SUPERNUS PHARMACEUTICALS INC
Form 10-K
March 09, 2016

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015

COMMISSION FILE NUMBER: 001-35518

or

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

FOR THE TRANSITION PERIOD FROM TO

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware		**20-2590184**
(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification Number)
1550 East Gude Drive, Rockville, MD	**(301) 838-2500**	**20850**
(Address of Principal Executive Offices)	(Registrant's telephone number, including area code)	(zip code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

TITLE OF EACH CLASS:	**NAME OF EACH EXCHANGE ON WHICH REGISTERED:**
Common Stock, $0.001 Par Value	The NASDAQ Stock Market LLC

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) 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. Yes o No ý

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

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

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

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, or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of June 30, 2015, the aggregate market value of the common stock held by non-affiliates of the registrant based on the closing price of the common stock on The NASDAQ Global Market was $659,264,478.

The number of shares of the registrant's common stock outstanding as of February 29, 2016 was 49,400,473.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2016 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's 2015 fiscal year end, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Unless the content requires otherwise, the words "Supernus," "we," "our" and "the Company" refer to Supernus Pharmaceuticals, Inc. and its subsidiary.

We are the owners of various U.S. federal trademark registrations(®) and registration applications( ), including the following marks referred to in this Annual Report on Form 10-K pursuant to applicable U.S. intellectual property laws: "Supernus®," "Oxtellar XR®," "Trokendi XR®," "Microtrol®," "Solutrol®," and the registered Supernus Pharmaceuticals logo.

All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are referred to without the ® and *TM* symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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PART I

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933, that involve risks and uncertainties. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Annual Report other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "seek," "anticipate," "should," "could," "would," "potential," or the negative of those terms and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. All of these forward-looking statements are based on information available to us at this time, and we assume no obligation to update any of these statements. Actual results could differ from those projected in these forward-looking statements as a result of many factors, including those identified in "Business," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere. We urge you to review and consider the various disclosures made by us in this report, and those detailed from time to time in our filings with the Securities and Exchange Commission, that attempt to advise you of the risks and factors that may affect our future results.

ITEM 1. BUSINESS.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. In 2013, we launched Oxtellar XR (extended-release oxcarbazepine) and Trokendi XR (extended-release topiramate), our two novel treatments for patients with epilepsy. In addition, we are developing multiple product candidates in psychiatry to address significant unmet medical needs and market opportunities for the treatment of Impulsive Aggression (IA) and for the treatment of attention deficit hyperactivity disorder (ADHD). With SPN-810, we are initially developing the product to treat IA in patients who have ADHD. There are currently no approved products indicated for the treatment of IA. We subsequently plan to develop SPN-810 for treatment of IA in other CNS diseases, such as autism, bipolar disorder, schizophrenia, and some forms of dementia.

Our extensive expertise in product development has been built over the past 25 years: initially as a standalone development organization, then as a U.S. subsidiary of Shire plc and, upon our acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals. We market our products in the United States through our own specialty sales force and have and will continue to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

Our neurology portfolio consists of Oxtellar XR and Trokendi XR, which are the first once-daily extended release oxcarbazepine and topiramate products, respectively, indicated for epilepsy in the U.S. market. These products are differentiated compared to their immediate release counterpart products by offering convenient once-daily dosing and unique pharmacokinetic profiles. We believe that a once-daily dosing regimen improves compliance, and that the unique smooth and steady pharmacokinetic profiles of once-daily dosing mitigate the blood level fluctuations that are typically associated with immediate release products that can result in adverse events (AEs) or decreased efficacy.

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Underlying our net product revenues of $143.5 million in 2015 is strong growth in prescriptions for Oxtellar XR and Trokendi XR. Total prescriptions as reported by Intercontinental Marketing Services (IMS) have shown a steady increase quarter over quarter as shown in the following graph.

Strong Prescription Growth
Two Successful Product Launches

Source: IMS Monthly Prescriptions

Given the large and growing base of prescriptions for both topiramate and oxcarbazepine (annualized prescriptions of total topiramate market of 14.3 million and total oxcarbazepine market of 4.5 million), we expect to continue to expand our revenues for Oxtellar XR and Trokendi XR for the foreseeable future. We believe these products, together, have the potential to collectively achieve peak net sales in excess of $500 million annually.

Oxtellar XR is indicated for add-on, adjunctive or concomitant therapy of partial seizures in adults and in children 6 years to 17 years of age. Trokendi XR is indicated for initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures, and as add-on therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures or with seizures associated with Lennox-Gastaut syndrome.

Our psychiatry product candidates include SPN-810 (molindone hydrochloride) and SPN-812 (viloxazine hydrochloride). We are developing SPN-810 as a novel treatment for IA in patients who have ADHD and SPN-812 for the treatment of ADHD. We initiated the Phase III clinical trials for SPN-810 during the third quarter of 2015 and initiated a Phase IIb clinical trial for SPN-812 in the fourth quarter of 2015. Patient dosing for all trials are anticipated in the first quarter of 2016. We expect to receive data from the first trial for SPN-810 in mid-2017 and data from the Phase IIb trial for SPN-812 by early 2017.

We have a successful track record of developing and launching novel products by applying proprietary technologies to known drugs to improve existing therapies and expand the treatment to new indications. Our key proprietary technology platforms include: Microtrol, Solutrol and EnSoTrol. These technologies have been utilized to create nine marketed products, including Trokendi XR and Oxtellar

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XR, Adderall XR, Intuniv (developed for Shire), and Orenitram (developed for United Therapeutics Corporation) as well as our key product candidates SPN-810 and SPN-812.

Products and Product Candidates

The table below summarizes our current pipeline of novel products and product candidates.

Product	Indication	Status
Oxtellar XR	Epilepsy	Launched
Trokendi XR	Epilepsy*	Launched
SPN-810	IA**	Phase III
SPN-812	ADHD	Phase IIb
SPN-809	Depression	Phase II ready

*
Supplemental New Drug Application submitted in August 2015 for treatment in adults for prophylaxis of migraine headache.

**
Initial program is in patients with ADHD, with a plan to follow on in other indications, such as IA in patients with autism, bipolar disorder, schizophrenia, and some forms of dementia.

We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies, products, and product candidates. We currently have five U.S. patents issued covering Oxtellar XR and six U.S. patents issued covering Trokendi XR, providing patent protection expiring no earlier than 2027 for each product.

Our Strategy

Our vision is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry. Key elements of our strategy to achieve this vision are to:

Drive growth and profitability. We will continue to drive the revenue growth of Trokendi XR and Oxtellar XR by continuing to dedicate sales and marketing resources in the United States.

Advance our pipeline toward commercialization. In 2015, we started trials for our product candidates in our psychiatry portfolio: SPN-810 as a novel treatment for IA in patients who have ADHD and SPN-812 for the treatment of ADHD. We initiated the Phase III clinical trials for SPN-810 during the third quarter of 2015 and a Phase IIb clinical trial for SPN-812 in the fourth quarter of 2015.

Target strategic business development opportunities. We are actively exploring a broad range of strategic opportunities that fit well with our strong presence in CNS. This includes in-licensing products and entering into co-promotion partnerships which are synergistic with our sales force call point for our marketed products and product candidates, co-development partnerships for our pipeline products, and growth opportunities through value-creating and transformative merger and acquisition transactions.

Continue to grow our pipeline. We plan to continue to evaluate and develop additional CNS product candidates that we believe have significant commercial potential through our internal research and development efforts.

Our Neurology Portfolio

Oxtellar XR and Trokendi XR are the first once-daily extended release oxcarbazepine and topiramate products indicated for patients with epilepsy in the U.S. market. These products differ from the immediate release products by offering once-daily dosing and unique pharmacokinetic profiles which we

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believe can have very positive clinical effects for some patients. We believe a once-daily dosing regimen improves adherence, making it more probable that patients maintain sufficient levels of medication in their bloodstream to protect against seizures. In addition, the unique smooth and steady pharmacokinetic profiles of our once-daily formulations reduce the peak to trough blood level fluctuations that are typically associated with immediate release products and may result in increased AEs, more symptomatic side effects and decreased efficacy.

Epilepsy Overview

Epilepsy is a complex neurological disorder characterized by spontaneous recurrence of unprovoked seizures, which are sudden surges of electrical activity in the brain that impair a person's mental and/or physical abilities.

Compliance with drug treatment regimens is critically important to achieving effective control for patients with epilepsy. Patient non-compliance with anti-epileptic drug (AED) therapy is a serious issue and remains the most common cause of breakthrough seizures. Not only is taking all prescribed doses critical for epileptic patients, but the timing of when patients take their prescribed doses can also be crucial.

We believe extended release products, and in particular Trokendi XR and Oxtellar XR, offer important advantages in the treatment of epilepsy. The release profiles of extended release products can produce more consistent and steadier plasma concentrations as compared to immediate release products, potentially resulting in fewer side effects, better tolerability, fewer emergency room visits, and improved efficacy. Improved tolerability may help patients improve adherence, have fewer breakthrough seizures and, correspondingly, enjoy a better quality of life.

Trokendi XR

Trokendi XR is the first once-daily extended release topiramate product indicated for patients with epilepsy in the U.S. market, and is designed to improve patient adherence over the current immediate release products, which must be taken multiple times per day. Trokendi XR's pharmacokinetic profile results in lower peak plasma concentrations, higher trough plasma concentrations, and slower input rate. This results in smoother and more consistent plasma concentrations than immediate release topiramate formulations can deliver. We believe that such a profile mitigates blood level fluctuations that are frequently associated with many side effects as well as mitigating the likelihood of breakthrough seizures that patients can suffer when taking immediate release products. Side effects may lead patients to skip doses, which could place them at higher risk for breakthrough seizures.

In August 2015, the United States Food and Drug Administration (FDA) accepted for review the Company's Supplemental New Drug Application (sNDA) for Trokendi XR, requesting FDA approval to expand the indication for Trokendi XR to include treatment in adults for prophylaxis of migraine headache. Under the Prescription Drug User Fee Act guidelines, the FDA has set a target date in the second quarter of 2016 to complete its review.

Oxtellar XR

Oxtellar XR is the only once-daily extended release oxcarbazepine product indicated for the treatment of patients with epilepsy in the U.S. as adjunctive therapy. With its novel pharmacokinetic profile showing lower peak plasma concentrations, a slower rate of input, higher trough plasma concentrations, and smoother and more consistent blood levels compared to immediate release products, we believe Oxtellar XR improves the tolerability of oxcarbazepine and thereby reduces symptomatic side effects. In addition, Oxtellar XR once-per-day dosing is designed to improve patient adherence compared to the current immediate release products that must be taken multiple times per day.

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In a retrospective medical chart review of 200 patients treated with immediate release oxcarbazepine or Oxtellar XR, Oxtellar XR was associated with a significantly lower rate of inpatient hospitalization stays, lower rate of emergency department visits, and a higher rate of compliance. The patient charts were obtained from 17 geographically and clinically diverse sites across the U.S. and included non-academic and academic affiliated practices, general neurology, pediatric neurology, and epilepsy centers.

Oxtellar XR was one of several products prescribed to children whose safety profile was reviewed at a Pediatric Advisory Committee meeting in March 2015. The committee voted for the FDA to continue its safety monitoring of this product per its current routine. As suggested by the FDA as part of its routine review, safety information has been added to the Oxtellar XR label so that it comports with the Reference Listed Drug, Trileptal.

Sales and Marketing

We have established a commercial organization in the U.S. to support current and future sales of Oxtellar XR and Trokendi XR. We believe our current sales force of over 150 sales representatives is effectively targeting healthcare providers, primarily neurologists, to support and grow our epilepsy franchise. Simultaneously promoting two epilepsy products allows us to leverage our commercial infrastructure with these prescribers. Assuming our sNDA is approved by the FDA, our intentions are to support the migraine indication without incrementally expanding the sales force.

If we obtain FDA approval for any of our product candidates in our psychiatry portfolio, we anticipate adding sales representatives who can market our psychiatry products to the relevant population of physicians.

Manufacturing

We currently depend on third-party commercial manufacturing organizations (CMOs) for all manufacturing operations, including raw materials, dosage form production, and packaging. This encompasses product for commercial use, as well as product for preclinical research and clinical trials.

We have entered into agreements with Patheon Pharmaceuticals Inc., Packaging Coordinators, Inc and Catalent Pharma Solutions, leading CMOs headquartered in North America, for the manufacture and packaging of the final commercial products Oxtellar XR and Trokendi XR. These CMOs offer a comprehensive range of contract manufacturing and packaging service. Both commercial products as well as our product candidates are sourced from single third-party suppliers.

We do not own or operate manufacturing facilities for the production of any of our product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently employ internal resources to manage our manufacturing contractors.

Epilepsy Competition

Trokendi XR competes with all immediate release and extended release topiramate products, including Topamax, Qudexy XR, their related generic products as well as other anti-epileptic products. Oxtellar XR competes with all immediate release oxcarbazepine products, including Trileptal and its related generics as well as other anti-epileptic products.

Our Psychiatry Portfolio

Our psychiatry portfolio includes three product candidates for the treatment of psychiatric disorders. The most advanced product candidate, SPN-810, has fast track status and is expected to be the first product approved for IA. SPN-812 and SPN-809 are the same active ingredient being developed for

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ADHD and depression, respectively. SPN-812 is currently in a Phase IIb trial and SPN-809 is Phase II ready.

IA Overview

The ADHD market, estimated as 69 million prescriptions as of 2015, is projected to grow at 3% annually, to approximately 75 million prescriptions by 2019. Market research we have conducted shows that, for adolescents and children, approximately 40% of ADHD prescriptions are currently written by child psychiatrists, psychiatrists, child neurologists, and high prescribing pediatricians. By 2019, we project that this group of physicians will collectively write approximately 16 million prescriptions for ADHD medication. Of these 16 million ADHD prescriptions, roughly one-third will be written for patients with IA or with IA and other comorbidities.

IA is not limited to individuals with ADHD. IA occurs in patients with other CNS disorders, including autism, alzheimer's, bipolar disorder, oppositional defiant disorder, conduct disorder, and intermittent explosive disorder. Market research we have conducted indicates that the prevalence of IA in autistic children and adolescents is approximately 45%, and the prevalence of IA in children and adolescents with bipolar disorder is approximately 60%. By 2019, we project that the estimated number of prescriptions for IA in these two categories would range between 4.0 million and 4.5 million.

