 11,691 | 10,574 |
| Selling and Marketing Expenses(1) | 44,133 | 46,881 | 49,291 | 5,672 | 229 |
| General and Administrative Expenses | 13,915 | 13,805 | 12,625 | 7,078 | 5,036 |
| Interest, Loss on Debt Extinguishment and Other Expense | 8,179 | 9,231 | 6,927 | 4,203 | 2,377 |
| Net Loss(1) | $ (51,675) | $ (65,772) | $ (82,751) | $ (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 | $ (51,675) | $ (65,772) | $ (82,751) | $ (33,171) | $ (24,152) |
| Net Loss per Share B*asic and Diluted(2)* | $ (1.60) | $ (2.66) | $ (5.16) | $ (4.38) | $ (27.56) |
| Shares Used to Compute Net Loss per Share *Basic and Diluted(2)* | 32,288,555 | 24,751,091 | 16,052,390 | 7,581,881 | 876,318 |

(1) The Company began selling Adzenys XR-ODT on May 16, 2016, initiated an early experience program for Cotempla XR-ODT with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017 and began selling Adzenys ER on February 26, 2018. Net product sales represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER include savings offers, prompt payment discounts, wholesaler fees, estimated rebates to be incurred on the selling price of the respective product sales and estimated allowances for product returns. The Company began selling generic Tussionex in August 2014. Gross to net sales adjustments for generic Tussionex include prompt payment discounts, estimated allowances for product returns, wholesaler fees, estimated government rebates and estimated chargebacks to

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be incurred on the selling price of generic Tussionex related to the respective product sales. The Company recognizes total gross product sales less gross to net sales adjustments as revenue based on shipments from 3PLs to the Company's wholesaler customers. Also, the Selling and Marketing Expenses and Net Loss amounts in 2018, 2017 and 2016 reflect the sales and marketing expenses associated with the commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER.

(2)

See Note 3 to the notes to our consolidated 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.

**Consolidated Balance Sheet Data:**

| | December 31, | | | | |
|---|---|---|---|---|---|
| | **2018** | **2017** | **2016** | **2015** | **2014** |
| | **(in thousands)** | | | | |
| Cash and Cash Equivalents | $ 46,478 | $ 31,969 | $ 24,352 | $ 90,763 | $ 13,343 |
| Short-Term Investments | | 18,448 | 15,430 | | 3,000 |
| Working Capital | 31,573 | 46,095 | 34,206 | 82,306 | 13,380 |
| Total Assets | 111,357 | 104,108 | 79,571 | 122,510 | 45,230 |
| Current Portion of Long Term Debt(1) | 8,557 | 896 | 4,921 | 7,973 | 1,653 |
| Long Term Debt, net of Current Portion(1) | 43,217 | 58,938 | 58,599 | 26,271 | 23,121 |
| Redeemable Convertible Preferred Stock(2) | | | | | 90,149 |
| Stockholders' Equity (Deficit) | 7,845 | 8,947 | (966) | 78,374 | (78,782) |

(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 Facility) and Deerfield Special Situations Fund, L.P. ($33^{1}/_{3}$% of Facility) (collectively, "Deerfield"), as lenders. See Note 11 to the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further details.

(2)

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 microparticle modified-release drug delivery technology platform, which we have already used to develop Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER oral suspension ("Adzenys ER"), for the treatment of attention deficit hyperactivity disorder ("ADHD"). Our products and product candidates are extended-release ("XR"), medications in patient-friendly, orally disintegrating tablets ("ODT") or liquid suspension dosage forms. Our microparticle technology 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. We received approval from the FDA for Cotempla XR-ODT, our methylphenidate XR-ODT for the treatment of ADHD in patients 6 to 17 years old, on June 19, 2017. We initiated an early experience program with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017. Also, we received approval from the FDA for Adzenys ER, our amphetamine extended-release liquid suspension, on September 15, 2017, and launched the commercialization of this product on February 26, 2018. We believe Adzenys XR-ODT and Cotempla XR-ODT are the first amphetamine XR-ODT and the first methylphenidate XR-ODT, respectively, for the treatment of ADHD on the market. In addition to our marketed products, we are developing NT-0400, our XR-ODT product candidate, for nausea and vomiting and NT0502, our product candidate, for the treatment of sialorrhea.

We are commercializing Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in the United States using our own commercial infrastructure. We manufacture Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in our current Good Manufacturing Practice ("cGMP") and U.S. Drug Enforcement Administration ("DEA")-registered manufacturing facilities, thereby 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 ("generic Tussionex").

On October 23, 2018, we entered into an Exclusive License Agreement (the "License Agreement") with NeuRx Pharmaceuticals LLC ("NeuRx"), pursuant to which NeuRx granted an exclusive, royalty-bearing license to us to develop, manufacture, and commercialize certain pharmaceutical products containing NeuRx's proprietary compound designated as NRX 101, referred to by us as NT0502, on a world-wide basis. NT0502 is a new chemical entity and a selective muscarinic receptor antagonist that will utilize our microparticle technology, which is used in our four on-market products. NT0502 will be developed to address the significant unmet medical needs for the treatment of chronic sialorrhea (excessive salivation or drooling) in adult and pediatric patients with neurological conditions including cerebral palsy, Parkinson's disease, mental retardation, and amyotrophic lateral sclerosis (ALS).

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

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lawsuit in federal district court in the District of Delaware against Actavis, Inc. alleging 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. On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the "Actavis Agreement") with Actavis. The Actavis Agreement resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we have granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

On October 31, 2017, we received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. ("Teva") advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT. We have new product exclusivity for a three-year period from the date of approval for Cotempla XR-ODT. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva alleging that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Teva's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. On December 21, 2018, we entered into the Agreement with Teva (the "Teva Agreement"), which resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, we granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies.

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 commercial products and 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.

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We have incurred significant losses in each year since our reorganization in 2009. Our net losses were $51.7 million for the year ended December 31, 2018. As of December 31, 2018, we had an accumulated deficit of approximately $317.0 million. We expect to continue to incur significant expenses and operating losses in the near term as we:

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

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

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 Facility) and Deerfield Special Situations Fund, L.P. ($33^{1}/_{3}$% of Facility) (collectively, "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 was initially 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 had an option, which we exercised, to defer payment of each of the first four interest payments, adding such amounts to the outstanding loan principal. The aggregate $6.6 million in deferred interest payments ("Accrued Interest") was to be paid in cash on June 1, 2017.

On June 1, 2017 (the "Amendment Date"), we entered into a First Amendment (the "Amendment") with Deerfield to the Facility which extended the date to repay the Accrued Interest under the Facility to June 1, 2018 (the "PIK Maturity Date"), which may have been extended to June 1, 2019 at our election if certain conditions had been met as specified in the Amendment. The right to payment of the Accrued Interest was memorialized in the form of Senior Secured Convertible Notes (the "Convertible Notes") issued to Deerfield on the Amendment Date. Interest is due quarterly at a rate of 12.95% per year. The $6.6 million of Convertible Notes were convertible into shares of our common stock at the noteholder's option at any time up to the close of business on the date that is five days prior to the PIK Maturity Date.

On October 26, 2017, Deerfield provided a conversion notice electing to convert the entire $6.6 million of Convertible Notes into shares of our common stock at a conversion price of $7.08 per share. The conversion price was based on 95% of the average of the volume weighted average prices per share of the Company's common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion. This resulted in issuing 929,967 shares of our common stock to Deerfield on this date and the Convertible Notes were cancelled.

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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 its 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 its common stock from time to time in "at-the-market" offerings under the Shelf (the "Sales Agreement"). The Shelf was declared effective by the SEC on August 12, 2016.

In February 2017, we closed an underwritten public offering under the Shelf of 5,750,000 shares of our common stock at a public offering price of $5.00 per share, which included 750,000 shares of our common stock resulting from the underwriters' exercise of their over-allotment option on February 17, 2017. Deerfield, our senior lender, participated in the purchase of our common shares as part of this public offering, and as a result, was classified as a related party. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $26.7 million.

On June 30, 2017, we closed an underwritten public offering of 4,800,000 shares of our common stock at a public offering price of $6.25 per share for total proceeds of $30.0 million before estimated offering costs of $0.2 million. We also granted the underwriters a 30-day option to purchase up to an additional 720,000 shares of our common stock which was exercised in full on July 26, 2017. The net proceeds to us through July 26, 2017 from this offering, after deducting offering expenses payable by us, were approximately $34.3 million.

On November 8, 2018, we closed an underwritten public offering under the Shelf of 19,999,999 shares of our common stock at a public offering price of $2.30 per share, which includes 2,608,695 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $43.4 million. Also, on November 5, 2018, we entered into a Second Amendment to the Facility with Deerfield under which we used $7.5 million of proceeds of the offering to prepay $7.5 million of principal on the Facility otherwise due on May 11, 2018. Pursuant to the Second Amendment, the schedule of principal repayments under the facility was further modified to allow for the $15.0 million payment otherwise due on May 11, 2020 to be deferred until either May 2021 or May 2022 if certain revenue milestones for the years ended December 31, 2019 and December 31, 2020 are achieved. Finally, the Second Amendment provides us with a right, subject to the terms and conditions of the Facility and certain other limitations, to make interest and principal payments through the issuance of our common stock, and provides Deerfield with a right, subject to the terms and conditions of the Facility and the amended and restated convertible notes (the "A&R Notes") issued under the Facility and certain other limitations, to convert principal under the A&R Notes into our common stock, subject to a floor of 95% of $10.00 per share.

During the year ended December 31, 2018, we sold an aggregate 651,525 shares of common stock under the Sales Agreement, at an average sale price of approximately $6.25 per share for gross proceeds of $4.1 million and net proceeds of $3.9 million, and paid total compensation to the sales agent and other costs of approximately $0.2 million. On November 5, 2018, we reduced the size of the Sales Agreement to up to $7,825,113 of our common stock (inclusive of amounts previously sold thereunder prior to the date hereof), effective on November 5, 2018. As of the date hereof, aggregate gross proceeds of sales of our common stock under the Sales Agreement total $7,825,113, and sales of our common stock under the Sales Agreement have been suspended.

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

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not be profitable even if we succeed in commercializing Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, and, if approved, any of our product candidates that we may develop.

**FINANCIAL OPERATIONS OVERVIEW**

**Revenue**

Prior to 2017, our revenue was generated primarily from product sales of our generic Tussionex recorded on a net sales basis. Sales of our generic Tussionex are seasonal and correlate with the cough and cold season. We launched commercialization of Adzenys XR-ODT on May 16, 2016, initiated an early experience program with Cotempla XR-ODT with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017 and launched commercialization of Adzenys ER on February 26, 2018. 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 continuing commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, we expect our future revenue to increase from historical levels.

We expect the number of prescriptions filled for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to continue to increase. In addition, we expect product shipments to our wholesalers to correspondingly increase. For the year ended December 31, 2018, wholesalers purchased 275,476 units of Adzenys XR-ODT, as compared to 216,679 units for the year ended December 31, 2017. Unit shipments of Cotempla XR-ODT, which launched in the third quarter of 2017, for the year ended December 31, 2018 were 211,440, as compared to 21,443 units for the year ended December 31, 2017. Unit shipments of Adzenys ER, which launched commercially on February 26, 2018, were 1,836 units for the year ended December 31, 2018.

