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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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 90th day after the delivery of a Forecast constitutes a binding purchase commitment with respect to the products listed in such Forecast. In October 2014, we re-launched the product under our own label. We sell our product to drug wholesalers in the United States. We have also established indirect contracts with drug, food and mass retailers that order and receive our product through wholesalers. We have obtained required state licenses, set up distribution channels and established trade relations in order to commercialize our generic Tussionex.

Commercialization

We are commercializing Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, in the United States using our existing commercial infrastructure. We sell our Adzenys XR-ODT, Cotempla XR-ODT