ADHD Overview

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States(1). An estimated 50% of children with ADHD continue to meet criteria for ADHD into adolescence(2). For the year ended December 31, 2015, according to data from IMS, the U.S. market for ADHD prescription drugs was $11.0 billion with 69 million prescriptions.

Diagnosis of ADHD requires a comprehensive clinical evaluation based on identifying patients who exhibit the core symptoms of inattention, hyperactivity, and impulsivity. Although many children may be inattentive, hyperactive or impulsive, the level of severity and degree of functional impairment, as well as considerations of what may be behind the underlying symptoms, determine which children meet the diagnosis and should be treated for ADHD.

Current Treatments for IA in Patients with ADHD

Currently, there are no approved medications for the treatment of IA. IA is characteristic of individuals who spontaneously react more strongly than normal to stimuli by committing verbal or physical acts against other people, property, or themselves. Based on our discussions with medical experts, the current treatment options for IA in patients with ADHD include psychosocial interventions, such as school-based or family-based behavioral therapies, which are usually not wholly effective. In the large, multisite Multimodal Treatment Study of Children with ADHD(3), a seminal clinical trial designed by experts from key stakeholder communities such as the National Institute of Mental Health, researchers observed that after 14 months of either ADHD medication-only or a regimen that combined ADHD medication with behavioral interventions, 44% of those children with ADHD (or 26% of the total sample size in the trial) who initially exhibited aggression still had what can be described as IA at the end of the trial, demonstrating that psychosocial interventions may not work for a large percentage of children with ADHD who exhibit aggressive behaviors.

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(1) Dopheide, J.A., *Attention-Deficit- Hyperactivity Disorder: An Update*, published June 2009 in *Pharmacotherapy*.

(2) Floet, A.M.W., *Attention- Deficit/Hyperactivity Disorder*, published February 2010 in *Pediatrics in Review*.

(3) The MTA Cooperative Group, *A 14-month randomized clinical trial of treatment strategies for attention- deficit/hyperactivity disorder*, published December 1999 in *Archives of General Psychiatry*.

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In response, doctors have also tried to treat this group with off-label use of prescription medicines, such as mood stabilizers, stimulants and anti-psychotic drugs. Results have varied, but anti-psychotic drugs appear to have the best therapeutic potential. Unfortunately, many of these agents are associated with adverse effects including obesity, dyskinesia, lipid abnormalities, marked increases in prolactin, and increase in diabetes, which is of particular concern when treating pediatric populations.

SPN-810 (molindone hydrochloride)

We are developing SPN-810 (molindone hydrochloride) as a novel treatment for IA in patients who have ADHD. During 2014, the FDA granted fast track designation for SPN-810 for the treatment of IA in ADHD in conjunction with standard ADHD treatment. The fast track designation allows for more frequent interactions with the FDA, for the early submission of some sections of the marketing application, and carries the potential for an expedited review category for the New Drug Application (NDA). In early April 2015, the Company submitted to the FDA the IA outcome and assessment scale we propose to use in the Phase III SPN-810 trials. This scale was developed by the Company in close cooperation with the FDA, using current, stringent standards of testing theory and scale development. We met with the FDA in July 2015 to review this scale and to review our proposed primary endpoint for the Phase III trials. The FDA accepted our scale and agreed with our proposed primary endpoint. In December 2015, Supernus and FDA came to an agreement, via the Special Protocol Assessment process, on the conduct of our Phase III program for SPN-810.

Molindone hydrochloride was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban, albeit at much higher dosages (50 to 225mg/day) than we are using in our development program (18 and 36 mg/day). Moban has not been commercially available since 2010 and the FDA has confirmed that this withdrawal from the market was not due to issues with safety or efficacy. Molindone hydrochloride is unusual among anti-psychotics in that it is less likely to be associated with weight gain and, in preclinical models, has not caused increases in prolactin levels as seen with other drugs.

In addition, we believe the lower doses tested for the proposed indication of IA in ADHD should be better tolerated than the higher doses approved to treat schizophrenia. The Phase IIb trial with SPN-810, which included 121 patients, showed that there was no difference in weight gain between patients treated with SPN-810 and placebo. Although initially we are developing SPN-810 as a novel treatment for IA in patients who have ADHD, if we are successful in demonstrating the effectiveness of SPN-810 in ADHD, we may then develop the product candidate for the treatment of other indications that can exhibit IA, e.g., patients with IA in autism, bipolar disorder, schizophrenia, and some forms of dementia. In the aggregate, we believe the addressable market for SPN-810 is greater than $5.5 billion, including $3.0 billion in ADHD, $1.5 billion in autism and $1.0 billion in bipolar disorder.

We are developing an intellectual property position around the novel synthesis process for this product candidate, its novel use in IA, and novel formulations. Patents, if issued, from the applications could expire from 2029 to 2033. We have one patent issued in each of the U.S., Mexico and Australia markets, covering modified release formulations of molindone. In another family, covering the novel process of synthesis of the active ingredient, we have one patent issued in the U.S. In a third family, covering use of molindone in treating IA, we have one patent issued in Japan. We own all of the pending applications.

SPN-810 Development Program

In 2012, we completed a Phase IIb multicenter, randomized, double-blind, placebo-controlled trial in the United States in pediatric subjects 6 to 12 years of age diagnosed with ADHD and IA that is not controlled by optimal stimulant and behavioral therapy. The primary objective of the study was to

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assess the effect of SPN-810 in reducing IA as measured by the Retrospective-Modified Overt Aggression Scale (R-MOAS) after at least three weeks of treatment. Secondary endpoints included the rate of remission of IA and measurement of the effectiveness of SPN-810 on Clinical Global Impression (CGI) and ADHD scales as well as evaluation of the safety and tolerability of the drug. Patients who completed the study were offered the opportunity to continue into an open-label phase of six months duration.

Analysis of treatment comparison was performed using both parametric and non-parametric statistical methods. The parametric method assumes that data are normally distributed. Under this method, mean results of each treatment group at the end of three weeks of treatment were compared to baseline in R-MOAS score for each of the four dose groups (high, medium, low and placebo) using the t-test. The non-parametric method does not assume that data are normally distributed. Under this method, the median results of the change from baseline at the end of three weeks of treatment in R-MOAS were computed for each of the four dose groups (high, medium, low and placebo). These are compared using the Wilcoxon Rank-sum test. Statistical analyses were performed to compare the median of each of the treatment groups: high, medium, low, with placebo at the end of 3 weeks of treatment using change from baseline to visit 10 in R-MOAS score as outcome variable. There was a statistically significant difference between the low dose and placebo ($p=0.031$) and also between the medium dose and placebo ($p=0.024$) at the $\alpha=0.05$ level. There was no statistically significant difference between the high dose and placebo. Both the medium dose and low dose are superior to placebo. These results convinced us that both low and medium doses were effective, and this range of doses will be further evaluated in Phase III clinical trials.

A secondary efficacy variable was the proportion of children whose impulsive aggressive behavior remitted, with remission defined as R-MOAS ≤ 10 at the end of the study. Low and medium doses of SPN-810 showed statistically significant results versus placebo, with percent of patients who experienced remission of impulsive aggressive behavior of 51.9% ($p=0.009$) and 40.0% ($p=0.043$), respectively.

The CGI results (Severity and Improvement) are consistent with the findings for the R-MOAS, in that notable improvement (reduction in severity) occurred primarily in the low dose and medium dose groups. Scores on SNAP-IV Hyperactivity and Impulsivity items did not exhibit statistically significant differences across treatment groups, indicating that our efficacy against IA was specific, rather than being efficacious against the underlying ADHD. Numerical trends in SNAP-IV Oppositional Defiant Disorder scores, while not always significant, consistently favored the low dose and medium dose groups over placebo.

SPN-810 was well tolerated throughout the study across all doses. Sedation was the most frequently reported adverse reaction, with two subjects (7%) reporting this event in each of the four treatment groups including the placebo group. The next most frequently reported adverse reaction was increased appetite with two subjects (7%) reporting this event in each of the three active treatment groups and one subject (3%) in the placebo group. The two serious adverse events (AEs) that occurred were not drug-related. One patient in the low dose arm and two patients in the medium dose arm had severe AEs that were considered either possibly or definitely related to the drug. Six patients in total discontinued the study because of AEs in the active treatment arms: one in low dose; two in medium dose; and three in high dose. AEs requiring dose reduction were infrequent.

The frequency of AEs associated with extra-pyramidal symptoms was also low and the events were reversible. The data are too sparse to evaluate dose-related aspects of these reports, thus no clear dose-response relationship is evident. SPN-810 exhibited a very good safety and tolerability profile, with low incidence of AEs, and no unexpected, life threatening, or dose-limiting safety issues.

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SPN-812 (viloxazine hydrochloride)

We are developing SPN-812 as a novel non-stimulant for the treatment of ADHD. A Phase IIa trial, completed in 2011, showed that SPN-812 was effective in treating ADHD in adults.

In the second quarter of 2014, we initiated and completed a pharmacokinetic study for extended release formulations for SPN-812. The study was successful and we have selected an extended release formulation that will be the basis of our future trial. The FDA accepted our Investigational New Drug application (IND) for the extended-release formulation and we initiated a Phase IIb trial during the fourth quarter of 2015. We anticipate patient dosing in the first quarter of 2016.

ADHD affects 6% to 9% of all school-age children and 3% to 5% of all adults. As a non-stimulant, SPN-812 has the potential to address a $2.5 billion market opportunity. Current non-stimulant treatments for ADHD have achieved peak product sales of approximately $700 million each. SPN-812, a norepinepherine reuptake inhibitor, would provide an additional option to the few non-stimulant therapies currently available. We believe that SPN-812 could be more effective than other non-stimulant therapies due to its different pharmacological profile.

In addition, due to its demonstrated efficacy as an anti-depressant, SPN-812, if studied in that specific patient population and shown to be effective, may exhibit increased benefit in up to an estimated 40% of ADHD patients who also suffer from major depression(4).

We expect SPN-812, if approved, to have five year market exclusivity given its new chemical entity (NCE) status in the U.S.

We are developing an intellectual property position around the novel synthesis process for this product candidate, its novel use in ADHD and its novel delivery with extended release.

Our SPN-812 product candidate has three families of pending U.S. non-provisional and foreign counterpart patent applications. Patents, if issued, from the applications could expire from 2029 to 2033. We have one patent issued in Europe and one in Canada in one of these families, covering a method of treating ADHD using viloxazine hydrochloride. In another family, covering the novel process of synthesis, we have one patent issued each in Europe, Mexico, and Australia. We own all of the pending applications.

SPN-812 Development Program

We completed a proof-of-concept Phase IIa U.S. clinical trial of SPN-812 in adults for the treatment of ADHD in 2011. The trial was a randomized, double-blind, placebo-controlled trial in 52 adults with a current diagnosis of ADHD (26 subjects per treatment group). Patients received treatment three times a day for a one-week titration followed by five weeks of maintenance therapy.

In this trial, SPN-812 was well tolerated and demonstrated a statistically significant improvement over placebo as a treatment for ADHD. The trial met the primary endpoints of safety and tolerability, and showed statistically significant median reduction versus placebo in both investigator-rated and patient-rated ADHD symptom scores.

Secondary endpoints of efficacy were measured by: (1) Total ADHD Symptom Score on the Conners' Adult ADHD Rating Scale (CAARS, a commonly-used measurement for ADHD in adults) as rated by each of the investigators, (2) the same scale as rated by each patient, and (3) the Clinical Global Improvement (CGI-I) score. When compared to baseline, patients receiving SPN-812 achieved overall

(4) Biederman, J., *New Insights Into the Comorbidity Between ADHD and Major Depression in Adolescent and Young Adult Females*, published in April 2008 in *Journal of the American Academy of Child and Adolescent Psychiatry* and Report of CME Institute of Physicians Postgraduate Press, Inc., published in August 2008 in *Journal of Clinical Psychiatry*.

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significant median reductions in scores for both the investigator-rated CAARS (11.5 vs. 6.0 points for placebo, p=0.0414) and in self-rated CAARS (10.5 vs. 1.0 point for placebo, p=0.0349). Although not statistically significant, a trend was observed for greater improvement in CGI-I scores in the SPN-812 treated group compared to placebo.

We initiated a Phase IIb clinical trial for SPN-812 in the fourth quarter of 2015. We anticipate patient dosing in the first quarter of 2016.

SPN-809 (viloxazine hydrochloride)

SPN-809 is a novel once-daily product candidate for the treatment of depression. SPN-809 is based on the same active ingredient as SPN-812. We currently have an open investigational new drug application (IND) for SPN-809 as a treatment of depression, the indication for which the active ingredient in SPN-809 was approved and marketed in Europe for many years, but was never approved in the U.S..

Because SPN-809 contains the same active ingredient as SPN-812, we expect that many of our activities related to the development of SPN-812 will also benefit the development of SPN-809.

ADHD Competition

Competition in the U.S. ADHD market has increased with the commercial launch of several products in recent years, including the launch of generic versions of branded drugs, such as Adderall XR. Shire plc is one of the leaders in the U.S. ADHD market with three products: Vyvanse, a stimulant prodrug product launched in 2007; Intuniv, a non-stimulant treatment launched in November 2009, and Adderall XR, an extended release stimulant treatment designed to provide once-daily dosing. Other stimulant products for the treatment of ADHD in the U.S. market include the following once-daily formulations: Concerta, Metadate CD, Ritalin LA, Focalin XR, Daytrana, and Adzenys XR-ODT. Other non-stimulants are Strattera and Kapvay. We are also aware of clinical development efforts by several other organizations including Alcobra, Sunovion, Neos Therapeutics, and Neurovance to develop additional treatment options for ADHD.

Our Proprietary Technology Platforms

We have a successful track record of developing novel products by applying proprietary technologies to known drugs to improve existing therapies and enable the treatment of new indications. Our key proprietary technology platforms include Microtrol, Solutrol and EnSoTrol. These technologies create novel customized product profiles designed to meet efficacy needs, more convenient and less frequent dosing, enhanced patient compliance, and improved tolerability in certain specific applications. We have employed our technologies in the development of a total of nine products that are currently on the market, including Trokendi XR and Oxtellar XR along with the other seven products being marketed by companies for whom we have developed sustained release formulations. Trokendi XR uses the Microtrol multiparticulate delivery platform and Oxtellar XR uses the Solutrol matrix delivery platform. EnSoTrol was utilized to develop Orenitram, an oral formulation of treprostinil diethanolamine, or treprostinil, which was launched by United Therapeutics Corporation in 2014.