In the future, we will seek to generate additional revenue from product sales of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and generic Tussionex. If we fail to successfully market Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and generic Tussionex, 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 conduct 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 products and product candidates. Indirect costs related to our research and development

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activities that are not allocated to a product or product candidate are included in "Other Research and Development Activities" in the table below.

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, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| | (in thousands) | | |
| NT-0102 Cotempla XR-ODT | $ 1,724 | $ 2,034 | $ 1,613 |
| NT-0201 Adzenys ER | 23 | 155 | 2,403 |
| NT-0202 Adzenys XR- ODT | 1,248 | 760 | 650 |
| NT-0400 | 144 | | |
| NT-0502 | 83 | | |
| Other Research and Development Activities(1) | 5,286 | 6,008 | 7,541 |
| | $ 8,508 | $ 8,957 | $ 12,207 |

(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 explore new product candidates, but will decrease as a percentage of revenue if Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER are 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, Cotempla XR-ODT and Adzenys ER and, if approved, our product candidates that we may develop.

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.

**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, Cotempla XR-ODT and Adzenys ER, pre-commercialization activities for Adzenys ER, commercial sales organization costs incurred in the preparation for and in the commercialization of Adzenys XR-ODT and Cotempla XR-ODT, and in the preparation for the launch and commercialization of Adzenys ER 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, medical marketing, sales support tools, sales planning and market data and analysis.

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We believe that our selling and marketing expenses may continue at these levels with the continuing commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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, information technology 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, 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 our products, and, if approved, our product candidates. In addition, general and administrative expenses include our Paragraph IV litigation costs. 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 ("SAB") 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 continue at these levels and may increase as we incur costs professional fees associated with future business development activities, if any. In addition, although we have settled our recent Paragraph IV litigation cases, we may be subject to future Paragraph IV litigation costs, and could incur material legal fees in the enforcement of our intellectual property rights.

**Interest expense, net**

On May 11, 2016, we entered into a $60.0 million senior secured credit facility (the "Facility") with Deerfield Private Design Fund III, L.P. ($66^{2}/_{3}$% of Facility) and Deerfield Special Situations Fund, L.P. ($33^{1}/_{3}$% of Facility) (collectively, "Deerfield") as lenders. Deerfield participated in the purchase of our common shares as part of our February 2017 public offering, and as a result, was classified as a related party at the time of the corresponding transactions. Approximately $33.0 million of the Facility proceeds were used to prepay the existing senior Loan and Security Agreement (the "LSA") with Hercules Technology III, L.P. ("Hercules") and the 10% subordinated debt (the "Note") issued by Essex Capital Corporation ("Essex") that was otherwise payable in 2016 and 2017. We entered into an amendment (the "Amendment") to the Facility on June 1, 2017 (the "Agreement Date") to provide a one-year deferral, with an option for a second year of deferral, of payment of the first year accrued interest of $6.6 million (the "Accrued Interest"), provided that we met certain sales revenue targets and obtained FDA approval of certain of our product candidates on or before the Prescription Drug User Fee Act (the "PDUFA") goal date. Before the Amendment, this accrued interest had been deferred until June 1, 2017 per the terms of the Facility. The right to payment of the $6.6 million of accrued interest was memorialized in the form of senior secured convertible notes (the "Convertible Notes") issued to Deerfield on the Amendment Date. Interest was due quarterly at a rate of 12.95% per year. Deerfield had an option to convert these notes into our common stock. On October 26, 2017, Deerfield provided a conversion notice electing to convert the entire $6.6 million of Convertible Notes into shares of our common stock at a conversion price of $7.08 per share. This resulted in issuing 929,967 shares of our common stock to Deerfield on this date and the Convertible Notes were cancelled.

On November 5, 2018, we entered into a Second Amendment to the Facility with Deerfield under which we used $7.5 million of proceeds of an underwritten public offering of shares of our common

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stock which closed on November 8, 2018, to prepay $7.5 million of principal on the Facility otherwise due on May 11, 2018. Pursuant to the Second Amendment, the schedule of principal repayments under the facility was further modified to allow for the $15.0 million payment otherwise due on May 11, 2020 to be deferred until either May 2021 or May 2022 if certain revenue milestones for the years ended December 31, 2019 and December 31, 2020 are achieved. Finally, the Second Amendment provides us with a right, subject to the terms and conditions of the Facility, and certain other limitations, to make interest and principal payments through the issuance of our common stock, and provides Deerfield with a right, subject to the terms and conditions of the Facility and the amended and restated convertible notes (the "A&R Notes") issued under the Facility and certain other limitations, to convert principal under the A&R Notes into our common stock, subject to a floor of 95% of $10.00 per share.

Interest expense to date has consisted primarily of interest expense on senior debt, including the amortization of debt discounts, the Note and the capitalized leases from Essex resulting from the sale-leaseback transactions of our existing and newly-acquired property and equipment. We amortize debt issuance costs over the life of the notes which are reported as interest expense in our consolidated statements of operations.

**Other income (expense), net**

Other income and expense to date has primarily consisted of amortization of the net gain recorded on the sale-leaseback of our property and equipment. The first sale-leaseback financings occurred in five separate transactions in 2013 and 2014, each with a 42-month lease term. The gains on the transactions were recognized on a straight-line basis over the respective 42-month lease term. In February 2017, we entered into an additional agreement for the sale-leaseback of newly acquired assets of up to $5.0 million to finance our capital expenditures. Under this agreement, we entered into leases and sold assets with a total capitalized cost of $481,000 and $2,742,000 at effective interest rates of 14.3% and 14.9% on February 13, 2017 and June 30, 2017, respectively. The February sale resulted in a net gain of $14,000 which has been deferred and is being amortized over the 36-month term of the lease. There was no gain or loss on the June 2017 sale. (See Notes 11 and 17 to the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details). Other income and expense also includes interest earned, accretion and gains on our cash and cash equivalents and short-term investments and changes resulting from the remeasurement of the fair value of our earnout and derivative liabilities. The primary objective of our investment policy is liquidity and capital preservation.

**RESULTS OF OPERATIONS**

***Year ended December 31, 2018 compared to the year ended December 31, 2017***

**Revenues**

The following table summarizes our revenues for the year ended December 31, 2018 and 2017:

| | Year Ended December 31, | | Increase | % Increase |
|---|---|---|---|---|
| | 2018 | 2017 | (Decrease) | (Decrease) |
| | (in thousands) | | | |
| Product | $ 49,988 | $ 27,132 | $ 22,856 | 84.2% |

Total product revenues were $50.0 million for the year ended December 31, 2018, an increase of $22.9 million or 84.2%, from the $27.1 million for the year ended December 31, 2017. The increase was primarily due to a $17.4 million increase in net sales of Cotempla XR-ODT, which commenced commercialization on September 5, 2017 with an early experience program. Sales from Adzenys XR-ODT increased approximately $6.3 million to $26.6 million for the year ended December 31, 2018

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from $20.4 million for the year ended December 31, 2017. Net sales of Adzenys ER, which launched on February 26, 2018, were negligible for the year ended December 31, 2018. These increases were partially offset by an $0.8 million decrease in net sales of our generic Tussionex to $4.4 million for the year ended December 31, 2018 from $5.2 million for the year ended December 31, 2017, primarily due to alternative treatment options for this product.

**Cost of goods sold**

The following table summarizes our cost of goods sold for the year ended December 31, 2018 and 2017:

| | Year Ended December 31, | | Increase | % Increase |
|---|---|---|---|---|
| | 2018 | 2017 | (Decrease) | (Decrease) |
| | (in thousands) | | | |
| Cost of goods sold | $ 26,928 | $ 14,030 | $ 12,898 | 91.9% |

The total cost of goods sold was $26.9 million for the year ended December 31, 2018, an increase of $12.9 million or 91.9%, from the $14.0 million for the year ended December 31, 2017. This increase was due to a $9.3 million increase in product costs and an associated increase of $1.7 million of finished drug, royalty fees and logistic costs relating to the 30.7% increase in sales of Adzenys XR-ODT for the year ended December 31, 2018 as compared to the year ended December 31, 2017 and sales of Cotempla XR-ODT and Adzenys ER, which commenced on September 5, 2017 and February 26, 2018, respectively. In addition, increased investment in labor and indirect production activities associated with increased manufacturing demand for our products of $1.6 million also contributed to the higher cost of goods sold for the year ended December 31, 2018.

**Research and development expenses**

The following table summarizes our research and development expenses for the year ended December 31, 2018 and 2017:

| | Year Ended December 31, | | Increase | % Increase |
|---|---|---|---|---|
| | 2018 | 2017 | (Decrease) | (Decrease) |
| | (in thousands) | | | |
| Research and development expenses | $ 8,508 | $ 8,957 | $ (449) | (5.0)% |

Research and development expenses were $8.5 million for the year ended December 31, 2018, a decrease of approximately $0.4 million or 5.0%, from $9.0 million for the year ended December 31, 2017. The decrease was primarily related to lower product development expenses for the year ended December 31, 2018 as a result of the FDA approvals of Cotempla XR-ODT in June 2017 and Adzenys ER in September 2017.

**Selling and marketing expenses**

The following table summarizes our selling and marketing expenses for the year ended December 31, 2018 and 2017:

| | Year Ended December 31, | | Increase | % Increase |
|---|---|---|---|---|
| | 2018 | 2017 | (Decrease) | (Decrease) |
| | (in thousands) | | | |
| Sales and marketing expenses | $ 44,133 | $ 46,881 | $ (2,748) | (5.8)% |

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The total selling and marketing expenses were $44.1 million for the year ended December 31, 2018, a decrease of $2.7 million or 5.8%, from $46.9 million for the year ended December 31, 2017. The main decreases in selling and marketing expenses for the year ended December 31, 2018 as compared to the year ended December 31, 2017 were contract sales organization expenses of $17.4 million due to the internalization of our sales force in April 2018, marketing expenses of $1.1 million and professional service expenses of $0.8 million. Partially offsetting the decreases were increased salary and benefit expenses of $11.4 million, travel and entertainment expenses of $3.6 million and administrative expenses of $1.1 million due to the establishment of our internal sales team in April 2018 and to support the sales of Cotempla XR-ODT and Adzenys ER, which commenced on September 5, 2017 and February 26, 2018, respectively.

**General and administrative expenses**

The following table summarizes our general and administrative expenses for the year ended December 31, 2018 and 2017:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2018 | 2017 | | |
| | (in thousands) | | | |
| General and administrative expenses | $ 13,915 | $ 13,805 | $ 110 | 0.8% |

The total general and administrative expenses were $13.9 million for the year ended December 31, 2018, an increase of $0.1 million or 0.8%, from the $13.8 million for the year ended December 31, 2017. The increase was primarily from higher administrative expenses and professional service expenses for the year ended December 31, 2018.

**Interest expense**

The following table summarizes interest expense for the year ended December 31, 2018 and 2017:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2018 | 2017 | | |
| | (in thousands) | | | |
| Interest expense | $ (8,974) | $ (10,085) | $ 1,111 | 11.0% |

The total interest expense was $9.0 million for the year ended December 31, 2018, a decrease of $1.1 million or 11.0%, from the $10.1 million for the year ended December 31, 2017. Interest expenses for both periods were primarily from interest on the Facility (see Note 11 to the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details).