Intellectual Property and Exclusivity

Overview

We have been building and continue to build our intellectual property portfolio relating to our products and product candidates, including Oxtellar XR and Trokendi XR. We seek patent protection, where appropriate, in the United States and internationally for our products and product candidates. Our policy is to protect our innovations and proprietary products by, among other things, filing patent applications in the United States and abroad (including Europe, Canada and other countries when

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appropriate). We also rely on trade secrets, know-how, continuing technological innovation and 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.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technologies and products we consider important to our business, defend our patents, preserve the confidentiality of our trade secrets and operate our business without infringing the patents and proprietary rights of third parties.

We have established and continue to build proprietary positions for Oxtellar XR, Trokendi XR, our pipeline product candidates and technologies in the United States and abroad.

Patents for both Oxtellar XR and Trokendi XR have received numerous Paragraph IV Notice Letters and we have filed claims for infringement of our patents against the third-parties. As of February 5, 2016, litigation with respect to Oxtellar XR was resolved in favor of the Company pending appeal when a federal court ruled that three of our patents were found to be valid, and that Actavis infringed two of these three patents. For more information, please see Item 3 Legal Proceedings contained within this Form 10-K.

Patent Portfolio

Our extended release oxcarbazepine patent portfolio currently includes eight U.S. patents, five of which cover Oxtellar XR. We have also obtained two patents for extended release oxcarbazepine in Europe and one patent each in Canada, Japan, Australia, China, and Mexico. In addition, we have certain pending U.S. patent applications that cover various extended release formulations containing oxcarbazepine. The five issued U.S. patents covering Oxtellar XR will expire no earlier than 2027. We own all of the issued patents and the pending applications.

In addition to the patents and patent applications relating to Oxtellar XR, we currently have six U.S. patents that cover Trokendi XR. We have one patent issued each in Mexico, Australia, Japan and Canada for extended release topiramate. We have two patents issued in Europe for extended release topiramate and have a pending U.S. patent application that covers extended release formulations containing topiramate. The six issued U.S. patents covering Trokendi XR will expire no earlier than 2027. We own all of the issued patents and pending applications.

Our patent portfolio also contains patent applications relating to our other pipeline products. We have four families of pending U.S. non-provisional and foreign counterpart patent applications relating to our SPN-810 product candidate. Patents, if issued, could have terms expiring from 2029 to 2033. We have one patent issued each in the U.S., Mexico and Australia in one of these families, covering modified release formulations of molindone. In another family, covering a process for preparing molindone, we have one patent issued in the U.S. In a third family, covering use of molindone in treating IA, we have one patent issued in Japan. We own all of the pending applications.

With regard to our SPN-812 product candidate, we have three families of pending U.S. non-provisional and foreign counterpart patent applications. Patents, if issued, from the applications could expire from 2029 to 2033. We have one patent each issued in Europe and Canada in one of these families, covering a method of treating ADHD using viloxazine. In another family, covering the novel process of synthesis, we have one patent issued each in Europe, Mexico, and Australia. We own all of the issued patents and the pending applications.

The United States patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the United States Patent and

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Trademark Office (USPTO), and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. A provisional patent application is not examined for patentability, and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into a patent. The requirements for filing a provisional patent application are not as strict as those for filing a non-provisional patent application. Provisional applications are often used, among other things, to establish an early filing date for a subsequent non-provisional patent application. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the U.S., a patent's term may be lengthened by patent term adjustment (PTA), which compensates a patentee for administrative delays by the USPTO in granting a patent. In view of a recent court decision, the USPTO is under greater scrutiny regarding its calculations because the USPTO erred in calculating the PTA, which resulted in denying the patentee a portion of the patent term to which it was entitled. Alternatively, a patent's term may be shortened if a patent is terminally disclaimed over another patent.

In evaluating the patentability of a claimed invention, the filing date of a non-provisional patent application is used by the USPTO to determine what information is prior art. If certain requirements are satisfied, a non-provisional patent application can claim the benefit of the filing date of an earlier filed provisional patent application. As a result, the filing date accorded by the provisional patent application may supersede information that otherwise could preclude the patentability of an invention.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension (PTE) which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA or other regulatory approval, we may be able to apply for PTEs on patents covering those products. Depending upon the timing, duration and specifics of FDA approval of our SPN-810 and SPN-812 product candidates and issuance of a U.S. patent we may obtain a U.S. patent that is eligible for limited patent term restoration.

Other Intellectual Property Rights

We seek trademark protection in the U.S. and internationally where available and when appropriate. We have filed for trademark protection for several marks, which we use in connection with our pharmaceutical research and development collaborations as well as products. We are the owner of various United States federal trademark registrations (®) and registration applications ( ), including the following marks referred to in this Annual Report on Form 10-K pursuant to applicable U.S. intellectual property laws: "Supernus®," "Microtrol®," "Solutrol®," "Trokendi XR®," "Oxtellar XR®," and the registered Supernus Pharmaceuticals logo.

From time to time, we may find it necessary or prudent to obtain licenses from third party intellectual property holders. Where licenses are readily available at reasonable cost, such licenses are considered a normal cost of doing business. In other instances, however, we may use the results of freedom-to-operate inquiries and internal analyses to guide our early-stage research away from areas where we are likely to encounter obstacles in the form of third party intellectual property. For example, where a third party holds relevant intellectual property and is a direct competitor, a license might not be available on commercially reasonable terms or available at all. We strive to identify potential third

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party intellectual property issues in the early stages of our research programs, in order to minimize the cost and disruption of resolving such issues.

To protect our competitive position, it may be necessary to enforce our patent rights through litigation against infringing third parties. We presently have cases pending against four parties to enforce our patent rights. See Item 3 Legal Proceedings. Litigation to enforce our own patent rights is subject to uncertainties that cannot be quantified in advance. In an adverse outcome in litigation, we could be prevented from commercializing a product or using certain aspects of our technology platforms as a result of patent infringement claims asserted against us. This could have a material adverse effect on our business. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize products or use technologies that are similar to ours, and then compete directly with us, without payment to us. See "Risk Factors If we are sued for infringing intellectual property rights of third parties, it could be costly and time consuming to defend such a suit. An unfavorable outcome in that litigation could have a material adverse effect on our business."

In-Licensing Arrangements

Afecta Pharmaceuticals, Inc.

We have entered into two license agreements with Afecta Pharmaceuticals, Inc. (Afecta) pursuant to which we obtained an exclusive option to evaluate Afecta's CNS pipeline and to obtain exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. We may pay up to $300,000 upon the achievement of certain milestones. If a product candidate is successfully developed and commercialized, we will be obligated to pay royalties to Afecta based on worldwide net product sales in the low-single digits.

Rune HealthCare Limited

In June 2006, we entered into a purchase and sale agreement with Rune HealthCare Limited (Rune) where we obtained the exclusive worldwide rights to a product concept from Rune for SPN-809. If we receive approval to market and sell any products covered by the agreement, we will be obligated to pay royalties to Rune based on net sales worldwide in the low-single digits.

Confidential Information and Inventions Assignment Agreements

We require our employees, temporary employees and consultants to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions resulting from work performed for us or relating to our business and conceived or completed by the individual during employment or assignment, as applicable, shall be our exclusive property to the extent permitted by applicable law.

We seek to protect our products, product candidates and our technologies through a combination of patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure.

Government Regulation

Product Approval

Government authorities in the United States at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution,

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marketing, export and import of products such as those we are developing. Our product candidates must receive final approval from the FDA before they may be marketed legally in the U.S.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and through implementation of regulations. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, product detention, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices (GCP) to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA inspection of the clinical study sites and/or manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Clinical Practices and Good Manufacturing Practices (cGMP); and
- FDA review and approval of the NDA.

The testing and approval 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. Our total research and development expense was approximately $29.1 million and $19.6 million for each of 2015 and 2014, respectively. In order to continue the progress of our product candidates, significant increases in these expenditures will be required.

Once a suitable product candidate is successfully created, a preliminary development strategy is determined. Usually, an IND is opened with adequate preclinical and clinical trial material manufacturing supportive information to permit initiation of the first proposed clinical trial. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board (IRB) must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

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Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted with the IND for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials for product candidates are typically conducted in three sequential phases that may overlap or be combined:

Phase I. The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.

Phase II. Phase II trials involve investigations in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

Phase III. In Phase III, clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the product 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, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, 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.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

NDAs are either standard 505(b)(1) or 505(b)(2) applications. For a standard application, all pertinent information must be part of the regulatory submission under that NDA number. For a 505(b)(2) application, the FDA permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

The submission of an NDA is subject to the payment of a substantial user fee; a waiver of such fee may be obtained under certain limited circumstances.

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In addition, under the Pediatric Research Equity Act of 2003, which was reauthorized under the Food and Drug Administration Safety and Innovation Act of 2012, an NDA must contain, *a priori*, or propose clinical work that supports the product's use in all relevant pediatric subpopulations. The FDA may grant deferrals for submission of data or full or partial waivers of the data requirements. Pursuant to the FDA's approval of Oxtellar XR, we must conduct four pediatric post-marketing studies; however, the FDA granted a waiver for the pediatric study requirements for ages birth to one month and a deferral for submission of post-marketing assessments for children one month to six years of age. Pursuant to the FDA's approval of Trokendi XR, the FDA granted a deferral for submission of post-marketing pediatric studies in the following categories: (1) adjunctive therapy in partial onset seizures (POS) for children one month to less than six years of age, (2) initial monotherapy in POS and primary generalized tonic-clonic (PGTC) for children two years to less than ten years of age, and (3) adjunctive therapy in PGTC and adjunctive therapy in Lennox-Gastaut Syndrome from two years to less than six years of age. We are moving forward with a revised pediatric plan, in consultation with the FDA.

Section 505(b)(2) New Drug Applications

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve, as applicable, a Section 505(b)(2) NDA application until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of an NCE, three year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

A section 505(b)(2) NDA applicant must send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. If the relevant patent holder elects to initiate litigation, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 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 Section 505(b)(2) NDA that we submit.

In the NDA submissions for our product candidates, we intend to follow the 505(b)(2) development pathway when appropriate.

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FDA Review of New Drug Applications

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately 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 we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or then request an opportunity for a hearing.

If a product receives regulatory 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. In addition, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term restoration of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the drug. The

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USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active pharmaceutical ingredient (API) or active moiety, which is the molecule or ion responsible for the therapeutic action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. As an alternative to submission via 505(b)(2) approval, an applicant may choose to submit a full Section 505(b)(1) NDA, but such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. Further, a Section 505(b)(2) application may be submitted after four years if it contains a Paragraph IV certification.

The FDCA also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. This exclusivity, sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product or Section 505(b)(2) product that did not incorporate the exclusivity-protected changes of the approved drug product. The FDCA, FDA regulations and other applicable regulations and policies 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.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to be attached to any existing exclusivity (e.g., three or five year exclusivity) or patent protection for a drug. This six month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial. The current pediatric exclusivity provision was reauthorized in September 2007.

Post-Approval Requirements

Any drugs for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of AEs with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. 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 risk evaluations and mitigation strategies approved by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance

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with the provisions of the approved label. Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, certain changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug manufacturers and other entities involved in the manufacturing 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 cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed by the United States Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. For example, in July 2012, the Food and Drug Administration Safety and Innovation Act was enacted, expanding drug supply chain requirements and strengthening FDA's response to drug shortages, among other things. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

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Third-Party Payor Coverage and Reimbursement

In both the United States and foreign markets, our ability to commercialize our product and product candidates successfully, and to attract commercialization partners for our product and product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services (CMS), through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payors.

The United States Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act as amended by the HealthCare and Education Reconciliation Act of 2010, which we refer to collectively as the HealthCare Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the healthcare industry and impose additional healthcare policy reforms. Effective October 1, 2010, the HealthCare Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, since 2011, the HealthCare Reform Law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the HealthCare Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the HealthCare Reform Law, the new law appears likely to continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

The cost of pharmaceuticals continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Indeed, several candidates for election as President of the United States have publicly stated that the prices of pharmaceutical drugs are too high and that, if elected, will take efforts to enact policies to reduce and/or control these prices. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot

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predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

Other HealthCare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. These regulations include:

the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the federal transparency requirements under the HealthCare Reform Law and similar state law provisions require manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

the FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Employees

As of December 31, 2015, we employed 344 full-time employees. seventy-three employees are engaged in research and development activities and 271 employees are engaged in selling, general and administrative activities. We consider relations with our employees to be good. None of our employees are represented by a labor union.

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ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below with all of the other information we include in this report and the additional information in the other reports we file with the Securities and Exchange Commission (the "SEC" or the "Commission"). These risks may result in material harm to our business and our financial condition and results of operations. In this event, the market price of our common stock may decline and you could lose part or all of your investment.

Risks Related to Our Business and Industry

We are dependent on the commercial success of Oxtellar XR and Trokendi XR.

A substantial majority of our resources are focused on expanding the revenue generated by our approved products in the United States, Oxtellar XR and Trokendi XR.

Our ability to generate significant product revenue from sales of Oxtellar XR and Trokendi XR in the near term will depend on, among other things, our ability to:

- defend our patents and intellectual property from generic competition;
- maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, through a validated process, sufficiently large quantities of inventory of our products to meet demand;
- continue to maintain a wide variety of internal sales, distribution and marketing capabilities sufficient to sustain growth in sales of our products;
- continue to maintain and grow widespread acceptance of our products from physicians, health care payors, patients, pharmacists and the medical community;
- properly price and obtain adequate coverage and reimbursement of these products 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;
- obtain approval from the FDA to expand the labeling of our approved products for additional indications;
- adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights; and
- adequately protect against and effectively respond to any unanticipated adverse effects or unfavorable publicity that develops in respect to our products, as well as the emergence of new or existing competitive products, which may be proven to be more clinically effective and cost-effective.

There are no guarantees that we will be successful in completing these tasks. In addition, we will need to continue investing substantial financial and management resources to maintain our commercial sales and marketing infrastructure and to recruit and train qualified marketing, sales and other personnel. In addition, we have expressed certain long term revenue expectations. If we cannot achieve those revenue expectations with respect to Oxtellar XR and Trokendi XR, this could result in a material adverse impact on our anticipated revenue, earnings and liquidity.

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Continued increase in sales of Oxtellar XR or Trokendi XR may be slow or limited for a variety of reasons including competing products or safety issues. If either Oxtellar XR or Trokendi XR is not successful in gaining broad commercial acceptance, our business would be harmed.

Any increase in sales of Oxtellar XR and Trokendi XR will be dependent on several factors including our ability to educate physicians and to increase physician awareness of the benefits and cost-effectiveness of our products relative to competing products. The degree of further market acceptance of any of our products or market acceptance of approved product candidates among physicians, patients, health care payors and the medical community will depend on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects; and
- availability of alternative treatments.
- pricing and cost effectiveness;

In addition, Oxtellar XR and Trokendi XR will be subject to continual review by the FDA, and we cannot assure that newly discovered or reported safety issues will not arise. With the use of any newly marketed drug by a wider patient population, serious AEs may occur from time to time that initially do not appear to relate to the drug itself. Any safety issues could cause us to suspend or cease marketing of our approved products, cause us to modify how we market our approved products, subject us to substantial liabilities and adversely affect our revenues and financial condition. In the event of a withdrawal of either Oxtellar XR or Trokendi XR from the market, our revenues would decline significantly and our business would be seriously harmed and could fail.

We are involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. For example, we are involved in several matters related to Paragraph IV Certification Notice Letters that we have received in connection with our products and our collaborators' products. In connection with an ANDA, a Paragraph IV Certification Notice Letter notifies the FDA that one or more patents listed in the FDA's Orange Book is alleged to be invalid, unenforceable or will not be infringed by the ANDA product. These matters include claims related to Oxtellar XR and Trokendi XR, and are discussed in Part I, Item 3 Legal Proceedings.

In any infringement proceeding, including the foregoing, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patients at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us or at all. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our

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proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In addition, there could be public announcements of the results of hearings, motions or other interim proceeding or developments. If securities analysts or investors perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the price of our common stock. There can be no assurance that our products or product candidates will not be subject to the same risks.

We are dependent on obtaining regulatory approval of our product candidates and for additional indications for existing products.

Our ability to successfully commercialize any of our product candidates and for additional indications of existing products will depend on, among other things, our ability to:

- successfully complete our clinical trials;
- receive marketing approvals from the FDA;
- produce, through a validated process, sufficiently large quantities of our product candidates to permit successful clinical development and commercialization;
- establish commercial manufacturing arrangements with third-party manufacturers;
- build and maintain strong sales, distribution and marketing capabilities sufficient to commercially launch our product candidates;
- secure acceptance of our product candidates from physicians, health care payors, pharmacies, wholesalers, patients and the medical community; and
- manage our spending as costs and expenses increase due to undertaking clinical trials and commercially launching product candidates.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize any of our other product candidates in a timely manner, or at all, in which case we may be unable to maximize our revenues. In addition, if we experience unanticipated delays or problems, development costs could substantially increase and our business, financial condition and results of operations may be adversely affected.

We may not be able to effectively market and sell our product candidates, if approved, in the United States.

We plan on building our sales and marketing capabilities in the United States to commercialize our product candidates if approved. We will build such capabilities by investing significant amounts of financial and management resources. Furthermore, the cost of establishing and maintaining marketing and sales capabilities may not be justifiable in light of the revenues generated by any of our product candidates.

If we are unable to establish and maintain adequate sales and marketing capabilities for our product candidates or are unable to do so in a timely manner, we may not be able to generate product revenues from these product candidates which may prevent us from maintaining profitability.

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Final marketing approval of any of our product candidates or additional indications for existing products by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

Our business depends on the successful development and commercialization of our product candidates. 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 typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. We cannot predict whether or when 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. In addition, we have sought approval from the FDA for Trokendi XR as a treatment for migraines; however, we cannot predict if, or when, we will obtain regulatory approval for this indication and, therefore, cannot predict the timing of any future revenues, if any, from the sale of Trokendi XR for this indication.

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

could reject or delay the marketing application for an NCE;

could determine that we cannot rely on Section 505(b)(2) for any of our product candidates;

could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the 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 clinical and other benefits of our product candidates outweigh their safety risks;

may disagree with our trial design or our interpretation of data from preclinical 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, the outcome and measurement scale used in the trials, and the clinical protocols whether with or without a special protocol assessment process;

may determine that we have identified the wrong reference listed drug or drugs or that approval of our Section 505(b)(2) application of our product candidate is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;

may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of raw materials, including the API or manufactured product candidates used in our product candidates, wherein those deficiencies may result in interruption in the ability to supply product;

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, or the addition of new indications to the label of our existing products.

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Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(1) and 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 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 Section 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.

We are subject to uncertainty relating to payment or reimbursement policies which, if not favorable for our products or product candidates, could hinder or prevent our commercial success.

Our ability or our collaborators' ability to successfully commercialize our products, including Oxtellar XR and Trokendi XR, and our product candidates, will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers, managed care organizations and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products be approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. Government authorities and these third-party payors have attempted to control costs, in some instances, by limiting coverage and the amount of reimbursement for particular medications or encouraging the use of lower-cost generic AEDs. We cannot be sure that reimbursement will be available for any of the products that we develop and, if reimbursement is available, the level of reimbursement. Moreover, that level of reimbursement may change over time as a result of decisions made by payors. Reduced or partial payment or reimbursement coverage could make our products or product candidates, including Oxtellar XR and Trokendi XR, less attractive to patients and prescribing physicians. We also may be required to sell our products or product candidates at a significant discount, which would adversely affect our ability to realize an appropriate return on our investment in our products or product candidates or compete on price.

We expect that private insurers and managed care organizations will consider the efficacy, cost effectiveness and safety of our products or product candidates, including Oxtellar XR and Trokendi XR, in determining whether to approve reimbursement for such products or product candidates and at what level. Moreover, they will consider the efficacy and cost effectiveness of comparable or competitive products in making reimbursement decisions for our products. Because each third-party payor individually approves payment or reimbursement, obtaining these approvals can be a time consuming and expensive process that could require us to provide scientific or clinical support for the use of each of our products or product candidates separately to each third-party payor. In some cases, it could take several months or years before a particular private insurer or managed care organization reviews a particular product, and we may ultimately be unsuccessful in obtaining coverage. Our competitors may have larger organizations, as well as existing business relationships with third-party payors relating to their products. Our business would be materially adversely affected if we do not receive approval for reimbursement of our products or product candidates from private insurers on a timely or satisfactory basis. Our products and product candidates may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products or product candidates on a profitable basis. Our business would also be adversely affected if private insurers, managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which our products or product candidates will be reimbursed.

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing

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approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products or product candidates to other available therapies. If reimbursement for our products or product candidates is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

In addition, many managed care organizations negotiate the price of products and establish formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. If our products or product candidates are not included within an adequate number of formularies or adequate payment or reimbursement levels are not provided, or if those policies increasingly favor generic products, our market share and gross margins could be negatively affected, which would have a material adverse effect on our overall business and financial condition.

We expect to experience pricing pressures due to potential healthcare reforms discussed elsewhere in this Annual Report on Form 10-K, as well as due to cost control measures instituted by health maintenance organizations.

Our failure to successfully develop and market product candidates would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional product candidates. We may spend several years completing our development of any particular current or future internal product candidate, during which process, we can experience failure can occur at any stage. The product candidates to which we allocate our resources may not end up being commercially 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 products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical 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, including financial resources, to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased operating expenses;

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

inability to retain and/or motivate key employees of any acquired businesses.

Our clinical trials may fail to demonstrate acceptable levels of safety, efficacy or any other requirements of our product candidates, which could prevent or significantly delay regulatory approval.

We may be unable to sufficiently demonstrate the safety and efficacy of our product candidates to obtain regulatory approval. We must demonstrate with substantial evidence gathered in well-controlled studies, and to the satisfaction of the FDA with respect to approval in the United States and to the satisfaction of similar regulatory authorities in other jurisdictions with respect to approval in those jurisdictions, that each product candidate is safe and effective for use in the target indication. The FDA may require us to conduct or perform additional studies or trials to adequately demonstrate safety and efficacy, which could prevent or significantly delay our receipt of regulatory approval, increase clinical costs significantly, and, ultimately, delay the commercialization of that product candidate.

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 applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

In addition, the results from the trials that we have completed for our product candidates may not be replicated in future trials, or we may be unable to demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our product candidates. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced development, even after promising results in earlier trials. If our product candidates are not shown to be safe and effective, our clinical development programs could be delayed or might be terminated.

We rely and will continue to rely on outsourcing arrangements for certain of our activities, including clinical research of our product candidates and manufacturing of our compounds and product candidates beyond Phase II clinical trials.

We rely on outsourcing arrangements for some of our activities, including manufacturing, preclinical and clinical research, data collection and analysis, and electronic submission of regulatory filings. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner. Our reliance on third parties, including third-party clinical research organizations (CROs) and CMOs entails risks including, but not limited to:

non-compliance by third parties with regulatory and quality control standards;

sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third party supplier or manufacturer fail to comply with applicable regulatory standards;

the possible breach of the agreements by the CROs or CMOs because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and

termination or non-renewal of an agreement by the third parties, at a time that is inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

We do not own or operate manufacturing facilities for the production of any of our products or product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable

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future. We currently depend on third-party CMOs for all of our required raw materials and drug substance for our preclinical research and clinical trials. For Oxtellar XR and Trokendi XR, we currently rely on single suppliers for raw materials, including API, and rely on third-party suppliers and manufacturers for the final commercial products. If any of these vendors are unable to perform their obligations to us, including due to violations of the FDA's requirements, our ability to meet regulatory requirements, projected timelines, necessary quality standards for successful manufacture of our development and commercialization product would be adversely affected. Further, if we were required to change vendors, it could result in delays in our regulatory approval efforts and significantly increase our costs. Accordingly, the loss of any of our current or future third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition and prospects.

We have entered into supply agreements for both Oxtellar XR and Trokendi XR with leading CMOs headquartered in North America for the manufacture of the final commercial products. However, there is a risk that the counterparties to these agreements will not perform their respective obligations or will terminate these agreements. We could also become embroiled in disputes with third party manufacturers for Oxtellar XR and Trokendi XR regarding the terms of our agreements, their performance or intellectual property rights, any of which could disrupt the sales of our products and adversely affect our reputation and revenue. In addition, we do not have contractual relationships for the manufacture of commercial supplies of all of our product candidates. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture drug substance and final drug product on a commercial scale is limited. Therefore, we may not be able to enter into such arrangements with third-party manufacturers in a timely manner, on acceptable terms, or at all. Failure to secure such contractual arrangements would harm the commercial prospects for our product candidates. Our costs could increase and our ability to generate revenues could be delayed.

Delays or failures in the completion of clinical development of our product candidates would increase our costs and delay or limit our ability to generate revenues.

Delays or failures in the completion of clinical trials for our product candidates could significantly raise our product development costs. We do not know whether current or planned trials will be completed on schedule, if at all. The commencement and completion of clinical development can be delayed or halted 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 failure to reach agreement on acceptable terms with prospective CROs trial sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites, and investigators;
- insufficient or inadequate supply or quantity of a product candidate for use in trials;
- difficulties obtaining IRB or ethics committee approval to conduct a trial at a prospective site;
- challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- difficulty retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues; and
- clinical holds; and

clinical trials may also be delayed as a result of ambiguous or negative interim results.

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In addition, clinical trials may be suspended or terminated by us, a Data Safety Monitoring Board (DSMB) or ethics committee overseeing the clinical trial at a trial site (with respect to that site), the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols;
- observations during inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that ultimately result in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the trial.

In addition, failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols may result in the inability to use the data to support product approval. Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If we experience delays in completion of, or if we terminate any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues will be diminished.

If other versions of extended or controlled release oxcarbazepine or topiramate are approved and successfully commercialized, then our business could be materially harmed.

Third parties have and may receive approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate anti-epileptic drugs in the United States. For example, Upsher-Smith launched Qudexy XR (extended release topiramate) and its own authorized generic, both of which compete with Trokendi XR. Since Trokendi XR was not granted marketing exclusivity by the FDA, we may not be able to prevent the submission or approval of another full NDA for any competitor's extended or controlled release topiramate product candidate. However, we do have the right to defend our products against third parties who may infringe or are infringing our patents. In addition, we are aware of companies who are marketing modified-release oxcarbazepine products outside of the United States, such as Apydan, which is developed by Desitin Arzneimittel GmbH and requires twice-daily administration. If companies with modified-release oxcarbazepine products outside of the United States pursue or obtain approval of their products within the United States, such competing products may limit the potential success of Oxtellar XR in the United States, and our business and growth prospects would be materially impaired. Accordingly, if any third party is successful in obtaining approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate in the United States, we may not be able to recover expenses incurred in connection with the development of or prospectively realize revenues from Oxtellar XR or Trokendi XR.

If we do not obtain marketing exclusivity for our product candidates, our business may suffer.

Under the Hatch-Waxman Amendments, three years of marketing exclusivity may be granted for the approval of new and supplemental NDAs, including Section 505(b)(2) applications, for, among other things, new indications, dosage forms, routes of administration, or strengths of an existing drug, or for a new use, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. This exclusivity, which is

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sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product or Section 505(b)(2) product that did not incorporate the exclusivity-protected changes of the approved drug product. Under the Hatch-Waxman Amendments, newly-approved drugs and indications may also benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Amendments provide five-year marketing exclusivity to the first applicant to gain approval of an NDA for an NCE, meaning that the FDA has not previously approved any other drug containing the same API, or active moiety, which is the molecule responsible for the action of the drug substance. Although protection under the Hatch-Waxman Amendments will not prevent the submission or approval of another full Section 505(b)(1) NDA, such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness.

While the FDA granted a three year marketing exclusivity period for Oxtellar XR, it did not grant a similar marketing exclusivity period for Trokendi XR. If we are unable to obtain marketing exclusivity for our subsequent product candidates, then our competitors may obtain approval of competing products more easily than if we had such marketing exclusivity, and our future revenues could be reduced, possibly materially.

Our products and product candidates may cause undesirable side effects or have other characteristics that limit their commercial potential or delay or prevent their regulatory approval.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt development and could result in the denial of regulatory approval by the FDA or other regulatory authorities, and result in potential products liability claims. Undesirable side effects caused by any of our products could cause regulatory authorities to temporarily or permanently halt product sales which could have a material adverse effect on our business as a whole.

Immediate release oxcarbazepine and topiramate products, which use the same active pharmaceutical ingredients as Oxtellar XR and Trokendi XR, are known to cause various side effects, including but not limited to dizziness, paresthesia, headaches, cognitive deficiencies such as memory loss and speech impediment, digestive problems, somnolence, double vision, gingival enlargement, nausea, weight gain, oral malformation birth defects, visual field defects, and fatigue. The use of Oxtellar XR and Trokendi XR may cause similar side effects as compared to their reference products, or may cause additional or different side effects.