**Other income, net**

The following table summarizes our other income for the year ended December 31, 2018 and 2017:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2018 | 2017 | | |
| | (in thousands) | | | |
| Other income, net | $ 795 | $ 854 | $ (59) | (6.9)% |

Other income, net was $0.8 million for the year ended December 31, 2018, a slight decrease of 6.9% from the $0.9 million for the year ended December 31, 2017. Other income, net mainly consisted

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of change in fair value of the Deerfield debt derivative and interest income for both of the years ended December 31, 2018 and 2017.

***Year ended December 31, 2017 compared to the year ended December 31, 2016***

**Revenues**

The following table summarizes our revenues for the year ended December 31, 2017 and 2016:

| | Year Ended December 31, | | Increase | % Increase |
|---|---|---|---|---|
| | 2017 | 2016 | (Decrease) | (Decrease) |
| | (in thousands) | | | |
| Product | $ 27,132 | $ 10,033 | $ 17,099 | 170.4% |

Total product revenues were $27.1 million for the year ended December 31, 2017, an increase of $17.1 million or 170.4% from the $10.0 million for the year ended December 31, 2016. The increase was primarily due to a $16.6 million increase in net sales of Adzenys XR-ODT which launched on May 16, 2016 from $20.4 million of net sales for the year ended December 31, 2017 versus $3.8 million for the year ended December 31, 2016. Net sales of Cotempla XR-ODT which commenced on September 5, 2017 were $1.6 million. The increase was partially offset by an approximately $1.1 million decline in net sales of our generic Tussionex to $5.1 million for the year ended December 31, 2017 from $6.2 million for the year ended December 31, 2016 primarily due to competitive pricing pressures for this product.

**Cost of goods sold**

The following table summarizes our cost of goods sold for the year ended December 31, 2017 and 2016:

| | Year Ended December 31, | | Increase | % Increase |
|---|---|---|---|---|
| | 2017 | 2016 | (Decrease) | (Decrease) |
| | (in thousands) | | | |
| Cost of goods sold | $ 14,030 | $ 11,734 | $ 2,296 | 19.6% |

Total cost of goods sold was $14.0 million for the year ended December 31, 2017, an increase of $2.3 million or 19.6%, from the $11.7 million for the year ended December 31, 2016. This increase was primarily from a $4.9 million increase in product costs and an associated increase of $1.7 million of royalty fees, freight and logistics costs relating to the increased sales of Adzenys XR-ODT in 2017 which launched on May 16, 2016 and sales from of Cotempla XR-ODT which commenced on September 5, 2017. Partially offsetting these increased costs were lower production cost of $4.5 million relating to efficiencies from increased production to meet sales demand, manufacturing costs for the production of Cotempla XR-ODT being capitalized into inventory after June 30, 2017, following the FDA approval date of June 19, 2017 and manufacturing costs for the production of Adzenys ER being capitalized into inventory after June 30, 2017, September 30, 2017, following the FDA approval date of September 15, 2017.

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**Research and development expenses**

The following table summarizes our research and development expenses for year ended December 31, 2017 and 2016:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2017 | 2016 | | |
| | (in thousands) | | | |
| Research and development expenses | $ 8,957 | $ 12,207 | $ (3,250) | (26.6)% |

Research and development expenses were $9.0 million for the year ended December 31, 2017, a decrease of approximately $3.3 million or 26.6%, from the $12.2 million for the year ended December 31, 2016. This decrease was primarily due to a $1.4 million decrease in clinical expenses and a $1.0 million decrease in FDA filing fees associated with Adzenys ER and Cotempla XR-ODT, which completed in 2016. Additionally, development cost for materials, professional fees, employee and related administrative expenses declined $0.9 million.

**Selling and marketing expenses**

The following table summarizes our selling and marketing expenses for the year ended December 31, 2017 and 2016:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2017 | 2016 | | |
| | (in thousands) | | | |
| Sales and marketing expenses | $ 46,881 | $ 49,291 | $ (2,410) | (4.9)% |

The total selling and marketing expenses were $46.9 million for the year ended December 31, 2017, a decrease of $2.4 million or 4.9%, from the $49.3 million for the year ended December 31, 2016. The decrease was primarily due to a decrease of $7.0 million in advertising expenses, $0.4 million in media management and creative design and $2.0 million in commercial team training activities associated with the launch of our initial branded product, Adzenys XR-ODT, in 2016. These decreases were partially offset by $6.4 million increase in the commercial sales organization salesforce costs and $0.6 million increase in salaries and benefits, as this salesforce and support organization was in place for the full year of 2017, whereas in 2016, we were in the process of building out this operation in anticipation of the May 2016 launch of our initial branded product.

**General and administrative expenses**

The following table summarizes our general and administrative expenses for the year ended December 31, 2017 and 2016:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2017 | 2016 | | |
| | (in thousands) | | | |
| General and administrative expenses | $ 13,805 | $ 12,625 | $ 1,180 | 9.3% |

The total general and administrative expenses were $13.8 million for the year ended December 31, 2017, an increase of $1.2 million or 9.3%, from the $12.6 million for the year ended December 31, 2016. Salaries and benefits expense primarily increased $0.6 million due to additional corporate personnel supporting increased compliance requirements. Legal cost for patent defense increased $1.0 million, partially offset by a $0.5 million decrease in business development and office supplies.

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**Interest expense**

The following table summarizes interest expense and loss on debt extinguishment for the year ended December 31, 2017 and 2016:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2017 | 2016 | | |
| | (in thousands) | | | |
| Interest expense and loss on debt extinguishment | $ (10,085) | $ (8,124) | $ 1,961 | 24.1% |

The total interest expense was $10.1 million for the year ended December 31, 2017, an increase of $2.0 million or 24.1%, from the $8.1 million for the year ended December 31, 2016. Interest on debt was $3.1 million higher due to the higher debt balance in 2017 and interest expense related to the additional debt discounts recorded in June 2017 as a result of the modification of the Facility (see Note 11 to the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details).

Partially offsetting increased senior debt interest expense was the early prepayment of the LSA in 2016 which 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.

**Other income, net**

The following table summarizes our other income for the year ended December 31, 2017 and 2016:

| | Year Ended December 31, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2017 | 2016 | | |
| | (in thousands) | | | |
| Other income, net | $ 854 | $ 1,197 | $ (343) | (28.7)% |

Other income, net was $0.9 million for the year ended December 31, 2017, a decrease of $0.3 million or 28.7%, from $1.2 million for the year ended December 31, 2016. Other income, net in 2017 consisted of changes in fair value of the Deerfield debt derivative and the Tussionex earn-out liability amounting to $0.5 million, interest income of $0.3 million and amortized gain on the sale-leasebacks of $0.1 million. Other income, net in 2016 consisted of $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 interest income of $0.3 million.

**LIQUIDITY AND CAPITAL RESOURCES**

**Sources of liquidity**

From our reorganization in 2009 until our initial public offering ("IPO"), we financed our operations primarily through private placements of common stock and redeemable convertible preferred stock and bank and other lender financing. On July 28, 2015, we closed our IPO whereby we sold 5,520,000 shares of our common stock, at a public offering price of $15.00 per share, which includes 720,000 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the IPO price on July 23, 2015. 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. 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.

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On May 11, 2016, we entered into the Facility with Deerfield. 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 Note that was issued by us to Essex, which payments were otherwise payable in 2016 and 2017. Principal on the Facility was initially 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 had an option, which we exercised, to defer payment of each of the first four interest payments under the Facility, adding such amounts to the outstanding loan principal. The aggregate $6.6 million Accrued Interest was to be paid in cash on June 1, 2017.

On the Amendment Date, we entered into the Amendment to the Facility with Deerfield which extended the date to repay the Accrued Interest under the Facility to June 1, 2018 (the "PIK Maturity Date"), which may have been extended to June 1, 2019 at our election if certain conditions had been met as specified in the Amendment. The right to payment of the Accrued Interest was memorialized in the Convertible Notes issued to Deerfield on the Amendment Date. Interest was due quarterly at a rate of 12.95% per year.

The $6.6 million of Convertible Notes were convertible into shares of our common stock at the noteholder's option at any time up to the close of business on the date that was five days prior to the PIK Maturity Date. The per share conversion price was to be the greater of (A) 95% of the average of the volume weighted average prices per share of our common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion, and (B) $7.00. On June 30, 2017, we filed a registration statement on form S-3 with the SEC registering 940,924 shares of our common stock that may be offered from time to time by Deerfield, the maximum number of shares of our common stock which would be issued upon conversion of the Convertible Notes assuming the lowest possible conversion price of $7.00 per share, and such registration statement was declared effective by the SEC on July 11, 2017. On October 26, 2017, Deerfield provided a conversion notice electing to convert the entire $6.6 million of Convertible Notes into shares of the Company's common stock at a conversion price of $7.08 per share. The conversion price was based on 95% of the average of the volume weighted average prices per share of the Company's common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion. This resulted in issuing 929,967 shares of the Company's common stock to Deerfield on this date and the Convertible Notes were cancelled.

In February 2017, we entered into an agreement with Essex for the sale-leaseback of newly acquired assets of up to $5.0 million to finance our capital expenditures. Each lease under this master agreement is for an initial term of 36 months and will have a bargain purchase option at the end of the respective lease. Under this agreement, we entered into leases and sold assets with a total capitalized cost of $481,000 and $2,742,000 at effective interest rates of 14.3% and 14.9% on February 13, 2017 and June 30, 2017, respectively.

In February 2017, we closed an underwritten public offering of 5,750,000 shares of our common stock at a public offering price of $5.00 per share, which includes 750,000 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price on February 17, 2017. Deerfield, our senior lender, participated in the purchase of our common shares as part of this public offering, and as a result, was classified as a related party at the time of the corresponding transactions. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us were approximately $26.7 million.

On June 30, 2017, we closed an underwritten public offering of 4,800,000 shares of our common stock at a price of $6.25 per share for total proceeds of $30.0 million before estimated offering costs of

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$0.2 million. We also granted the underwriters a 30-day option to purchase up to an additional 720,000 shares of our common stock which the underwriters exercised in full on July 26, 2017. The net proceeds to us from this offering, after deducting offering expenses payable by us, were approximately $34.3 million.

The shares of common stock for both the June 2017 and February 2017 offerings were offered pursuant to a shelf registration statement on Form S-3, including a base prospectus, filed by us on August 1, 2016, and declared effective by the SEC on August 12, 2016. This shelf registration statement 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 "Sales Agreement"). During the year ended December 31, 2017, we sold an aggregate 749,639 shares of common stock under the Sales Agreement, at an average sale price of approximately $5.01 per share for gross proceeds of $3.7 million and net proceeds of $3.6 million after paying compensation to the sales agent of $0.1 million. During the year ended December 31, 2018, we sold an aggregate 651,525 shares of common stock under the Sales Agreement, at an average sale price of approximately $6.25 per share for gross proceeds of $4.1 million and net proceeds of $3.9 million and paying total compensation to the sales agent and other costs of approximately $0.2 million. On November 5, 2018, we supplemented the Shelf to reduce the size of the Sales Agreement to up to $7,825,113 of our common stock (inclusive of amounts previously sold thereunder prior to the date hereof), effective on November 5, 2018. As of the date hereof, aggregate gross proceeds of sales of our common stock under the Sales Agreement total $7,825,113, and sales of our common stock under the Sales Agreement have been suspended.