If our products cause side effects or if any of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by our products or product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of the product candidate or otherwise require us to take the approved product off the market;
- regulatory authorities may require additional warnings, or a narrowing of the indication, on the product label;
- we may be required to create a medication guide outlining the proper use of the medication and risks of side effects for distribution to patients;
- we may be required to modify the product in some way;

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- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of approved products may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining the commercial success of our products and product candidates and could substantially increase commercialization costs.

We may not be able to manage our business effectively if we are unable to attract, motivate and retain key members of our management team.

We may not be able to attract or motivate qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our objectives.

We are highly dependent on the development, regulatory, commercial and financial expertise of our management, particularly Jack A. Khattar, our President and Chief Executive Officer. Mr. Khattar has an employment agreement and other members of the senior management team have executive retention agreements. If we lose key members of our management team, we may not be able to find suitable replacements in a timely fashion, if at all. We cannot be certain that future management transitions will not disrupt our operations and generate concern among employees and those with whom we do business.

In addition to the competition for personnel, our corporate offices are located in the greater Washington D.C. metropolitan area, an area that is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our Company and may be required to expend significant financial resources in our employee recruitment efforts.

If our competitors develop or market alternatives for treatments of our target indications, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products and product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. The availability of new products or approvals for new indications of existing products may limit the demand for and the price we are able to charge for any of our products we are able to differentiate them from competitive offerings. In addition to competition with our currently marketed products, we anticipate that we will face intense competition when our pipeline product candidates are approved by regulatory authorities and we begin the commercialization process for these products.

There are currently no marketed products and no known products in development for the treatment of IA in patients with ADHD. However, the off-label use of risperidone (Risperdal) and aripiprazole (Abilify) is common. These products are approved for irritability in autism which, as a result, may influence use of the products to treat IA in patients with ADHD.

In addition, several companies have various product candidates they are developing for ADHD which may compete with our SPN-812 product candidate. Non-stimulant ADHD products in Phase III

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development include SEP-225289 (dasotraline), a dopamine, serotonin and norepinephrine reuptake inhibitor, being developed by Sunovion, and MG01CI (metadoxine), an extended release version of pyrrolidone carboxylate of pyridoxine, which is being developed by Alcobra. Sunovion reported positive data in adults from a first study with SEP-225289 at the American College of Neuropsychopharmacology meeting in 2014. An additional Phase III study in adults is planned, with pediatric work to follow. The Alcobra product did not meet its primary endpoint in an initial Phase III study reported in 2014. However, Alcobra is conducting additional clinical work in adults and adolescents.

Further, new developments, including the development of other drug technologies, may render our products

or product candidates obsolete or noncompetitive. As a result, our products and product candidates may become obsolete before we recover expenses incurred in connection with their development or realize revenues from commercialization. Further, many competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop drugs that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively with the products of our competitors or if such competitors are successful in developing products that compete with any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially and adversely affected. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated at competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment.

Our products and our product candidates, may be subject to restrictions or withdrawal from the market. We may be subject to penalties if we fail to comply with regulatory requirements.

Even though U.S. regulatory approval has been obtained for Trokendi XR and Oxtellar XR, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for costly post-approval studies. Our product candidates would also be, and our approved product and our collaborators' approved products are, subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other information. In addition, 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 cGMP regulations. If we, our collaborators or a regulatory authority discovers previously unknown problems with a product, including side effects that are unanticipated in severity or frequency, or

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problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we or our collaborators, or our or our collaborators' approved products or product candidates, or the manufacturing facilities for our or our collaborators' approved products or product candidates fail to comply with applicable regulatory requirements, a regulatory authority may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing bioequivalence and/or clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements, or suspension of production for a sustained period of time; or
- seize or detain products or require us to initiate a product recall.

In addition, our product labeling, advertising and promotion of our approved products, are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we are found to have promoted off-label uses, we may be enjoined from such off-label promotion and become subject to significant liability, which would have an adverse effect on our reputation, business and revenues, if any. All of this notwithstanding, physicians may nevertheless prescribe our products to their patients in a manner that is inconsistent with the approved label.

If we fail to produce our products and 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 delays in the development and commercialization of our products and product candidates, or withdrawal of products from the market.

We do not currently own or operate manufacturing facilities for the production of any of our products or for the commercial production of our product candidates, nor do we have plans to develop our own manufacturing operations for commercial products in the foreseeable future. We currently depend on third-party contract manufacturers for the supply of the APIs for our products or product candidates, including drug substance for our preclinical research and clinical trials. For Oxtellar XR and Trokendi XR, we currently rely on single suppliers for raw materials including API and we rely on single manufacturers to produce and package final dosage forms. Any future curtailment in the availability of raw materials could result in production or other delays with consequent adverse effects. 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.

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,

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quality control, 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 manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to maintain or obtain FDA approval and to market our products and product candidates, respectively, would be jeopardized. In addition, any delay or interruption in producing clinical trial supplies could delay or prohibit the completion of our clinical trials, increase the costs associated with conducting our 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 and other requirements as enforced by the FDA, including for electronic tracking and submission. These requirements include, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products and product candidates 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 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 regulatory approval for such product candidate or successfully commercialize such products, 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 product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates. Furthermore, if we fail to obtain the required commercial quantities on a timely basis from our suppliers and at commercially reasonable prices, we may be unable to meet demand for our approved products, and would lose potential revenues.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the sales of those products or product candidates would be adversely affected.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The FDCA, FDA regulations and other applicable regulations and policies 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 and 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 products and product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market. Companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, regardless of the regulatory approval pathway, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products and product candidates would materially, permanently and 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 products and product candidates. In particular, as disclosed in Part I, Item 3 Legal Proceedings of this Annual Report on Form 10-K, we received Paragraph IV Notice Letters against our Oxtellar XR and Trokendi XR Orange Book patents from several generic drug makers. We have filed a lawsuit against each of these drug makers alleging infringement of our Oxtellar XR and Trokendi XR patents. In October 2015, we reached a settlement agreement with one of these generic drug makers, Par Pharmaceutical Companies, Inc., on the Trokendi XR case. While we intend

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to vigorously defend our product rights, in the event that we are not successful in these lawsuits, our future sales of Oxtellar XR and Trokendi XR will be significantly, adversely and permanently affected by competition from these generic drug manufacturers.

We intend to rely on third-party collaborators to market and commercialize our products and product candidates outside the United States. They may fail to effectively commercialize our products and product candidates.

Outside the United States, we utilize strategic partners where appropriate, to assist in the commercialization of our products. We currently possess limited resources and may not be successful in establishing collaborations or licensing arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and licensing partners. By entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Our collaborators may fail to develop or effectively commercialize our products because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our products outside the United States would diminish our revenues and harm our results of operations.

Limitations on our patent rights relating to our products and product candidates may limit our ability to prevent third parties from competing against us.

To a significant degree, our success will depend on our ability to obtain and maintain patent protection for our proprietary technologies and our products, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. To that end, we seek patent protection in the United States and internationally for our product. Our policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad (including Europe, Canada and certain other countries when appropriate) relating to proprietary technologies that are important to the development of our business.

The strength of patents in the pharmaceutical industry involves complex legal and scientific questions and can have uncertain results. Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we were the first to conceive inventions covered by our patents and pending patent applications or that we were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property or that such patents will not be challenged, narrowed, invalidated or circumvented.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. Any failure to adequately prevent disclosure of our trade secrets and other proprietary information could have a material adverse impact on our business.

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In addition, the laws of certain foreign countries do not protect proprietary rights to the same extent or in the same manner as the United States, and therefore, we may encounter problems in protecting and defending our intellectual property in certain foreign jurisdictions.

If we are sued for infringing intellectual property rights of third parties, it could be costly and time consuming to defend such a suit. An unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell their approved products and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our collaborators' approved products and our product candidates may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware, that may be infringed by our collaborators' approved products or Oxtellar XR or Trokendi XR, which could prevent us from being able to maximize revenue generated by Oxtellar XR, Trokendi XR or any of our 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 collaborators' approved products or our product candidates may infringe.

We may be exposed to, or threatened with, future litigation by third parties alleging that our collaborators' approved products or our products or product candidates infringe their intellectual property rights. If one of our collaborators' approved products or 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, 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;
- 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. 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 Oxtellar XR, Trokendi XR, 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 Oxtellar XR, Trokendi XR, or any of our product candidates so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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We depend on collaborators to work with us to develop, manufacture and commercialize their and our products and product candidates.

We have a license agreement with United Therapeutics Corporation to use one of our proprietary technologies for an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension, as well as for other indications. United Therapeutics Corporation launched Orenitram (treprostinil) in 2014, which triggered a milestone payment due to us of $2.0 million. In the third quarter of 2014 we recognized $30.0 million in revenue from HeatlhCare Royalty Partners III, L.P.'s purchase of certain of our rights under our license agreement with United Therapeutics Corporation related to the commercialization of Orenitram. We will retain full ownership of the royalty rights after a certain cumulative threshold payment to Health Care Royalty Partners has been reached. We are entitled to receive milestones and royalties for use of this formulation in other indications. If we materially breach any of our obligations under the license agreement, however, we could lose the potential to receive any future royalty payments thereunder, which could be financially significant to us.

Our future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties. Much of the potential revenues from these future collaborations may consist of contingent payments, such as payments for achieving development milestones and royalties payable on sales of developed products. The milestone and royalty revenues that we may receive under these collaborations will depend upon our collaborators' ability to successfully develop, introduce, market and sell new products. Future collaboration partners may fail to develop or effectively commercialize products using our products, product candidates or technologies because they, among other things, may:

- change the focus of their development and commercialization efforts or may have insufficient resources to effectively develop our product candidates. Pharmaceutical and biotechnology companies historically have re-evaluated their development and commercialization priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of some of our product candidates to reach their potential could be limited if our future collaborators decrease or fail to increase development or commercialization efforts related to those product candidates;

- decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise or limited cash resources, or the belief that other drug development programs may have a higher likelihood of obtaining marketing approval or may potentially generate a greater return on investment;

- develop and commercialize, either alone or with others, drugs that are similar to or competitive with the product candidates that are the subject of their collaborations with us;

- not have sufficient resources necessary to carry the product candidate through clinical development, marketing approval and commercialization;

- fail to comply with applicable regulatory requirements;

- not be able to obtain the necessary marketing approvals; or

- breach or terminate their arrangement with us.

If collaboration partners fail to develop or effectively commercialize our products for any of these reasons, we may not be able to replace the collaboration partner with another partner to develop and commercialize the product under the terms of the collaboration. Further, even if we are able to replace the collaboration partner, we may not be able to do so on commercially favorable terms. As a result, the development and commercialization of the affected product or product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to

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continue development and commercialization of the product candidate on our own, which could adversely affect our results of operations.

We have in-licensed or acquired a portion of our intellectual property necessary to develop certain of our psychiatry product candidates. If we fail to comply with our obligations under any of these arrangements, we could lose such licenses or intellectual property rights.

We are a party to and rely on several arrangements with third parties, such as those with Afecta and Rune, which give us rights to intellectual property that is necessary for the development of certain of our product candidates, including SPN-810 and SPN-809, respectively. In addition, we may enter into similar arrangements in the future for other product candidates. Our current arrangements impose various development, financial and other obligations on us. If we materially breach these obligations or if Afecta or Rune fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which would result in our inability to develop, manufacture and sell products that are covered by such intellectual property.

Even if our product candidates receive regulatory approval in the United States, we or our collaborators may never receive approval to commercialize our product candidates outside of the United States.

To market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FDCA in the United States, which relates to the ability of an NDA applicant to use published data not developed by such applicant, may not exist in other countries. In territories where data is not freely available, we may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds.

In addition, regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that any of our product candidates may not be approved for all indications requested which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly post-marketing studies.

Guidelines and recommendations published by various organizations can reduce the use of our products and product candidates.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products and product candidates. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our products.

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We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liabilities.

The use of our product candidates in clinical trials and the sale of any of our products expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our products and product candidates. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, product liability claims may result in:

- decreased demand for any product that has received approval and is being commercialized;
- impairment of our business reputation and exposure to adverse publicity;
- withdrawal of bioequivalence and/or clinical trial participants;
- initiation of investigations by regulators;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize products for which we obtain marketing approval.

Our product liability insurance coverage for our clinical trials is limited to $10 million per claim and $10 million in the aggregate, and covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. On occasion, 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 could cause our stock price to decline. If judgments exceed our insurance coverage, could decrease our cash balance and adversely affect our business.

Healthcare reform measures could hinder or prevent the commercial success of our products or product candidates.

The U.S. government (federal and certain states) and other non-U.S. governments have shown significant and increased interest in pursuing healthcare reform. Government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U. S. or internationally and adversely impact the amount of reimbursement available from governmental agencies or commercial third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce health care costs may adversely affect our ability to set prices for any approved product or to increase prices once launched. These initiatives could adversely impact our ability to generate revenues and achieve and maintain profitability.

In both the U. S. (federal and certain states) and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could adversely affect our ability to sell any approved product profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a comprehensive changes to the United States healthcare system,

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known as the Patient Protection and Affordable Care Act of 2010, as amended by the HealthCare and Education Reconciliation Act of 2010. These laws and their regulations, which we refer to collectively as the HealthCare Reform Law, may have far reaching consequences for biopharmaceutical companies like us. As a result of the HealthCare Reform Law, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend benefits to those who currently lack insurance coverage or changing coverage parameters. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services and drugs. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a new government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring healthcare delivery system in the United States could impact the reimbursement for prescribed drugs, including our products and product candidates. If reimbursement for our approved products is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

In 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 risk evaluations and mitigation strategies approved by the FDA. In 2012, the Food and Drug Administration Safety and Innovation Act was enacted, expanding drug supply chain requirements and strengthening FDA's response to drug shortages, and other changes. 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 assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of any approved product. The Drug Quality and Security Act (DQSA) became law in 2013. The DQSA creates the requirement for companies to trace, verify and identify all products across all changes of ownership from manufacturer to dispenser.

Future federal and state proposals and other countries health care reforms could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially and adversely affected by the HealthCare Reform Law by reducing the amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

Implementation of the HealthCare Reform Law could cause us to incur significant compliance expenses or could subject us to substantial penalties and fines if our business is found to violate these requirements.

The HealthCare Reform Law is multi-faceted and is being implemented in phases. The financial impact of the HealthCare Reform Law on our business is on-going, and there can be no assurance that our business will not be materially harmed by future implementation of the HealthCare Reform Law. In addition, if we are not in full compliance with the HealthCare Reform Law, we could face enforcement action, fines and other penalties and we could receive adverse publicity.

The HealthCare Reform Law includes various provisions designed to strengthen fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge or specific intent to violates the statute.

If our past or present operations are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs and/or the curtailment or restructuring of our operations.

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The risk of our being found in violation of the HealthCare Reform Law, its underlying regulations, or other laws impacted by its implementation is made more complex by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a supplier of pharmaceuticals, certain U.S. federal and state health care laws and regulations pertaining to patients' rights to privacy fraud and abuse are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the HealthCare Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- the FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback, Sunshine Act, and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations could be costly. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and impair our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our

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management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

As we continue to increase the size of our organization we may experience difficulties in managing growth.

Our personnel, systems and facilities currently in place may not be adequate to support future growth. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage our recent and any future growth. In 2015, we increased from 309 employees to 344 employees and increased revenues to $144.4 million from $122.0 million in 2014. Our need to effectively execute our growth strategy requires that we:

manage our regulatory approvals and clinical trials effectively;

manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;

commercialize our product candidates;

improve our operational, financial and management controls, reporting systems and procedures; and

attract, retain and motivate sufficient numbers of talented employees.

This growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. In addition, our growth will cause us to comply with an increasing number of regulations and statutory requirements. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy.

Our business involves the use of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to federal, state, city and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures we use for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations, including our commercialization and research and development efforts. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently maintain biological or hazardous materials insurance coverage.

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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.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors and, as such, we may be subject to claims that we or these employees have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data in our data centers and on our networks, including: intellectual property; our proprietary business information; that of our customers, suppliers and business partners; and personally identifiable information of our employees and patients in our clinical trials. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and regulatory penalties, and could disrupt our operations and damage our reputation, which could adversely affect our business, revenues and competitive position.

Provisions in our agreement with Shire impose restrictive covenants on us, which could limit our ability to operate effectively in the future.

In 2005, we purchased substantially all of the assets of Shire Laboratories Inc. Pursuant to this agreement, we agreed to refrain perpetually from engaging in any research, formulation development, analytical testing, manufacture, technology assessment or oral bioavailability screening that relate to five specific drug compounds (amphetamine, carbamazepine, guanfacine, lanthanum and mesalamine) and any derivative thereof. Although these various restrictions and covenants on us do not currently impact our products, product candidates or business, they could in the future limit or delay our ability to take advantage of business opportunities that may relate to such compounds.

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Risks Related to Our Finances and Capital Requirements

We have been profitable from operations since the fourth quarter of 2014 and there is no assurance that we will continue to generate net income in the future.

In recent years, we have focused primarily on developing our current products and product candidates, with the goal of commercializing these products and supporting regulatory approval for these product candidates. We have financed our operations through various transactions including the following:

- the completion of our $52.3 million initial public offering in May 2012;
- the completion of our follow-on $49.9 million equity offering in November 2012; and
- the completion of our $90 million private placement offering of 7.50% Convertible Senior Secured Notes Due 2019 (the Notes) in May 2013; and
- the monetization of certain future royalty streams in 2014, under our existing license for Orenitram.

We have incurred significant operating losses since inception. As of December 31, 2015, we had an accumulated deficit of approximately $144.6 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, expenses associated with launching our products, and from selling, general and administrative costs associated with our operations. We expect our research and development costs to continue to be substantial and to increase with respect to our product candidates as we advance those product candidates through preclinical studies, clinical trials, manufacturing scale-up and other pre-approval activities. We expect our selling, general and administrative costs to continue to increase as we continue to support the ongoing commercialization of our products.

Our prior losses have had an adverse effect on our stockholders' equity and and cash position. While we anticipate maintaining profitability in 2016 and beyond, we cannot be certain that we will do so. Any potential future losses, if and when they occur, could have an adverse impact on our stockholders' equity and working capital. Furthermore, since the completion of our initial public offering in May 2012, we have incurred additional costs associated with operating as a public company.

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 product candidates, conducting clinical trials, establishing manufacturing relationships and marketing drugs are expensive and uncertain processes.

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. 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:

- our ability to successfully support our products in the marketplace and the rate of increase in the level of sales in the marketplace;
- the rate of progress, clinical success, and cost of our trials and other product development programs for our product candidates;
- the costs and timing of in-licensing additional product candidates or acquiring other complementary companies;

the timing of any regulatory approvals of our product candidates;

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- the actions of our competitors and their success in selling competitive product offerings including generics; 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, or at all. 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 one or more of our development programs or our commercialization efforts.

We may not be able to maintain or increase profitability.

Our ability to remain profitable depends upon our ability to generate increasing levels of revenues from sales of our products, Oxtellar XR and Trokendi XR, and while simultaneously funding the requisite research expenditures to gain FDA approval for our product candidates. 2013 was the first year in which we generated revenue from our first commercial products. Since that time, we have demonstrated the ability to become profitable, and subsequently maintain profitability while allocating cash flow to company's needs. Future revenues from these products will highly depend on our ability to grow demand for them and defend against potential generic competition.

Our operating results may fluctuate significantly.

We expect that any revenues we generate will fluctuate from quarter to quarter and year to year as a result of revenue from approved products, our license agreements, the amount of and timing for development milestones and product revenues received under our collaboration license agreements.

Our net income and other operating results will be affected by numerous factors, including:

- the level of market acceptance for any approved product candidate and underlying demand for that product and wholesalers' buying patterns;

- variations in the level of expenses related to our development programs;

- the success of our bioequivalence and clinical trials through all phases of clinical development;

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

- any delays in regulatory review and approval of product candidates in clinical development;

- the timing of any regulatory approvals, if received, of additional indications for our existing products;

- potential side effects of our products and our future products that could delay or prevent commercialization, cause an approved drug to be taken off the market, or result in litigation;

- any intellectual property infringement lawsuit in which we may become involved;

our ability to maintain an effective sales and marketing infrastructure;

our dependency on third-party manufacturers to supply or manufacture our product candidates;

competition from existing products, new products, or potential generics to our products that may emerge;

regulatory developments affecting our products and product candidates; and

changes in reimbursement environment and regulatory changes.

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

Complying with increased financial reporting and securities laws reporting requirements has increased our costs and requires additional management resources. We may fail to meet these obligations.

We face increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act of 2010, as well as rules of the Securities and Exchange Commission and NASDAQ, for example, has resulted in significant initial cost to us as well as ongoing increases in our legal, audit and financial reporting cost. We anticipate that these costs will further increase when we are no longer an "emerging growth company", which we will anticipate occurring no later than December 31, 2017. Beginning in 2015, we transitioned from being a "smaller reporting company" to an "accelerated filer" status which led to further increases in our legal, audit, NASDAQ listing fees and financial compliance costs. The Securities Exchange Act of 1934, as amended (the Exchange Act) requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our board of directors, management and outside advisors need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and require us to incur substantial costs to maintain the same or similar coverage.

As a public company, we are subject to Section 404(a) of the Sarbanes-Oxley Act relating to internal controls over financial reporting. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404(a). We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any necessary changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify or replace our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls. Any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. We cannot assure that our internal controls over financial reporting will prove to be effective.

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. Together with adequate disclosure controls and procedures, these 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. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act after we no longer qualify as an "emerging growth company," may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses; or may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors

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

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b). We could be an "emerging growth company" until December 31, 2017 unless one of three events occurs earlier than December 31, 2017; (1) we generate $1.0 billion of annual revenue at an earlier date, (2) we issue more than $1.0 billion in non-convertible debt, or (3) we qualify as a large accelerated filer. An independent assessment of the effectiveness of our internal controls will be very expensive and could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

Our ability to utilize our U.S. Federal and state net operating losses or U.S. Federal tax credits is currently limited, and may be limited further, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders change their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period, which is typically three years or since the last ownership change. We are already subject to Section 382 limitations due to cumulative ownership changes that, as of November 15, 2013, totaled more than 50%. As of December 31, 2015, we had U.S. Federal and state net operating loss carryforwards of $91.8 million and research and development tax credit carryforwards of $5.5 million available. Future changes in stock ownership may also trigger an additional ownership change and, consequently, another Section 382 limitation. Any limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization which would reduce our gross deferred income tax assets and corresponding valuation allowance. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and tax credit carryforwards to reduce U.S. Federal and state income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

Risks Related to Our Indebtedness

The Indenture governing the Notes contains restrictions that will limit our operating flexibility.

The Indenture governing the Notes contains covenants that, among other things, restrict our and our existing and future subsidiaries' ability to take specific actions, even if we believe them to be in our best interest. These covenants include restrictions on our ability to:

- incur additional indebtedness and issue certain types of preferred stock; and
- enter into mergers, consolidations or sales or leases of all or substantially all of our assets.

These covenants may limit our operational flexibility and could prevent us from taking advantage of business opportunities as they arise, growing our business or competing effectively.

We may not be permitted, by the agreements governing our existing or future indebtedness, to pay any interest make-whole payment upon conversion in cash, requiring us to issue shares for such amounts, which could result in significant dilution to our stockholders.

If a holder elects to convert some or all of their Notes, if, for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading day period ending within five trading days prior to a

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conversion date, the last reported sale price of our common stock exceeds the applicable conversion price on each such trading day, we will pay such holder an interest make-whole payment in cash or common stock for the Notes being converted. We have the option to issue our common stock to any converting holder in lieu of making the interest make-whole payment in cash. If we elect to issue our common stock for such payment, then the stock will be valued at 95% of the simple average of the daily volume-weighted average price (VWAP) of our common stock for the 10 trading days ending on and including the trading day immediately preceding the conversion date. Agreements governing our existing or future indebtedness may prohibit us from making cash payments in respect of the interest make-whole amount upon a conversion. Notwithstanding the foregoing, in no event will the shares we deliver in connection with a conversion, including those delivered in connection with the interest make-whole amount and repayment of principal, exceed 221.7294 shares per $1,000 principal amount of Notes, subject to adjustment or, in aggregate, 19.96 million shares. If, pursuant to our election to deliver common stock in connection with the payment of the interest make-whole amount, we would be required to deliver a number of shares of common stock in excess of such threshold, we will deliver cash in lieu of any shares otherwise deliverable upon conversions in excess thereof (based on the simple average of the daily VWAP for the 10 trading days ending on and including the trading day immediately preceding the conversion date).

Risks Related to Securities Markets and Investment in Our Stock

We may issue additional shares of our common stock or instruments convertible into shares of our common stock, including in connection with the conversion of our Notes, and thereby materially and adversely affect the market price of our common stock.

Sales of our common stock, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock which would impair our ability to raise future capital through the sale of additional equity securities.

We may conduct future offerings of our common stock, preferred stock or other securities convertible into our common stock to fund acquisitions, finance operations or for other purposes. In addition, as of December 31, 2015, we had outstanding 49,004,674 shares of common stock, of which approximately 2,062,272 shares are restricted securities that may be sold in accordance with the resale restrictions under Rule 144 of the Securities Act or pursuant to a resale registration statement. Also, as of December 31, 2015, we had outstanding options to purchase 2,699,007 shares of common stock that, if exercised, would result in these additional shares becoming available for sale. Approximately 6.5% of these shares and options are held by senior management of the Company. We have also registered all common stock subject to options outstanding or reserved for issuance under our 2005 Stock Plan, 2012 Equity Incentive Plan and 2012 Employee Stock Purchase Plan. An aggregate of 1,330,973 and 206,584 shares of our common stock are reserved for future issuance under the 2012 Equity Incentive Plan and the 2012 Employee Stock Purchase Plan, respectively. In addition, as of December 31, 2015, 1,915,150 shares of our common stock are presently reserved for future issuance upon conversion of the Notes. These shares will be eligible for resale in the public market upon issuance.

On December 17, 2014, the SEC declared effective our registration statement on Form S-3. Under the registration statement, we may offer and sell securities at a maximum aggregate offering price of up to $112.8 million.

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result,

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capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have very limited research coverage by securities and industry analysts. If securities or industry analysts presently covering our business do not continue such coverage or if additional securities or industry analysts do not commence coverage of our Company, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could negatively impact the market price of our common stock.

Provisions in our certificate of incorporation and bylaws, as amended, may have the effect of delaying or preventing a change of control. These provisions include the following:

Our board of directors is divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time. This staggered board structure prevents stockholders from replacing the entire board at a single stockholders' meeting.

Our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors.

Our board of directors may issue, without stockholder approval, shares of preferred stock. The ability to authorize preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Stockholders must provide advance notice to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting. Furthermore, stockholders may only remove a member of our board of directors for cause. These provisions may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect such acquiror's own slate of directors or otherwise attempting to obtain control of our Company.

Our stockholders may not act by written consent. As a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions outside of a stockholders' meeting.

Special meetings of stockholders may be called only by the chairman of our board of directors or a majority of our board of directors. As a result, a holder, or holders, controlling a majority of our capital stock would not be able to call a special meeting.

A supermajority (75%) of the voting power of outstanding shares of our capital stock is required to amend or repeal or to adopt any provision inconsistent with certain provisions of our certificate of incorporation and to amend our by-laws, which make it more difficult to change the provisions described above.

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In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, our bylaws and in the Delaware General Corporation Law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors.

We may not be able to maintain an active public market for our common stock.

We cannot predict the extent to which investor interest in our common stock will allow us to maintain an active trading market on The NASDAQ Global Market or a similar market or how liquid that market might become. If an active public market is not sustained, it may be difficult to sell shares of common stock at a price that is attractive to the investor, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products, product candidates or technologies by using our shares of common stock as consideration.

To the extent outstanding stock options are exercised, there will be dilution to new investors.

As of December 31, 2015, we had options to purchase 2,699,007 shares of common stock outstanding, with exercise prices ranging from $0.40 to $21.21 per share and a weighted average exercise price of $8.94 per share. Upon the vesting of each of these options, the holder may exercise his or her options, which would result in dilution to investors.

The price of our common stock may fluctuate substantially.

The market price for our common stock is likely to be volatile. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, including:

- the commercial performance of Oxtellar XR, Trokendi XR, or any of our product candidates that receive marketing approval;
- substitution of our products in favor of generic versions;
- status of our ongoing patent infringement law suits;
- the filing of ANDAs by generic companies seeking approval to market generic versions of our products;
- plans for, progress in and results from clinical trials of our product candidates generally;
- FDA or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- fluctuations in stock market prices for the U.S. stock market;

variations in our quarterly operating results;

changes in accounting principles;

litigation or public concern about the safety of our products and/or potential products;

actual and anticipated fluctuations in our quarterly operating results;

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deviations in our operating results from the estimates of securities analysts;

additions or departures of key personnel;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

changes in third-party coverage and reimbursement policies for our products and/or product candidates; and

discussion by us or our stock price in the financial or scientific press or online investor communities.