On November 8, 2018, we closed an underwritten public offering 19,999,999 shares of our common stock at a public offering price of $2.30 per share, which includes 2,608,695 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $43.4 million. Also, on November 5, 2018, we entered into a Second Amendment to the Facility with Deerfield under which we used $7.5 million of proceeds of the offering to prepay $7.5 million of principal on the Facility otherwise due on May 11, 2018. Pursuant to the Second Amendment, the schedule of principal repayments under the facility was further modified to allow for the $15.0 million payment otherwise due on May 11, 2020 to be deferred until either May 2021 or May 2022 if certain revenue milestones for the years ended December 31, 2019 and December 31, 2020 are achieved. Finally, the Second Amendment provides us with a right, subject to the terms and conditions of the Facility and certain other limitations, to make interest and principal payments through the issuance of our common stock, and provides Deerfield with a right, subject to the terms and conditions of the Facility and the amended and restated convertible notes (the "A&R Notes") issued under the Facility and certain other limitations, to convert principal under the A&R Notes into our common stock, subject to a floor of 95% of $10.00 per share.

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 and short-term investments are invested in bank deposits, money market funds, financials and corporate debt securities, all of which are currently providing only minimal returns.

As of December 31, 2018, we had $46.5 million in cash and cash equivalents. We believe that our existing cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months after filing this Annual Report on Form 10-K.

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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, Cotempla XR-ODT and Adzenys ER.

**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) |
|---|---|---|---|---|---|---|
| | 2018 | 2017 | | 2017 | 2016 | |
| | (in thousands) | | | | | |
| **Net Cash (used in) provided by:** | | | | | | |
| Net Cash used in operating activities | $ (41,441) | $ (53,261) | $ 11,820 | $ (53,261) | $ (70,646) | $ 17,385 |
| Net Cash provided by (used in) investing activities | 17,219 | (2,533) | $ 19,752 | (2,533) | (19,322) | $ 16,789 |
| Net Cash provided by financing activities | 38,731 | 63,411 | $ (24,680) | 63,411 | 23,557 | $ 39,854 |
| Net increase (decrease) in cash and cash equivalents | $ 14,509 | $ 7,617 | $ 6,892 | $ 7,617 | $ (66,411) | $ 74,028 |

**Cash used in operating activities**

Net cash used in operating activities during these periods primarily reflected our net losses, partially offset by changes in working capital and non-cash charges including deferred interest on debt, changes in fair value of earnout, derivative and warrant liabilities, share-based compensation expense, depreciation expense, amortization of patents and other intangible assets and amortization of senior debt fees.

Net cash used in operating activities was $41.4 million and $53.3 million for the years ended December 31, 2018 and 2017, respectively. The $11.8 million decrease in net cash used from operating activities was due to the $14.1 million decrease in our net losses, as discussed in "Results of Operations" above, a $2.5 million decrease in noncash items and a $0.2 million increase in cash provided by working capital. The decrease of $2.5 million in noncash items was primarily due to a $2.1 million decrease in deferred interest on debt to Deerfield, a $0.7 million decrease in share-based compensation expense and a $0.4 million decrease on amortization of senior debt discounts, partially offset by a $0.1 million increase from the fair value change of earnout and derivative liabilities and a $0.4 million increase in depreciation and amortization of property and equipment. The $0.2 million increase in cash provided by working capital included a $7.6 million increase from decreased inventories due to increased sales for our branded products, Adzenys VR-ODT and Cotempla XR-ODT, in 2018, partially offset by a $6.6 million decrease in accounts receivable due to timing of collections, and a $0.7 million decrease from the discontinued deferred commercial sales organization costs due to the transitioning of our sales organization from contracted to internal in April 2018.

Net cash used in operating activities was $53.3 million and $70.6 million for the years ended December 31, 2017 and 2016, respectively. The $17.4 million decrease in net cash used from operating activities was due to the $17.0 million decrease in our net losses, a $2.0 million decrease in noncash items and a $2.4 million increase in the provision of cash from working capital. The increase in cash provided by working capital changes resulted primarily from the following: $9.2 million decreased cash usage for accounts payable and accrued expenses due to the timing of vendor invoicing and payments, $0.8 million increase from the deferred commercial sales organization costs as the ongoing operations

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contract commenced in March 2016 and $0.9 million increase from other assets related mainly to prepaid expenses. These increases were partially offset by $5.3 million for accounts receivable mainly due to increased sales in Adzenys XR-ODT and Cotempla XR-ODT in 2017 and $3.2 million from increased inventories due to increased production volume for Adzenys XR-ODT and Cotempla XR-ODT. The decrease in noncash items was principally due to a $2.6 million decrease in deferred interest on debt, a $0.9 million decrease resulting from the 2016 loss on debt extinguishment due to the early repayment of the Facility and the Note, a $0.5 million decrease in the fair value change of earnout and derivative liabilities and a $0.2 million decrease in depreciation and amortization expense, partially offset by a $0.6 million increase in share-based compensation expense, a $0.9 million increase in amortization of senior debt fees and a $0.9 million decrease in deferred gain on sale of equipment primarily due to the expiration of the 2013 and 2014 sale-leasebacks.

**Cash provided by (used in) investing activities**

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

Net cash provided by investing activities was $17.2 million for the year ended December 31, 2018 primarily due to $36.5 million of sales and maturities of short-term investments, partially offset by the $17.9 million purchase of short-term investments and $1.4 million of capital expenditures principally for production equipment.

Net cash used in investing activities was $2.5 million for the year ended December 31, 2017 primarily due to the $48.0 million purchase of short-term investments and $2.5 million of capital expenditures principally for production equipment, partially offset by the $45.1 million of sales and maturities of short-term investments and $3.2 million of proceeds from the sale-leaseback of equipment.

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, $3.6 million of capital expenditures principally for equipment and systems to be used in the production and testing of Adzenys XR-ODT and our other product candidates and a new Enterprise Resource Planning System.

**Cash provided by financing activities**

Net cash provided by financing activities of $38.7 million in the year ended December 31, 2018 principally included $47.3 million of proceeds from the issuance of common stock net of related underwriting discounts, commissions and issuance costs and partially offset by $8.4 million due to the $7.5 million principal payments of the senior facility under the Second Amendment with Deerfield and the principal payments under the sales-leasebacks.

Net cash provided by financing activities of $63.4 million in the year ended December 31, 2017 principally included $64.6 million of proceeds from the issuance of common stock net of related underwriting discounts, commissions and issuance costs and partially offset by $1.0 million of principal payments under the sales-leasebacks.

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 million 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

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principal payments under the sales leasebacks partially offset by $0.4 million of proceeds from the sale of related equipment.

**Credit facilities**

On May 11, 2016, we entered into a $60.0 million Facility with Deerfield. 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 Note that was issued by us to Essex which was to mature in March 2017, which were otherwise payable in 2016 and 2017. Principal on the Facility was initially 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. In connection with the Facility, we paid a $1,350,000 yield enhancement fee to Deerfield and approximately $0.2 million of legal fees. 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 $5.0 million.

We had an option, which we exercised, to defer payment of each of the first four interest payments, adding such amounts to the outstanding loan principal. The aggregate $6.6 million Accrued Interest was to be paid in cash on June 1, 2017.

On June 1, 2017, we entered into the Amendment to the Facility which extended the PIK Maturity Date to June 1, 2018, which may have been extended to June 1, 2019 at our election if certain conditions had been met as specified in the Amendment. The right to payment of the Accrued Interest was memorialized in the Convertible Notes issued to Deerfield on the Amendment Date. Interest is due quarterly at a rate of 12.95% per year.

The $6.6 million of Convertible Notes were convertible into shares of our common stock at Deerfield's option at any time up to the close of business on the date that is five days prior to the PIK Maturity Date. The per share conversion price was to be the greater of (A) 95% of the average of the volume weighted average prices per share of our common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion, and (B) $7.00. On June 30, 2017, we filed a registration statement on form S-3 with the SEC registering 940,924 shares of our common stock that may be offered from time to time by Deerfield, the maximum number of shares of our common stock which would be issued upon conversion of the Convertible Notes assuming the lowest possible conversion price of $7.00 per share, and such registration was declared effective by the SEC on July 11, 2017. Deerfield cannot own more than 9.985% of our outstanding shares at any one time, and the aggregate conversion could not exceed 19.9% of our outstanding common stock as of June 1, 2017.

The principal amount of the Convertible Notes issued under the Amendment and all accrued and unpaid interest thereon was to become due and payable upon written notice from the Deerfield, and if either (a) we did not meet certain quarterly sales milestones specified in the Amendment or (b) we did not receive and publicly announce FDA approval of the new drug applications on or before the applicable PDUFA goal date as set forth on the schedules to Amendment. Per the Amendment, we will prepay all of the outstanding obligations under the Facility and the Convertible Notes upon the occurrence of a change in control or a sale of substantially all of our assets and liabilities. The Amendment increased the staggered prepayment fees for prepayments due upon a change of control or any other prepayment made or required to be made by us by 300 basis points from June 1, 2017 through the period ending prior to May 11, 2020 for the change in control prepayment fees and through the period ending prior to May 11, 2022 for any other prepayments, respectively (the "Prepayment Premiums"). Such Prepayment Premiums, as amended, range from 12.75% to 2%.

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On October 26, 2017, Deerfield elected to convert the entire $6.6 million of Convertible Notes into shares of the Company's common stock at a conversion price of $7.08 per share. This resulted in issuing 929,967 shares of the Company's common stock to Deerfield on this date and the Convertible Notes were cancelled.

On November 5, 2018, we entered into a Second Amendment to the Facility with Deerfield under which we used $7.5 million of proceeds of an underwritten public offering of shares of our common stock to prepay $7.5 million of principal on the Facility otherwise due on May 11, 2018. Pursuant to the Second Amendment, the schedule of principal repayments under the facility was further modified to allow for the $15.0 million payment otherwise due on May 11, 2020 to be deferred until either May 2021 or May 2022 if certain revenue milestones for the years ended December 31, 2019 and December 31, 2020 are achieved. Finally, the Second Amendment provides us with a right, subject to the terms and conditions of the Facility and certain other limitations, to make interest and principal payments through the issuance of our common stock, and provides Deerfield with a right, subject to the terms and conditions of the Facility and the A&R Notes and certain other limitations, to convert principal under the A&R Notes into our common stock, subject to a floor of 95% of $10.00 per share.

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 $5.0 million. 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, 2018, we were in compliance with the covenants under the Facility.

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.

During the years ended December 31, 2017, 2014 and 2013, we entered into agreements with Essex for the sale-leaseback of existing and newly acquired assets with a total capitalized cost of $3.2 million, $795,000 and $5.5 million, respectively, with bargain purchase options at the end of each respective lease, all of which are classified as capital leases. The two February 2013 leases for a total of $3.5 million of assets expired in July 2016, the July 2013 lease for a total of $1.0 million of assets expired in December 2016, the November 2013 lease for a total of $1.0 million of assets expired in April 2017, the March 2014 lease for a total of $795,000 of assets expired in September 2017, and all lease buy-out liabilities were satisfied. The approximate imputed interest rate on these leases is 14.9%, 14.5% and 14.5%, respectively. See "Contractual Commitments and Obligations" below for future payments under these leases.