The realization of any of the risks described in these "Risk Factors" could have a dramatic, material and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility. Any such litigation brought against us could result in substantial costs and a diversion of management attention, which could hurt our business, operating results and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal executive offices are located at 1550 East Gude Drive, Rockville, Maryland 20850, where we occupy approximately 44,500 square feet of laboratory and office space. Our lease term expires in April 30, 2020 with an option for a five-year extension. We also lease approximately 20,530 square feet of office space in an adjacent building to our existing office space located at 1500 East Gude Drive, Rockville, MD 20850 with a co-terminus lease term date of April 30, 2020. We believe that these facilities are sufficient for our present and contemplated operations.

ITEM 3. LEGAL PROCEEDINGS.

From time to time and in the ordinary course of business, we are subject to various claims, charges and litigation. We may be required to file infringement claims against third parties for the infringement of our patents. We have filed such claims for infringement of the Orange Book patents listed for our products Oxtellar XR and Trokendi XR.

Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al., C.A. Nos. 13-4740; 14-1981 (RMB)(JS) (D.N.J.)

We received a Paragraph IV Notice Letter against two of our Oxtellar XR Orange Book patents (United States Patent Nos. 7,722,898 and 7,910,131) from generic drug maker Watson Laboratories, Inc. Florida (WLF) n/k/a Actavis Laboratories FL, Inc. (Actavis Labs FL) on June 26, 2013. On August 7, 2013, we filed a lawsuit against Actavis, Inc., Actavis Labs FL, Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc. (collectively Actavis) alleging infringement of United States Patent Nos. 7,722,898 and 7,910,131. We received a second Paragraph IV Notice Letter against later-issued Oxtellar XR Orange Book Patent United States Patent No. 8,617,600 on February 20, 2014. On March 28, 2014, we filed a second lawsuit against Actavis alleging infringement of United States Patent No. 8,617,600. We have since listed two additional Orange Book patents: United States Patent Nos. 8,821,930 and 9,119,791. Our United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, 8,821,930, and 9,119,791 generally cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. The FDA Orange Book lists all five of our Oxtellar XR patents as expiring on April 13, 2027.

Both Complaints filed in the U.S. District Court for the District of New Jersey allege, inter alia, that Actavis infringed our Oxtellar XR patents by submitting to the FDA an ANDA seeking to market a

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generic version of Oxtellar XR prior to the expiration of our patents. The two cases were consolidated for all purposes on October 8, 2015.

A seven-day bench trial for the consolidated action involving United States Patent Nos. 7,722,898, 7,910,131, and 8,617,600 was held between November 18 and December 4, 2015. On February 5, 2016, the Court issued an opinion and order finding that: (i) Actavis's ANDA products infringe United States Patent Nos. 7,722,898 and 7,910,131; (ii) Actavis's ANDA products do not infringe U.S. Patent No. 8,617,600 and (iii) United States Patent Nos. 7,722,898, 7,910,131, and 8,617,600 are valid. The Court entered a final judgment on February 18, 2016: (i) enjoining the FDA from approving Actavis's ANDA before the expiration date of United States Patent Nos. 7,722,898 and 7,910,131; and (ii) enjoining Actavis from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Actavis's ANDA Products until the expiration of United States Patent Nos. 7,722,898 and 7,910,131. On February 19, 2016, Actavis filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit. The appeal was docketed on February 24, 2016.

Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al., C.A. Nos. 15-2499 (RMB)(JS) (D.N.J.)

We received a Paragraph IV Notice Letter against United States Patent No. 8,821,930 from Actavis Labs FL on February 21, 2015. On April 7, 2015, we filed a third lawsuit against Actavis alleging infringement of United States Patent No. 8,821,930.

The Complaint filed in the U.S. District Court for the District of New Jersey alleges, inter alia, that Actavis infringed United States Patent No. 8,821,930 by submitting to the FDA an ANDA seeking to market a generic version of Oxtellar XR prior to the expiration of United States Patent No. 8,821,930. On April 30, 2015, Actavis answered the Complaint, denying the substantive allegations of that Complaint. Actavis Labs FL also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity of United States Patent No. 8,821,930. On June 9, 2015, we filed our Reply, denying the substantive allegations of those Counterclaims.

Following an October 7, 2015 Markman hearing, the Court issued a claim construction order for this case on October 9, 2015. The case is proceeding through fact discovery.

Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc., et al., C.A. Nos. 15-369 (RMB)(JS) (D.N.J.)

We received a Paragraph IV Notice Letter against United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930 from generic drug maker TWi Pharmaceuticals, Inc. on December 9, 2014. On January 16, 2015, we filed a lawsuit against TWi Pharmaceuticals, Inc. and TWi International LLC (d/b/a TWi Pharmaceuticals USA) (collectively TWi) alleging infringement of United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930.

The Complaint filed in the U.S. District Court for the District of New Jersey alleges, inter alia, that TWi infringed our Oxtellar XR patents by submitting to the FDA an ANDA seeking to market a generic version of Oxtellar XR prior to the expiration of our patents. Filing the Complaint within 45 days of receiving TWi's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving TWi's ANDA for 30 months from the date of our receipt of the first Paragraph IV certification notice. On February 13, 2015, TWi answered the Complaint and TWi Pharmaceuticals, Inc. and denied the substantive allegations of the complaint. TWi also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity of United States Patent Nos. 7,722,898 and 7,910,131. On March 20, 2015, we filed our Reply, denying the substantive allegations of those Counterclaims.

Following an October 7, 2015 Markman hearing, the Court issued a claim construction order for this case on October 9, 2015. The case is proceeding through fact discovery.

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Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al., C.A. Nos. 15-8342 (RMB)(JS) (D.N.J.)

We received a Paragraph IV Notice Letter against United States Patent No. 9,119,791 from Actavis Labs FL on October 15, 2015. On November 25, 2015, we filed a fourth lawsuit against Actavis alleging infringement of United States Patent No. 9,119,791.

The Complaint filed in the U.S. District Court for the District of New Jersey alleges, inter alia, that Actavis infringed United States Patent No. 9,119,791 by submitting to the FDA an ANDA seeking to market a generic version of Oxtellar XR prior to the expiration of United States Patent No. 9,119,791. On January 29, 2016, Actavis answered the Complaint, denying the substantive allegations of that Complaint. Actavis Labs FL also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity of United States Patent No. 9,119,791. We have not yet filed a Reply. A telephonic status conference is currently set for March 9, 2016.

Supernus Pharmaceuticals, Inc. v. Actavis, Inc., C.A. No. 14-6102 (SDW)(LDW) (D.N.J.)

We received three Paragraph IV Notice Letters against six Trokendi XR Orange Book patents, namely United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, 8,877,248, 8,889,191, and 8,992,989 from generic drug maker Actavis Laboratories FL, Inc. These patents cover once-a-day topiramate formulations and methods of treating seizures using those formulations. On October 1, 2014, we initiated a lawsuit against Actavis; the lawsuit alleges infringement of the Trokendi XR Orange Book patents. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on April 4, 2028 and United States Patent Nos. 8,298,580, 8,663,683, 8,877,248, 8,889,191, and 8,992,989 as expiring on November 16, 2027.

This action for patent infringement filed in the U.S. District Court for the District of New Jersey alleges Actavis infringed the Trokendi XR patents by, inter alia, submitting to the FDA an ANDA seeking to market a generic version of Trokendi XR prior to the expiration of these patents. Actavis answered these allegations with affirmative defenses and counterclaims of noninfringement and invalidity of the patents in suit. Filing its October 1, 2014 Complaint within 45 days of receiving the first of three Actavis Laboratories FL, Inc. Paragraph IV Notice Letters entitles Supernus to an automatic stay preventing the FDA from approving Actavis's ANDA for 30 months from the date of our receipt of such Notice Letter.

This case has been consolidated for pretrial purposes with two other actions pending in the District of New Jersey concerning infringement of the Trokendi XR Orange Book patents, those actions being C.A. No. 14-7272 (against Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited) and also C.A. No. 15-326 (against Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.). The Company has since entered into a settlement agreement with Par (see below). A Rule 16 scheduling conference was held on April 14, 2015. The Court issued a Scheduling Order on May 22, 2015, which was amended on July 28, 2015, August 24, 2015, October 5, 2015, and November 17, 2015. The case is proceeding through fact discovery. A Markman hearing took place on February 3, 2016. No date has been set for trial.

Supernus Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc., C.A. No. 14-7272 (SDW)(LDW) (D.N.J.)

We received three Paragraph IV Notice Letters against six Trokendi XR Orange Book patents, namely United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, 8,877,248, 8,889,191, and 8,992,989 from generic drug maker Zydus Pharmaceuticals (USA) Inc. These patents cover once-a-day topiramate formulations and methods of treating seizures using those formulations. On November 21, 2014, we initiated a lawsuit against Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively Zydus); the lawsuit alleges infringement of the Trokendi XR Orange Book patents. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on April 4, 2028 and

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United States Patent Nos. 8,298,580, 8,663,683, 8,877,248, 8,889,191 and 8,992,989 as expiring on November 16, 2027.

This action for patent infringement filed in the U.S. District Court for the District of New Jersey alleges Zydus infringed the Trokendi XR patents by, inter alia, submitting to the FDA an ANDA seeking to market a generic version of Trokendi XR prior to the expiration of these patents. Zydus answered these allegations with affirmative defenses and counterclaims of noninfringement and invalidity of the patents in suit. Filing its November 21, 2014 Complaint within 45 days of receiving the first of three Paragraph IV Notice Letters from Zydus Pharmaceuticals (USA) Inc. entitles Supernus to an automatic stay preventing the FDA from approving Zydus's ANDA for 30 months from the date of our receipt of such Notice Letter.

This case has been consolidated for pretrial purposes with two other actions pending in the District of New Jersey concerning infringement of the Trokendi XR Orange Book patents, those actions being C.A. No. 14-6102 (against Actavis, Inc., Actavis Laboratories FL, Inc., Actavis plc, Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc.) and also C.A. No. 15-326 (against Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.). The Company has since entered into a settlement agreement with Par (see below). A Rule 16 scheduling conference was held on April 14, 2015. The Court issued a Scheduling Order on May 22, 2015, which was amended on July 28, 2015, August 24, 2015, October 5, 2015, and November 17, 2015. The case is proceeding through fact discovery. A Markman hearing took place on February 3, 2016. No date has been set for trial.

Supernus Pharmaceuticals, Inc. v. Par Pharmaceutical Companies, Inc., C.A. No. 15-326 (SDW)(LDW) (D.N.J.)

We received three Paragraph IV Notice Letters against six Trokendi XR Orange Book patents, namely United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, 8,877,248, 8,889,191, and 8,992,989 from generic drug maker Par Pharmaceutical, Inc. These patents cover once-a-day topiramate formulations and methods of treating seizures using those formulations. On January 16, 2015, we initiated a lawsuit against Par; the lawsuit alleges infringement of the Trokendi XR Orange Book patents. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on April 4, 2028 and United States Patent Nos. 8,298,580, 8,663,683, 8,877,248, 8,889,191, and 8,992,989 as expiring on November 16, 2027.

This action for patent infringement filed in the U.S. District Court for the District of New Jersey alleges Par infringed the Trokendi XR patents by, inter alia, submitting to the FDA an ANDA seeking to market a generic version of Trokendi XR prior to the expiration of these patents. Par answered these allegations with affirmative defenses and counterclaims of noninfringement and invalidity of the patents in suit. Filing its January 16, 2015 Complaint within 45 days of receiving the first of three Paragraph IV Notice Letters from Par Pharmaceutical, Inc. entitles Supernus to an automatic stay preventing the FDA from approving Par's ANDA for 30 months from the date of our receipt of such Notice Letter.

The Company announced on October 15, 2015 that it has entered into a settlement agreement with Par regarding this case. The settlement permits Par to begin selling a generic version of Trokendi XR on April 1, 2025, or earlier under certain circumstances. The agreement is subject to a consent judgment that was entered by the U.S. District Court for the District of New Jersey. In the consent judgment, Par acknowledges that the Orange Book-listed patents for Trokendi XR owned by Supernus, namely United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, 8,877,248, 8,889,191, and 8,992,989, are valid and enforceable with respect to Par's ANDA product, and would be infringed by Par's ANDA product. The agreement has been submitted to the applicable governmental agencies.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES.

Our common stock has been listed on The NASDAQ Global Market under the symbol "SUPN" since May 1, 2012. Prior to that date, there was no public trading market for our common stock. The following table sets forth for the periods indicated the high and low intra-day sales prices per share of our common stock as reported on the Nasdaq Global Market.

	High	Low
2015		
First Quarter	$ 12.38	$ 7.97
Second Quarter	$ 18.55	$ 11.11
Third Quarter	$ 23.30	$ 13.32
Fourth Quarter	$ 20.39	$ 12.54
2014		
First Quarter	$ 10.55	$ 7.36
Second Quarter	$ 11.20	$ 7.09
Third Quarter	$ 11.47	$ 7.94
Fourth Quarter	$ 9.53	$ 7.31

On December 31, 2015, the closing price of our common stock on The NASDAQ Global Market was $13.44 per share. As of December 31, 2015, we had 16 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders 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 stockholders whose shares may be held in trust by other entities.

We have never declared or paid any cash dividends on our capital stock and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

During the three months ended December 31, 2015, the Company granted options to employees to purchase an aggregate of 20,700 shares of common stock at an exercise price of $13.17 per share. The options are exercisable for a period of ten years from the grant date. These issuances were exempt from registration in reliance on Section 4(a)(2) of the Securities Act as transactions not involving any public offering.

The following graph sets forth the Company's total cumulative stockholder return as compared to the NASDAQ Stock Market Composite Index and the NASDAQ Biotechnology Index, for the period beginning May 1, 2012 and ending December 31, 2015. Total stockholder return assumes $100 invested at the beginning of the period in the common stock of the Company, the stocks represented in the NASDAQ Composite Index and the NASDAQ Biotechnology Index, respectively. Total return assumes reinvestment of dividends; the Company has paid no dividends on its common stock. Historical price performance should not be relied upon as indicative of future stock performance.