**Capital resources and funding requirements**

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.

In February 2017, pursuant to the Shelf, we closed an underwritten public offering of 5,750,000 shares of our common stock at a public offering price of $5.00 per share, which includes 750,000 shares

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of our common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price on February 17, 2017. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us were approximately $26.7 million.

On June 30, 2017, pursuant to the Shelf, we closed an underwritten public offering of 4,800,000 shares of our common stock at a price of $6.25 per share for total proceeds of $30.0 million before estimated offering costs of $0.2 million. We also granted the underwriters a 30-day option to purchase up to an additional 720,000 shares of our common stock which the underwriters exercised in full on July 26, 2017. The net proceeds to us from this offering, after deducting offering expenses payable by us, were approximately $34.3 million.

During the year ended December 31, 2017, we sold an aggregate 749,639 shares of common stock under the Sales Agreement at an average sale price of approximately $5.01 per share.

On November 5, 2018, we filed Supplement No. 1 to the prospectus dated August 12, 2016, which reduced the size of our continuous offering of our common stock pursuant to the Sales Agreement. Following the reduction, we are authorized to issue up to $7,825,113 of our common stock pursuant to the Sales Agreement (inclusive of amounts previously sold thereunder prior to the date hereof). As of the date hereof, aggregate gross proceeds of sales of our common stock under the Sales Agreement total $7,825,113, and sales of our common stock under the Sales Agreement have been suspended.

On November 8, 2018, the Company closed an underwritten public offering of 19,999,999 shares of its common stock at a public offering price of $2.30 per share, which includes 2,608,695 shares of its common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price. 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 $43.4 million.

During the year ended December 31, 2018, we sold an aggregate 651,525 shares of common stock under the Sales Agreement, at an average sale price of approximately $6.25 per share for gross proceeds of $4.1 million and net proceeds of $3.9 million and paying total compensation to the sales agent and other costs of approximately $0.2 million. As of December 31, 2018, $5.2 million of our common stock, preferred stock, debt securities, warrants and/or units remained available to be sold pursuant to the Shelf.

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, Cotempla XR-ODT, Adzenys ER or, if approved, our new product candidates. In addition, we may not be profitable even if we succeed in commercializing Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or, if approved, any of our new 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 and operate commercial infrastructure to support sales and marketing of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and, if approved, our product candidates that we may develop. We believe that our existing cash and cash equivalents and short-term investments 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 products and 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 of operating our sales, marketing and distribution capabilities;

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- the market acceptance of our products and, if approved, product candidates and related success in commercializing and generating sales from our products and, if approved, product candidates, that we may develop;

- the costs of our manufacturing capabilities to support our commercialization activities, including any costs associated with adding new capabilities;

- the costs and timing involved in obtaining regulatory approvals for our new product candidates;

- the timing and number of product candidates for which we obtain regulatory approval;

- 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 increased product sales and commercial operations, as well as sales and marketing personnel to commercialize our approved products.

We may not generate a sufficient amount of product revenues from sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to finance our cash requirements. Until we obtain regulatory approval to market our new 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, Cotempla XR-ODT and Adzenys ER, 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 ("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.

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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 recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services at a point in time. We make estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler fees, wholesaler chargebacks and estimated rebates) to be incurred on the selling price of the respective product sales, and recognize the estimated amount as revenue when it transfers control of the product to its customers (e.g., upon delivery). Variable consideration is determined using either an expected value or a most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint will require the use of significant management judgment and other market data. We provide for prompt payment discounts, wholesaler fees and wholesaler chargebacks based on customer contractual stipulations. We analyze recent product return history and other market data obtained from our third party logistics providers ("3PLs") to determine a reliable return rate. Additionally, we analyze historical savings offers and rebate payments based on patient prescriptions dispensed for Adzenys XR ODT, Cotempla XR ODT and Adzenys ER and information obtained from third party providers to determine these respective variable considerations.

We sell our generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to a limited number of pharmaceutical wholesalers, all subject to rights of return. 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.

Revenues for Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and generic Tussionex for the years ended December 31, 2018, 2017 and 2016, respectively, are as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| | (in thousands) | | |
| Adzenys XR-ODT | $ 26,631 | $ 20,377 | $ 3,803 |
| Cotempla XR-ODT | 19,014 | 1,590 | |
| Adzenys ER | (27) | | |
| Generic Tussionex | 4,370 | 5,165 | 6,230 |
| | $ 49,988 | $ 27,132 | $ 10,033 |

*Net product sales*

Net product sales represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER include savings offers, prompt payment discounts, wholesaler fees, estimated rebates to be incurred on the selling price of the respective product sales and estimated allowances for product returns.

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Gross to net sales adjustments for generic Tussionex include prompt payment discounts, estimated allowances for product returns, wholesaler fees, estimated government rebates and estimated chargebacks to be incurred on the selling price of generic Tussionex related to the respective product sales.

We recognize total gross product sales less gross to net sales adjustment as revenue based on shipments from 3PLs to the Company's wholesaler customers.

*Savings offers for branded products*

We offer savings programs for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. The Company records the amount of redeemed savings offers based on information from third-party providers against the estimated discount recorded as accrued expenses. The estimated discount is recorded as a gross to net sales adjustments at the time revenue is recognized.

*Prompt payment discounts*

Prompt payment discounts are based on standard programs with wholesalers and are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized.

*Wholesale distribution fees*

Wholesale distribution fees are based on definitive contractual agreements for the management of the Company's products by wholesalers and are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

*Rebates*

Our branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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. Calculations related to rebate accruals of branded products are estimated based on information from third-party providers.

Our generic Tussionex product is subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Generic Tussionex government rebates are estimated based upon rebate payment data available from sales of the Company's generic Tussionex product over the past three years.

Estimated rebates are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. Historical trends of estimated rebates will be continually monitored and may result in future adjustments to such estimates.

*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. Estimated returns are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized.

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We analyzed recent branded product return history and other market data obtained from the Company's 3PLs as well as data available from sales of our branded products to determine a reliable return rate for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Generic Tussionex product returns were estimated based upon return data available from sales of our generic Tussionex product over the past three years.

*Wholesaler chargebacks for generic product*

Our generic Tussionex 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. Estimated chargebacks are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized based on information provided by third parties.

Due to estimates and assumptions inherent in determining the amount of generic Tussionex returns, rebates and chargebacks, the actual amount of returns, 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 are recorded in the same period that the related revenue is recognized.

The following table presents our gross to net sales deductions for our Adzenys XR-ODT which we launched commercially on May 16, 2016, our Cotempla XR-ODT which we initiated an early experience program with limited product availability on September 5, 2017 and launched nationwide on October 2, 2017 and Adzenys ER which we launched commercially on February 26, 2018 for the years ended December 31, 2018, 2017 and 2016:

| | 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 | 5,816 | 1,082 | 274 | 567 | 8,123 |
| **Payments / credits** | (324) | (3,746) | (622) | | (62) | (4,754) |
| **Balance at December 31, 2016** | $ 60 | $ 2,070 | $ 460 | $ 274 | $ 505 | $ 3,369 |
| **Provision, net** | 1,468 | 30,978 | 6,791 | 1,625 | 7,793 | 48,655 |
| **Payments / credits** | (1,288) | (25,880) | (5,047) | (80) | (4,354) | (36,649) |
| **Balance at December 31, 2017** | $ 240 | $ 7,168 | $ 2,204 | $ 1,819 | $ 3,944 | $ 15,375 |
| **Provision, net** | 3,210 | 71,303 | 16,150 | 3,506 | 18,709 | 112,878 |
| **Payments / credits** | (2,997) | (67,183) | (14,362) | (1,145) | (14,973) | (100,660) |
| **Balance at December 31, 2018** | $ 453 | $ 11,288 | $ 3,992 | $ 4,180 | $ 7,680 | $ 27,593 |

Total items deducted from gross product sales were $112,878, $48,655 and $8,123, or 71.2%, 68.9% and 68.1% as a percentage of gross product sales, for the years ended December 31, 2018, 2017 and 2016, respectively, due principally to the savings offers being made to penetrate the ADHD market.

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The following table presents our gross to net sales deductions for our generic Tussionex for the years ended December 31, 2018, 2017 and 2016:

| | Chargebacks | Cash Discounts | Wholesaler Fees | Returns | Government Rebates | Total Gross to Net Sales Deductions |
|---|---|---|---|---|---|---|
| | | | (in thousands) | | | |
| **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 |
| **Provision, net** | 10,146 | 346 | 1,452 | 167 | 43 | 12,154 |
| **Payments / credits** | (10,109) | (359) | (1,360) | (158) | (18) | (12,004) |
| **Balance at December 31, 2017** | $ 816 | $ 98 | $ 141 | $ 893 | $ 63 | $ 2,011 |
| **Provision, net** | 8,565 | 308 | 1,263 | 297 | 37 | 10,470 |
| **Payments / credits** | (8,067) | (308) | (1,147) | (213) | (17) | (9,752) |
| **Balance at December 31, 2018** | $ 1,314 | $ 98 | $ 257 | $ 977 | $ 83 | $ 2,729 |

Total items deducted from gross product sales were $10,470, $12,154 and $13,091, or 70.6%, 70.2% and 67.8% as a percentage of gross product sales, for the years ended December 31, 2018, 2017 and 2016, 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.

**Inventories**

Inventories are stated at the lower of cost (first in, first out) or market in 2016 and, effective January 1, 2017, inventory is now required to be measured at the lower of cost (first in, first out) or net realizable value. The change to stating inventories at the lower of cost or net realizable value in 2017 was adopted prospectively and did not have a significant effect on the Company's ongoing financial reporting as valuing inventory at the lower of cost or net realizable value approximated the prior policy of valuing inventory at the lower of cost or market. Inventories 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 and finished goods.

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, for the production of Cotempla XR-ODT incurred after June 30, 2017, following the FDA approval date of June 19, 2017, and for the production of Adzenys ER incurred after September 30, 2017, following the FDA approval date of September 15, 2017, 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

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

**Share-based compensation expense**

Share-based compensation awards, including grants of employee stock options and restricted stock and modifications to existing stock options, are recognized in the statement of operations based on their fair values. Compensation expense related to awards to employees is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. The fair value of our share-based awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends.

Under recent guidance for accounting for share-based payments, we have elected to continue estimating forfeitures at the time of grant and, if necessary, revise the estimate 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. The adoption of this standard in 2017 did not have a material impact on our business, financial position, results of operations or liquidity.

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 a blended volatility rate of prior studies of historical volatility from a representative peer group of comparable companies' selected using publicly-available industry and market capitalization data and 30 months of our stock price volatility. 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 SAB Topic 110, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate was determined by reference to implied yields available from 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.

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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.

**Derivative liabilities**

We evaluate our debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives requiring separate recognition in our financial statements. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as a liability and the change in fair value is recorded in other income (expense) in the consolidated results of operations. In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

When we have determined that the embedded conversion options should not be bifurcated from their host instruments, we record, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption and recorded in interest expense in the consolidated financial statements.

**Intangible assets**

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

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**CONTRACTUAL COMMITMENTS AND OBLIGATIONS**

The following table reflects a summary of our estimates of future material contractual obligations as of December 31, 2018. 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 | $ 68,124 | $ 13,843 | $ 37,662 | $ 16,619 | |
| Capital leases for equipment | 2,096 | 1,257 | 819 | 20 | |
| Earnout liability | 37 | | | | 37 |
| Texas facility operating lease | 6,181 | 955 | 2,010 | 2,110 | 1,106 |
| Pennsylvania office space lease | 360 | 152 | 208 | | |
| Equipment operating leases | 112 | 73 | 39 | | |
| | $ 76,910 | $ 16,280 | $ 40,738 | $ 18,749 | $ 1,143 |

We had borrowed $60.0 million under the Deerfield Facility. On November 5, 2018, we amended the facility and prepaid $7.5 million otherwise due in May 2019, and currently have a balance of $52.5 million of senior secured credit as of December 31, 2018. The payments above are inclusive of related interest amounts as of December 31, 2018.

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 (the "2014 License Agreement") with Shire for a non-exclusive license to certain patents for certain activities with respect to our New Drug Application (the "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.

On March 6, 2017, after our NDA submission for Adzenys ER requiring a Paragraph IV certification notification to the producer of Adderall XR, Shire Pharmaceuticals, in accordance with the Hatch-Waxman Amendments, we entered into a License Agreement (the "2017 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 our NDA No. 204325 for an extended-release amphetamine liquid suspension. Under the terms of the agreement, after receiving regulatory approval by the FDA of our NDA for Adzenys ER, in October 2017, 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 ER during the life of the relevant Shire patents.

Due to the uncertainty of when these royalty payments will be made for Adzenys XR-ODT and Adzenys ER, they are not presented in the table above. The license fees are paid and recorded as an intangible asset and amortized over the term of the license. The royalties are being 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.

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**RECENT ACCOUNTING PRONOUNCEMENTS**

See Note 2 to the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further discussion of recent accounting pronouncements.

**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, 2018, we had cash and cash equivalents of $46.5 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates as our cash equivalents are invested in interest-bearing money market funds. The goals of our investment policy are liquidity and capital preservation to fund our operations. Due to the short-term duration and low risk profile of our cash equivalents portfolio, a 10% change in interest rates would not have a material effect on interest income we recognize or the fair market value of our investments. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates.

**Interest risk**

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

**Effects of Inflation**

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

**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

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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 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, 2018, 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, 2018, 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.

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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.

## 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, 2018 (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-39**, as follows:


| | Page |
|---|---|
| Report of Independent Registered Public Accounting Firm | **F-2** |
| Consolidated Balance Sheets at December 31, 2018 and 2017 | **F-3** |
| Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016 | **F-4** |
| Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018, 2017 and 2016 | **F-5** |
| Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2018, 2017 and 2016 | **F-6** |
| Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016 | **F-7** |
| Notes to Consolidated Financial Statements | **F-8** |


*(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.

*(b)*

*Exhibits:*

[Exhibit Index to be inserted by the Printer]

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

None.

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**Neos Therapeutics, Inc.**

**Index to Consolidated Financial Statements**


| | Page |
|---|---|
| Report of Independent Registered Public Accounting Firm | **F-2** |
| Financial Statements: | |
| Consolidated Balance Sheets | **F-3** |
| Consolidated Statements of Operations | **F-4** |
| Consolidated Statements of Comprehensive Loss | **F-5** |
| Consolidated Statements of Stockholders' Equity (Deficit) | **F-6** |
| Consolidated Statements of Cash Flows | **F-7** |
| Notes to Consolidated Financial Statements | **F-8** |

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Neos Therapeutics, Inc. and Subsidiaries (the "Company") as of December 31, 2018 and 2017, 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, 2018 and the related notes to the consolidated financial statements and schedule (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2010.

Dallas, Texas
March 18, 2019

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**Neos Therapeutics, Inc. and Subsidiaries**

**CONSOLIDATED BALANCE SHEETS**

**(In thousands, except share and per share data)**

| | December 31, | |
|---|---|---|
| | **2018** | **2017** |
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 46,478 | $ 31,969 |
| Short-term investments | | 18,448 |
| Accounts receivable, net of allowances for chargebacks and cash discounts of $1,865 and $1,154 at December 31, 2018 and December 31, 2017, respectively | 27,801 | 13,671 |
| Inventories | 10,367 | 11,732 |
| Other current assets | 4,032 | 3,575 |
| **Total current assets** | 88,678 | 79,395 |
| Property and equipment, net | 7,914 | 8,203 |
| Intangible assets, net | 14,616 | 16,348 |
| Other assets | 149 | 162 |
| **Total assets** | $ 111,357 | $ 104,108 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable | $ 12,730 | $ 11,460 |
| Accrued expenses | 35,818 | 20,944 |
| Current portion of long-term debt | 8,557 | 896 |
| **Total current liabilities** | 57,105 | 33,300 |
| Long-Term Liabilities: | | |
| Long-term debt, net of current portion | 43,217 | 58,938 |
| Derivative liability | 2,017 | 1,660 |
| Deferred rent | 989 | 1,083 |
| Other long-term liabilities | 184 | 180 |
| **Total long-term liabilities** | 46,407 | 61,861 |
| Stockholders' Equity (Deficit): | | |
| Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at December 31, 2018 and December 31, 2017 | | |
| Common stock, $0.001 par value, 100,000,000 authorized at December 31, 2018 and December 31, 2017; 49,710,104 and 49,676,303 issued and outstanding, respectively, at December 31, 2018; 29,030,757 and 28,996,956 issued and outstanding, respectively, at December 31, 2017 | 50 | 29 |
| Treasury stock, at cost, 33,801 shares at December 31, 2018 and December 31, 2017 | (352) | (352) |
| Additional paid-in capital | 325,130 | 274,584 |
| Accumulated deficit | (316,983) | (265,308) |
| Accumulated other comprehensive loss | | (6) |
| **Total stockholders' equity** | 7,845 | 8,947 |

| | | |
|---|---|---|
| **Total liabilities and stockholders' equity** | $ 111,357 | $ 104,108 |

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, | | |
|---|---|---|---|
| | **2018** | **2017** | **2016** |
| Revenues: | | | |
| Net product sales | $ 49,988 | $ 27,132 | $ 10,033 |
| Cost of goods sold | 26,928 | 14,030 | 11,734 |
| **Gross profit (loss)** | 23,060 | 13,102 | (1,701) |
| Research and development expenses | 8,508 | 8,957 | 12,207 |
| Selling and marketing expenses | 44,133 | 46,881 | 49,291 |
| General and administrative expenses | 13,915 | 13,805 | 12,625 |
| **Loss from operations** | (43,496) | (56,541) | (75,824) |
| Interest expense | (8,974) | (10,085) | (6,937) |
| Loss on debt extinguishment | | | (1,187) |
| Other income, net | 795 | 854 | 1,197 |
| **Net loss** | $ (51,675) | $ (65,772) | $ (82,751) |
| Weighted average common shares outstanding used to compute net loss per share, basic and diluted | 32,288,555 | 24,751,091 | 16,052,390 |
| **Net loss per share of common stock, basic and diluted** | $ (1.60) | $ (2.66) | $ (5.16) |

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, | | |
|---|---|---|---|
| | **2018** | **2017** | **2016** |
| **Net loss** | $ (51,675) | $ (65,772) | $ (82,751) |
| Other comprehensive loss: | | | |
| Gain (loss) on short-term investments | 6 | (5) | 2 |
| Reclassification of gains included in net loss | | | (3) |
| **Total other comprehensive income (loss)** | 6 | (5) | (1) |
| **Comprehensive loss** | $ (51,669) | $ (65,777) | $ (82,752) |

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 | | Common Stock | | Treasury Stock | | Additional Paid-in | | Accumulated Other | Total Stockholders' |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Accumulated Deficit | Comprehensive Loss | Equity (Deficit) |
| **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 | | | | | | | (82,751) | | | (82,751) |
| **Balance, December 31, 2016** | $ | 16,079,902 | $ 16 | (18,906) | $ (232) | $ 198,787 | $ (199,536) | $ | (1) $ | (966) |
| Issuance of common stock, net of issuance costs | | 12,019,639 | 12 | | | 64,548 | | | | 64,560 |
| Issuance of common stock upon conversion of convertible notes | | 929,967 | 1 | | | 6,585 | | | | 6,586 |
| Shares issued from exercise of stock options | | 1,249 | | | | | | | | |
| Purchase of treasury stock | | | | (14,895) | (120) | | | | | (120) |
| Share-based compensation expense | | | | | | 4,051 | | | | 4,051 |
| Recognition of beneficial conversion feature on convertible notes | | | | | | 613 | | | | 613 |
| Net unrealized loss on investments | | | | | | | | | (5) | (5) |
| Net loss | | | | | | | (65,772) | | | (65,772) |
| **Balance, December 31, 2017** | $ | 29,030,757 | $ 29 | (33,801) | $ (352) | $ 274,584 | $ (265,308) | $ | (6) $ | 8,947 |
| Issuance of common stock, net of issuance costs | | 20,651,524 | 21 | | | 47,271 | | | | 47,292 |
| Issuance of common stock upon RSU conversion | | 26,991 | | | | | | | | |
| Shares issued for exercise of stock options | | 832 | | | | | | | | |
| Payroll tax withheld for RSU releases | | | | | | (46) | | | | (46) |
| Share-based compensation expense | | | | | | 3,321 | | | | 3,321 |
| Net unrealized loss on investments | | | | | | | | | 6 | 6 |
| Net loss | | | | | | | (51,675) | | | (51,675) |
| **Balance, December 31, 2018** | $ | 49,710,104 | $ 50 | (33,801) | $ (352) | $ 325,130 | $ (316,983) | $ | $ | 7,845 |

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, | | |
|---|---|---|---|
| | **2018** | **2017** | **2016** |
| Cash Flows From Operating Activities: | | | |
| Net loss | $ (51,675) | $ (65,772) | $ (82,751) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Share-based compensation expense | 3,321 | 4,051 | 3,460 |
| Depreciation and amortization of property and equipment | 1,750 | 1,363 | 1,598 |
| Amortization of patents and other intangible assets | 1,737 | 1,660 | 1,662 |
| Changes in fair value of earnout, derivative and warrant liabilities | (387) | (509) | 18 |
| Amortization of senior debt discounts | 961 | 1,316 | 406 |
| Amortization of short-term investment purchase discounts | (131) | (126) | (156) |
| Deferred interest on debt | | 2,111 | 4,738 |
| Loss on debt extinguishment | | | 942 |
| Gain on sale of equipment | | (23) | (922) |
| Other adjustments | 48 | (91) | 5 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (14,130) | (7,536) | (2,232) |
| Inventories | 1,365 | (6,190) | (3,022) |
| Deferred contract sales organization fees | | 720 | (123) |
| Other assets | (444) | (414) | (1,278) |
| Accounts payable | 1,270 | 3,008 | 2,377 |
| Accrued expenses | 14,874 | 13,171 | 4,632 |
| **Net cash used in operating activities** | (41,441) | (53,261) | (70,646) |
| Cash Flows From Investing Activities: | | | |
| Purchases of short-term investments | (17,906) | (48,015) | (66,088) |
| Sales and maturities of short-term investments | 36,491 | 45,118 | 50,816 |
| Proceeds from sale-leaseback of equipment | | 3,222 | |
| Capital expenditures | (1,361) | (2,497) | (3,550) |
| Intangible asset expenditures | (5) | (361) | (500) |
| **Net cash provided by (used in) investing activities** | 17,219 | (2,533) | (19,322) |
| Cash Flows From Financing Activities: | | | |
| Proceeds from Deerfield debt note, net of fees | | | 58,419 |
| Prepayment of senior debt and fee | | | (26,063) |
| Proceeds from sale of equipment | | | 415 |
| Proceeds from the issuance of common stock, net of issuance cost | 47,292 | 64,560 | 13 |
| Payments made on borrowings | (8,425) | (989) | (9,166) |
| Payments made to purchase treasury stock | | (120) | (61) |
| Payment of payroll taxes withheld for releases of restricted stock units | (46) | | |
| Payments made on behalf of Deerfield | (90) | (40) | |
| **Net cash provided by financing activities** | 38,731 | 63,411 | 23,557 |
| **Increase (decrease) in cash and cash equivalents** | 14,509 | 7,617 | (66,411) |
| Cash and Cash Equivalents: | | | |
| Beginning | 31,969 | 24,352 | 90,763 |
| Ending | $ 46,478 | $ 31,969 | $ 24,352 |

| | | | |
|---|---|---|---|
| Supplemental Disclosure of Noncash Transactions: | | | |
| Exit Fee liability incurred in connection with Second Amendment to Facility | $ 750 | $ | $ |
| Derivative Liability incurred in connection with First Amendment to Facility | $ 611 | $ 2,107 | $ |
| Capital lease liability from purchase of equipment | $ 105 | $ | $ |
| Issuance of senior secured convertible notes in lieu of interest payment | $ | $ 6,586 | $ |
| Issuance of common stock upon conversion of senior secured convertible notes | $ | $ 6,586 | $ |
| Capital lease liability from sale-leaseback transactions | $ | $ 3,222 | $ |
| Prepaid assets included in accounts payable | $ | $ 654 | $ |
| Beneficial conversion feature incurred on convertible notes | $ | $ 613 | $ |
| Deferred contract sales organization fees | $ | $ | $ 597 |
| Supplemental Cash Flow Information: | | | |
| Interest paid | $ 8,158 | $ 6,769 | $ 2,857 |

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 three approved products for the treatment of attention deficit hyperactivity disorder ("ADHD"). Adzenys XR-ODT was approved by the US Food and Drug Administration (the "FDA") on January 27, 2016 and launched commercially on May 16, 2016. The Company received approval from the FDA for Cotempla XR-ODT, its methylphenidate XR-ODT for the treatment of ADHD in patients 6 to 17 years old, on June 19, 2017, and the Company initiated an early experience program with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017. Also, the Company received approval from the FDA for Adzenys ER oral suspension ("Adzenys ER") on September 15, 2017 and launched this product on February 26, 2018. 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. In addition to its marketed products, the Company is developing NT-0400, its XR-ODT product candidate for nausea and vomiting and NT0502, its product candidate for the treatment of sialorrhea.

**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 ("GAAP"), and with the rules and regulations of the Securities and Exchange Commission ("SEC").

*Principles of consolidation:* The consolidated financial statements include the accounts of the Company and its four wholly-owned subsidiaries. All significant intercompany transactions have been eliminated.

*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. Accounts receivable were due from fourteen customers in the years ended December 31, 2018 and 2017, respectively. Three customers accounted for 96% and 94% of the accounts receivable at December 31, 2018 and 2017, respectively.

There were fifteen, fourteen and thirteen customers that accounted for all gross revenue in the years ended December 31, 2018, 2017 and 2016, respectively. Of which, three customers accounted for 93% of the gross revenue for the years ended December 31, 2018 and 2017, respectively, and two customers accounted for 82% of the gross revenue for the year ended December 31, 2016.

*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

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

Company views its operations and manages its business in one operating segment, which is the development, manufacturing and commercialization of pharmaceuticals.

*Reclassifications:* In 2017, the Company reclassified certain patents from Other assets to Intangible assets, net as reported on the condensed consolidated balance sheets. There was no impact to the Company's consolidated statements of operations.

*Liquidity:* During 2018, 2017 and 2016, the Company produced operating losses and used cash to fund operations. Management intends to achieve profitability through revenue growth from pharmaceutical products developed with its extended-release technologies. The Company does not anticipate it will be profitable until after the successful commercialization of its approved products, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. In November 2018, the Company completed an offering of its common stock and restructured its outstanding debt to reduce and possibly delay the amount of principal payable in cash. Accordingly, management has performed the review required for going concern accounting and believes the Company presently has sufficient liquidity to continue to operate for the next twelve months after the filing of this Report on Form 10-K.

*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, if any, 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 material tax effects reported, as accumulated other comprehensive income or loss, which is a separate component of stockholders' equity (deficit). Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in other income 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 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, 2018 or December 31, 2017, as management believes that all receivables are fully collectible.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

*Inventories:* In 2016, inventories were stated at the lower of cost (first in, first out) or market and, effective January 1, 2017, inventory is now required to be measured at the lower of cost (first in, first out) or net realizable value. The change to stating inventories at the lower of cost or net realizable value in 2017 was adopted prospectively and did not have a significant effect on the Company's ongoing financial reporting as valuing inventory at the lower of cost or net realizable value approximated the prior policy of valuing inventory at the lower of cost or market. Inventories 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 and finished goods.

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, for the production of Cotempla XR-ODT incurred after June 30, 2017, following the FDA approval date of June 19, 2017, and for the production of Adzenys ER incurred after September 30, 2017, following the FDA approval date of September 15, 2017, are being capitalized into inventory.

*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, the costs to acquire the rights to Tussionex Abbreviated New Drug Application and patents, are recorded at cost and amortized over the estimated lives of the assets, which primarily range from 10 to 20 years. 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.

*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 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, 2018, 2017 or 2016.

*Derivative liabilities:* The Company evaluates its debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives requiring separate recognition in the Company's financial statements. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as a liability and the change in fair value is recorded in other income (expense) in the consolidated results of operations. In circumstances where there are multiple embedded instruments that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

When the Company has determined that the embedded conversion options should not be bifurcated from their host instruments, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption and are classified in interest expense in the consolidated results of operations.

*Revenue recognition:* Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company makes estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler fees, wholesaler chargebacks and estimated rebates) to be incurred on the selling price of the respective product sales, and recognizes the estimated amount as revenue when it transfers control of the product to its customers (e.g., upon delivery). Variable consideration is determined using either an expected value or a most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint will require the use of significant management judgment and other market data. The Company provides for prompt payment discounts, wholesaler fees and wholesaler chargebacks based on customer contractual stipulations. The Company analyzes recent product return history and other market data obtained from its third party logistics providers ("3PLs") to determine a reliable return rate. Additionally, management analyzes historical savings offers and rebate payments based on patient prescriptions dispensed for Adzenys XR ODT, Cotempla XR ODT and Adzenys ER and information obtained from third party providers to determine these respective variable considerations.

The Company sells its generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to a limited number of pharmaceutical wholesalers, all subject to rights of return. 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.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

*Disaggregation of revenue*

The following table disaggregates the Company's net product sales by product:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| | (in thousands) | | |
| Adzenys XR-ODT | $ 26,631 | $ 20,377 | $ 3,803 |
| Cotempla XR-ODT | 19,014 | 1,590 | |
| Adzenys ER | (27) | | |
| Generic Tussionex | 4,370 | 5,165 | 6,230 |
| | $ 49,988 | $ 27,132 | $ 10,033 |

*Net product sales*

Net product sales represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER include savings offers, prompt payment discounts, wholesaler fees, estimated rebates to be incurred on the selling price of the respective product sales and estimated allowances for product returns.

Gross to net sales adjustments for generic Tussionex include prompt payment discounts, estimated allowances for product returns, wholesaler fees, estimated government rebates and estimated chargebacks to be incurred on the selling price of generic Tussionex related to the respective product sales.

The Company recognizes total gross product sales less gross to net sales adjustments as revenue based on shipments from 3PLs to the Company's wholesaler customers.

*Savings offers for branded products*

The Company offers savings programs for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. The Company records the amount of redeemed savings offers based on information from third-party providers against the estimated discount recorded as accrued expenses. The estimated discount is recorded as a gross to net sales adjustments at the time revenue is recognized.

*Prompt payment discounts*

Prompt payment discounts are based on standard programs with wholesalers and are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized.

*Wholesale distribution fees*

Wholesale distribution fees are based on definitive contractual agreements for the management of the Company's products by wholesalers and are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

*Rebates*

The Company's branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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. Calculations related to rebate accruals of branded products are estimated based on information from third-party providers.

The Company's generic Tussionex product is subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Generic Tussionex government rebates are estimated based upon rebate payment data available from sales of the Company's generic Tussionex product over the past three years.

Estimated rebates are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. Historical trends of estimated rebates will be continually monitored and may result in future adjustments to such estimates.

*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. Estimated returns are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized.

The Company analyzed recent branded product return history and other market data obtained from the Company's 3PLs as well as data available from sales of its branded products to determine a reliable return rate for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Generic Tussionex product returns were estimated based upon return data available from sales of the Company's generic Tussionex product over the past three years.

*Wholesaler chargebacks for generic product*

The Company's generic Tussionex 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. Estimated chargebacks are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized based on information provided by third parties.

Due to estimates and assumptions inherent in determining the amount of generic Tussionex returns, rebates and chargebacks, the actual amount of returns, 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 are recorded in the same period that the related revenue is recognized.

*Research and development costs:* Research and development costs are charged to operations when incurred and include salaries and benefits, facilities costs, overhead costs, raw materials, laboratory and

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

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. 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.

*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 $0.6 million, $0.4 million and $7.4 million during the years ended December 31, 2018, 2017 and 2016 respectively.

*Share-based compensation:* Share-based compensation awards, including grants of employee stock options, restricted stock, restricted stock units ("RSUs") and modifications to existing stock options, are recognized in the statement of operations based on their fair values. Compensation expense related to awards to employees is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. The fair value of the Company's stock-based awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends.

For performance-based stock awards, compensation expense is recognized on a straight-line basis, based on the grant date fair value, over the performance period or through the vesting date, whichever is longer. Management monitors the probability of achievement of the performance conditions and adjusts stock-based compensation expense, if necessary.

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.

Under ASU No. 2017-09 guidance for accounting for share-based payments, the Company has elected to continue estimating forfeitures at the time of grant and, if necessary, revise the estimate 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. The adoption of this standard in 2017 did not have a material impact on the Company's business, financial position, results of operations or liquidity.

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 ("SAB") Topic 14 due to the increased number and amount of options and option compensation.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

*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.

*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, 2018 and 2017, 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, the Company considered that three years of cumulative operating losses was significant negative evidence outweighing projections for future taxable income. Therefore, at December 31, 2018 and 2017, the Company determined that it is more likely than not that the deferred tax assets will not be realized. Accordingly, the Company has recorded a valuation allowance to reduce deferred tax assets to zero. The Company may not ever be able to realize the benefit of some or all of the federal and state loss carryforwards, either due to ongoing operating losses or due to ownership changes, which limit the usefulness of the loss carryforwards.

*Recent accounting pronouncements:* In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2018-13, *Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement,* which modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The standard is effective for public entities for the fiscal years ending after December 15, 2020, with early adoption permitted for the removed disclosures and delayed adoption permitted for the new disclosures. The removed and modified disclosures will be adopted on a retrospective basis and the new disclosures will be adopted on a prospective basis. The Company is currently evaluating the impact of adopting ASU 2018-13 on its consolidated financial statements.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740) Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*, which was issued to state the income tax accounting implications of the Tax Cuts and Jobs Act of 2017 (the "TCJA"). The guidance clarifies the measurement period timeframe, changes in subsequent reporting periods and reporting requirements as a result of the TCJA. The measurement period begins in the period that includes the TCJA's enactment date, which was December 22, 2017, and as a result the Company has reflected the impact of this ASU on the deferred tax calculation as of December 31, 2017.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the TCJA, and requires certain disclosures about

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

stranded tax effects. ASU 2018-02 is effective for entities for fiscal years beginning after December 15, 2018 with early adoption permitted, and shall be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the corporate income tax rate in the TCJA is recognized. This standard became effective for the Company standard on January 1, 2019. The adoption of this standard will not have a material impact on the Company's consolidated results of operations or financial position.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation  Stock Compensation (Topic 718): Scope of Modification Accounting*. This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the modification. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. This standard became effective for the Company on January 1, 2018. The adoption of this standard did not have a material impact on the Company's consolidated results of operations or financial position.

In August 2016, the FASB issued 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. This standard became effective for the Company on January 1, 2018. The adoption of this standard did not have a significant effect on the Company's ongoing financial reporting as the Company had classified its debt prepayment and debt extinguishment costs in the Condensed Consolidated Statements of Cash Flows in accordance with the amendments.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (the "New Lease Standard"). 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 ("ROU") 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. In January, July and December 2018, the FASB issued additional amendments to the new lease guidance relating to, transition, and clarification. The July 2018 amendment, ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented.

Pursuant to ASU No. 2018-11, the Company will elect to use the effective date approach at transition. Therefore, no adjustments will be made to amounts in prior period financial statements. Capital leases will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. Operating leases will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases.

The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The Company plans to adopt this standard on the effective date of January 1, 2019.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

The Company is substantially complete with its evaluation of the new standard as it relates to its operating lease disclosed in Note 15 "Commitments and Contingencies". The remaining steps in the implementation process include finalizing lease liability and right of use asset schedules and the review and evaluation of disclosures and presentation in the Company's financial statements. In addition, an evaluation of whether there are existing contracts that may contain embedded leases has been performed and the Company is evaluating the impact of its findings. However, it does not expect that the identification of any embedded leases will result in a material impact to the consolidated financial statements and disclosures upon the adoption of this standard. In addition, the Company made an accounting policy election to combine the lease and non-lease components and the short-term lease practical expedients allowed under ASC 842. The adoption of ASC 842 will lead to an increase in the assets and liabilities recorded on the balance sheets primarily due to the lease agreement attributable to leased office space. This New Lease Standard will not have a material impact on the Company's balance sheets, consolidated statements of comprehensive loss or cash flows from operations. The Company will continue to monitor additional modifications, clarifications or interpretations undertaken by the FASB that may impact its current conclusions and will expand its analysis to include any new lease arrangements initiated prior to adoption.

We expect to recognize approximately $3.0 million to $4.8 million of additional assets and corresponding liabilities on our balance sheet as of the beginning of fiscal 2019 and will record any cumulative effect of adopting the New Lease Standard as an adjustment to the opening balance of Retained Earnings. We do not expect that any adjustment to Retained Earnings at adoption will have a material impact on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (the "New Revenue Standard"). The New Revenue Standard replaces transaction and industry-specific revenue recognition guidance under current U.S. GAAP with a principles-based approach for determining revenue recognition. The New Revenue Standard requires an entity to recognize the amount of revenue based on the value of transferred goods or services to customers. There is also additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

The New Revenue Standard became effective for the Company on January 1, 2018. For purposes of providing comparable periods upon adoption, the Company applied the full retrospective transition method, which required the Company to restate each prior reporting period presented. The impact of the New Revenue Standard relates to the Company's accounting for branded net product sales. There are no changes to the net product sales of generic Tussionex revenue since the Company has estimated product returns since inception of recognizing revenue in August 2014.

As a result, the Company revised its results for branded net product sales revenue which commenced in May 2016 with the launch of Adzenys XR-ODT for the years ended December 31, 2016 and 2017 and applicable interim periods within those years, as if the New Revenue Standard had been effective for those periods.

The Company implemented internal controls and key system functionality to enable the preparation of financial information and reached conclusions on key accounting assessments related to the New Revenue Standard, including management's assessment that the impact of accounting for costs incurred to obtain a contract is immaterial.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

Under the New Revenue Standard, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Therefore, the Company is required to make estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler fees and estimated rebates) to be incurred on the selling price of the respective branded product sales, and recognize the estimated amount as revenue, when it transfers control of the product to its customers (e.g., upon shipment or delivery). Variable consideration must be determined using either an expected value or most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint require the use of significant management judgment and other market data. To implement the New Revenue Standard, the Company analyzed recent branded product return history and other market data obtained from its 3PLs as well as data available from sales of its branded products to determine a reliable return rate. Additionally, management analyzed historical savings offers, prompt payment discounts, wholesaler fees and rebates payments based on patient prescriptions dispensed of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and information obtained from third-party providers to determine these respective variable considerations. Management has concluded that estimates of the above variable considerations are reasonably constrained, and estimates can be used for recognizing branded total gross product sales less gross to net sales adjustments as revenue beginning January 1, 2018. The Company had restated it's Consolidated Financial Statements for the years ended on December 31, 2017 and 2016 in the 8-K filed with SEC on December 11, 2018 for the adoption of the New Revenue Standard. Refer to Impacts to Previously Reported Results below for the impact of adoption of the New Revenue Standard included in the Company's condensed consolidated statements of operations.

Adoption of the New Revenue Standard resulted in the recognition of additional net branded product sales revenue of $2.1 million and $0.9 million for years ended December 31, 2017 and 2016, respectively, partially offset by associated increased cost of goods sold of $1.6 million and $0.3 million, respectively. As a result, the net loss reported was reduced by $0.5 million and $0.6 million reflecting the gross profit from the accelerated revenue and associated cost of goods sold for years ended December 31, 2017 and 2016, respectively. The net loss per share of common stock, basic and diluted reported was improved by $0.02 and $0.03 per share for December 31, 2017 and 2016, respectively. The adoption of the New Revenue Standard reduced the net operating loss carry forward for 2017 and 2016, respectively; however, there was no impact to the provision for income taxes because the Company's deferred tax asset benefits are fully reserved for December 31, 2017 and 2016, respectively. In addition, adoption of the New Revenue Standard resulted in a decrease in reported total current assets by $3.2 million as of December 31, 2017, due to the elimination of deferred cost of goods sold and wholesaler fees. Reported total current liabilities decreased by $4.3 million as of December 31, 2017, due to the elimination of deferred revenue partially offset by increases in accrued expenses for contract obligations related to savings offers, product returns and rebates. See Impacts of New Revenue Standard to Previously Reported Results below for the impact of adoption of the New Revenue Standard on the Company's consolidated financial statements.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Summary of significant accounting policies (Continued)**

**Impacts of New Revenue Standard to Previously Reported Results**

Adoption of the new revenue standard impacted the Company's reported results as follows:

| | Year Ended December, 31 | | | | | |
|---|---|---|---|---|---|---|
| | 2017 | | | 2016 | | |
| Condensed consolidated statements of operations: | As Reported | New Revenue Standard Adjustment | As Adjusted | As Reported | New Revenue Standard Adjustment | As Adjusted |
| | (In thousands, except per share data) | | | | | |
| Revenue: net product sales | $ 25,018 | $ 2,114 | $ 27,132 | $ 9,154 | $ 879 | $ 10,033 |
| Cost of goods sold | 12,391 | 1,639 | 14,030 | 11,437 | 297 | 11,734 |
| Gross profit (loss) | 12,627 | 475 | 13,102 | (2,283) | 582 | (1,701) |
| Net loss attributable to common stock | (66,247) | 475 | (65,772) | (83,333) | 582 | (82,751) |
| Net loss per share of common stock, basic and diluted | (2.68) | 0.02 | (2.66) | (5.19) | 0.03 | (5.16) |

| | December 31, 2017 | | |
|---|---|---|---|
| Condensed consolidated statements of balance sheet: | As Reported | New Revenue Standard Adjustment | As Adjusted |
| Inventories | $ 13,459 | $ (1,727) | $ 11,732 |
| Other current assets | 5,093 | (1,518) | 3,575 |
| Total current assets | 82,640 | (3,245) | 79,395 |
| Accrued expenses | 10,570 | 10,374 | 20,944 |
| Deferred revenue | 14,676 | (14,676) | |
| Total current liabilities | 37,602 | (4,302) | 33,300 |
| Accumulated deficit | (266,365) | 1,057 | (265,308) |
| Total liabilities and stockholder's equity | 107,353 | (3,245) | 104,108 |

Adoption of the New Revenue Standard had no impact to cash from or used in operating, financing, or investing on the Company's consolidated statements of cash flows.

**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 warrants, outstanding stock options under the stock option plan and shares issuable in future periods, such as RSU awards, 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. Restricted stock is considered legally issued and outstanding on the grant date, while RSUs are not considered legally issued and outstanding until the RSUs vest. Once the RSUs are vested, equivalent common shares will be issued or issuable to the grantee and therefore the RSUs are not considered for inclusion in total common shares issued and outstanding until vested.

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**Neos Therapeutics, Inc. and Subsidiaries**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 3. Net loss per share (Continued)**

The following potentially dilutive securities outstanding were excluded from consideration in the computation of diluted net loss per share of common stock for the years ended December 31, 2018, 2017 and 2016, respectively, because including them would have been anti-dilutive:

| | December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Series C Redeemable Convertible Preferred Stock Warrants (as converted) | 70,833 | 70,833 | 70,833 |
| Stock options outstanding | 3,446,885 | 2,454,973 | 2,107,344 |
| RSUs granted, not released | 75,314 | 85,000 | |

**Note 4. Fair value of financial instruments**

The Company records financial assets and liabilities at fair value. The carrying amounts of certain financial assets and liabilities including cash and cash equivalents, accounts receivable, other current assets, accounts payable, accrued liabilities and deferred revenue, approximated their fair value due to their short maturities. The remaining financial instruments were reported on the Company's consolidated balance sheets at amounts that approximate current fair values based on market based assumptions and inputs.

As a basis for categorizing inputs, the Company uses a three tier fair value hierarchy, which prioritizes the inputs used to measure fair value from market based assumptions to entity specific assumptions 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 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, 2018 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| | (in thousands) | | | |
| Cash and cash equivalents | $ 27,419 | $ 19,059 | $ | $ 46,478 |
| Total financial assets | $ 27,419 | $ 19,059 | $ | $ 46,478 |

| | | | | |
|---|---|---|---|---|
| Earnout liability | $ | $ | $ 37 | $ 37 |
| Derivative liability (see Note 11) | | | 2,017 | 2,017 |
| Total financial liabilities | $ | $ | $ 2,054 | $ 2,054 |