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COMPARISON OF 44 MONTH CUMULATIVE TOTAL RETURN*

Among Supernus Pharmaceuticals, Inc., the NASDAQ Composite Index
and the NASDAQ Pharmaceutical Index

*
$100 invested on 5/1/12 in stock or 4/30/12 in index, including reinvestment of dividends. Fiscal year ending December 31.

Performance Graph Data

	Supernus Pharmaceuticals, Inc.	NASDAQ Composite Index	NASDAQ Pharmaceuticals Index
May 1, 2012	$ 100.00	$ 100.00	$ 100.00
December 31, 2012	133.52	99.83	117.18
December 31, 2013	140.41	141.91	196.73
December 31, 2014	154.56	161.22	255.38
December 31, 2015	250.28	170.82	267.24

The performance graph and related information shall not be deemed "soliciting material" or be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference into such filing.

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ITEM 6. SELECTED FINANCIAL DATA.

The following selected financial data should be read together with the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes to those financial statement included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended December 31, 2015, 2014 and 2013 and balance sheet data as of December 31, 2015 and 2014 set forth below have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2012 and 2011 and the balance sheet data as of December 31, 2013, 2012 and 2011 set forth below has been derived from the audited financial statements for such year not included in this Annual Report on Form 10-K. The historical periods presented here are not necessarily indicative of future results.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Revenue					
Net product sales	$ 143,526	$ 89,571	$ 11,552	$	$
Revenue from royalty agreement		30,000			
Licensing revenue	901	2,474	467	1,480	803
Total revenue	144,427	122,045	12,019	1,480	803
Costs and expenses					
Cost of product sales	8,423	5,758	1,104		
Research and development	29,135	19,586	17,245	23,517	30,627
Selling, general and administrative	89,204	72,471	55,590	20,132	7,928
Total costs and expenses	126,762	97,815	73,939	43,649	38,555
Operating income (loss)	17,665	24,230	(61,920)	(42,169)	(37,752)
Other income (expense)					
Interest income	643	348	299	120	31
Interest expense	(1,229)	(4,963)	(7,849)	(3,575)	(1,866)
Changes in fair value of derivative liabilities	193	2,809	(13,354)	(710)	85
Loss on extinguishment of debt	(2,338)	(2,592)	(9,550)		
Other income	38	39	101	50	32
Total other expense	(2,693)	(4,359)	(30,353)	(4,115)	(1,718)
Earnings (loss) from continued operations before income tax	14,972	19,871	(92,273)	(46,284)	(39,470)
Income tax expense (benefit)	956				(16,245)
Income (loss) from continued operations	14,016	19,871	(92,273)	(46,284)	(23,225)
Income from discontinued operations, net of tax					2,188
Gain on disposal of discontinued operations, net of tax					74,852
Income (loss) from discontinued operations					77,040
Net Income (Loss)	14,016	19,871	(92,273)	(46,284)	53,815
Cumulative dividends on Series A convertible preferred stock				(1,143)	(3,430)
Net income (loss) attributable to common stockholders	$ 14,016	$ 19,871	$ (92,273)	$ (47,427)	$ 50,385

Income (loss) per common share:

Basic					
Continuing operations	$ 0.30	$ 0.47	$ (2.90)	$ (2.72)	$ (16.60)
Discontinued operations					47.99
Net income (loss)	0.30	0.47	(2.90)	(2.72)	31.39
Diluted					
Continuing operations	$ 0.28	$ 0.32	$ (2.90)	$ (2.72)	$ (16.60)
Discontinued operations					47.99
Net income (loss)	0.28	0.32	(2.90)	(2.72)	31.39
Weighted-average number of common shares outstanding:					
Basic	47,485,258	42,260,896	31,848,299	17,440,910	1,605,324
Diluted	51,160,380	50,583,511	31,848,299	17,440,910	1,605,324

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	Year Ended December 31,				
	2015	2014	2013	2012	2011
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents and marketable securities	$ 62,190	$ 74,336	$ 82,191	$ 88,508	$ 48,544
Long term marketable securities	55,009	19,816	8,756		
Working capital	49,880	81,399	70,761	68,479	30,629
Total assets	188,730	137,508	110,995	93,989	53,730
Convertible notes, net of discount	7,189	26,947	34,393		
Secured notes payable, including current portion				22,897	29,486
Accumulated deficit	(144,641)	(158,657)	(178,528)	(86,255)	(39,971)
Total stockholders' equity	118,875	71,354	33,464	57,570	9,443

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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 our consolidated financial statements and related notes thereto appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, some of the information in this discussion and analysis contains forward-looking statements reflecting our current expectations and involves risk and uncertainties. For example, statements regarding our expectations as to our plans and strategy for our business, future financial performance, expense levels and liquidity sources are forward-looking statements. Our actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under the "Risk Factors" section and elsewhere in this report.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. In 2013, we launched Oxtellar XR (extended-release oxcarbazepine) and Trokendi XR (extended-release topiramate), our two novel treatments for epilepsy. Since that time, we have significantly grown our net product sales.

Oxtellar XR and Trokendi XR were the first once-daily extended release oxcarbazepine and topiramate products to be launched, indicated for patients with epilepsy in the U.S. market. Total net revenues from these products reached $143.5 million in 2015 representing significant growth compared to the $89.6 million in product revenue in 2014.

We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies, products, and product candidates. We currently have five U.S. patents issued covering Oxtellar XR and six U.S. patents issued covering Trokendi XR, with the patents expiring no earlier than 2027 for each product.

In addition, we are developing multiple product candidates in psychiatry to address large unmet medical needs and market opportunities. With SPN-810, we are developing this product candidate to treat impulsive aggression (IA) in patients who have ADHD. There are currently no approved products indicated for the treatment of IA. With SPN-812, we are developing this product candidate to treat patients who have ADHD with a novel, non-stimulant medication.

Data from Intercontinental Marketing Services (IMS) shows 111,627 prescriptions filled for both drugs during the three months ended December 31, 2015, representing a 61.3% increase over the 69,208 product prescriptions for the fourth quarter of 2014 an increase of 10.8% as compared to the three months ended September 30, 2015. Product prescriptions for Trokendi XR and Oxtellar XR totaled 378,173 for the year ended 2015, a 90.6% increase over the 198,391 product prescriptions for the year ended 2014. We expect the number of prescriptions filled for Oxtellar XR and Trokendi XR to continue to increase in subsequent years.

Net product sales for the year ended December 31, 2015 totaled $143.5 million, an increase of 60.2% over the last year period. Total net product sales for the fourth quarter of 2015 were $42.6 million, compared to total net product sales of $30.5 million for the same quarter last year, an increase of 39.6%.

Operating income for the year ended December 31, 2015 totaled $17.7 million. Excluding the $30 million royalty revenue recognized in 2014, operating loss for 2014 was $5.6 million. Operating income increased by $23.3 million from year ended December 31, 2014 to year ended December 31, 2015.

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We have received several Paragraph IV Notice Letters concerning Oxtellar XR and Trokendi XR from various third-parties. In response to these Paragraph IV notice letters, we have initiated litigation against these third parties alleging infringement of our intellectual property rights. We intend to vigorously defend our intellectual property rights in each of these cases. We anticipate continuing to incur increasing amounts of legal fees and related expenses for these cases as they progress. (See Part I, Item 3 Legal Proceedings for additional information.)

We initiated two Phase III clinical trials for SPN-810 during the third quarter of 2015 and a Phase IIb clinical trial for SPN-812 in the fourth quarter of 2015.

On February 8, 2016, the Company announced a ruling that three patents covering Oxtellar XR were valid and that Actavis infringed on two of these three patents by submitting an ANDA to the FDA.

We expect to incur significant research and development expenses related to the continued development of each of our product candidates, with total cost of approximately $100 million for each of the two programs through FDA approval.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and bases of presentation for our consolidated financial statements are described in Note 2 "Summary of Significant Accounting Policies." The preparation of our financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

We believe the following accounting policies and estimates to be critical:

Revenue Recognition and Net Sales Deductions

Revenue from product sales is recognized when persuasive evidence of an arrangement exists; delivery has occurred and title to the product and associated risk of loss has passed to the customer; the price is fixed or determinable; collection from the customer has been reasonably assured; all performance obligations have been met; and returns and allowances can be reasonably estimated. Product sales are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions as well as estimated product returns (collectively, "sales deductions").

We derive our estimated sales deductions from an analysis of historical levels of deductions specific to each product. In addition, we also consider the impact of anticipated changes in product price, sales trends and changes in managed care coverage and co-pay assistance.

For a complete description of Trokendi XR and Oxtellar XR gross revenues and gross to net adjustments, see Part II, Item 8, Financial Statements and Supplemental Data, Note 2, Revenue Recognition.

In the third quarter of 2014, the Company recognized $30.0 million in revenue from a royalty agreement related to HealthCare Royalty's (HC Royalty) purchase of certain of the Company's rights under the license agreement with United Therapeutics Corporation related to the commercialization of Orenitram. The Company recognized this revenue immediately because (1) the executed contract constituted persuasive evidence of an arrangement, (2) the delivery of the license had occurred and the Company has no current or future performance obligations, (3) the total consideration for the license amendment was fixed and known at the time of its execution and there were no rights of return, and (4) the cash was received and is non-refundable.

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Deferred Legal Fees

Deferred legal fees are comprised of costs incurred in connection with defense of patents for Oxtellar XR and Trokendi XR (see Part I, Item 3 Legal Proceedings).

Deferred legal fees have been incurred in connection with legal proceedings related to patents for Oxtellar XR and Trokendi XR (see Part II, Item 8 Financial Statements and Supplementary Data, Note 6). Amortization of the deferred legal fees will begin upon successful outcome of the on-going litigation. Deferred legal fees will be charged to expense in the event of an unsuccessful outcome of the on-going litigation.

Research and Development Expenses

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee-related expenses, including salaries and benefits; share-based compensation expense; expenses incurred under agreements with clinical research organizations (CROs), investigative sites, consultants and other vendors that conduct the Company's clinical trials; the cost of acquiring and manufacturing clinical trial materials; the cost of manufacturing materials used in process validation, to the extent that those materials are manufactured prior to receiving regulatory approval for those products and are not expected to be sold commercially; facilities costs that do not have an alternative future use; related depreciation and other allocated expenses; license fees for and milestone payments related to in-licensed products and technologies; and costs associated with animal testing activities and regulatory approvals.

Results of Operations

Comparison of the year ended December 31, 2015 and December 31, 2014

	Year Ended December 31,		Increase/ (decrease)
	2015	2014	
	(in thousands)		
Revenues:			
Net product sales	$ 143,526	$ 89,571	53,955
Revenue from royalty agreement		30,000	(30,000)
Licensing revenue	901	2,474	(1,573)
Total revenues	144,427	122,045	
Costs and expenses			
Cost of product sales	8,423	5,758	2,665
Research and development	29,135	19,586	9,549
Selling, general and administrative	89,204	72,471	16,733
Total costs and expenses	126,762	97,815	
Operating income	17,665	24,230	
Other income (expense)			
Interest income and other income, net	681	387	294
Interest expense	(1,229)	(4,963)	3,734
Changes in fair value of derivative liabilities	193	2,809	(2,616)
Loss on extinguishment of debt	(2,338)	(2,592)	254
Total other expenses	(2,693)	(4,359)	
Earnings before income taxes	14,972	19,871	
Income tax	956		956
Net income	$ 14,016	$ 19,871	

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Net Product Sales. Our net product sales of $143.5 million for the year ended December 31, 2015 are comprised of $33.2 million of revenue from Oxtellar XR and $110.3 million of revenue from Trokendi XR. Net product sales are based on gross revenue from shipments to distributors, less estimates for discounts, rebates, other sales deductions and returns. The increase in net product sales from 2014 to 2015 is primarily driven by increased prescriptions.

Our net product sales of $89.6 million for the year ended December 31, 2014 are comprised of $24.7 million of revenue from Oxtellar XR and $64.9 million of revenue from Trokendi XR. Net product sales are based on gross revenue from shipments to distributors, less estimates for discounts, rebates, other sales deductions and returns.

Revenue from Royalty Agreement. Revenue of $30.0 million during the year ended December 31, 2014 was a one-time payment pursuant to an agreement with HC Royalty.

Licensing Revenue. Total licensing revenue for the year ended December 31, 2015 was $0.9 million. There was $0.8 million in revenue generated from achievement of milestones in the year ended December 31, 2015. The Company recognized $2.5 million in licensing revenue in 2014.

Research and Development Expense. Research and development expenses during the year ended December 31, 2015 were $29.1 million as compared to $19.6 million for the year ended December 31, 2014, an increase of $9.5 million or 48.75%. This increase is due to preclinical and clinical trials and manufacturing scale up activities for both of our product candidates, SPN-810 and SPN-812. During 2015, we initiated two Phase III trials for SPN-810 and a Phase IIb trial for SPN-812. We expect R&D costs to increase significantly in 2016 and beyond, as we continue to advance these trials and the related development activities for both of these programs.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses were $89.2 million during the year ended December 31, 2015 as compared to $72.5 million for the year ended December 31, 2014, an increase of $16.7 million or 23.1%. The increase in SG&A expenses is primarily due the continued expansion of our sales and marketing efforts for both Trokendi XR and Oxtellar XR, including promotional material and grants. In addition, we expended effort to prepare for the launch of the migraine indication for Trokendi XR in 2016.

Interest Expense. Interest expense was $1.2 million during the year ended December 31, 2015 as compared to $5.0 million for the year ended December 31, 2014. The decrease of $3.8 million was primarily due to a decrease in the principal amount of our outstanding 7.5% Convertible Senior Secured Notes due in 2019 (the Notes) from $36.1 million at December 31, 2014 to $8.5 million at December 31, 2015. During the year ended December 31, 2015, the $27.5 million of Notes and related accrued interest converted into 5.7 million common stock.

Changes in Fair Value of Derivative Liability. During the year ended December 31, 2015, we recognized a non-cash gain of $0.2 million related to a change in estimated fair value of the interest make-whole derivative liability related to our Notes. This gain is primarily due to the passage of time and because our stock price remains above the $5.30 conversion price. During the year ended December 31, 2014, we recognized a non-cash gain of $2.8 million related to a change in estimated fair value of the interest make-whole derivative liability related to our Notes. This gain is primarily due to the passage of time.

Loss on Extinguishment of Debt. During the year ended December 31, 2015, we recognized a non-cash loss on extinguishment of debt of $2.3 million related to the conversion of $27.5 million of our Notes. During the year ended December 31, 2014, we recognized a non-cash loss on extinguishment of debt of $2.6 million related to the conversion of $13.4 million of our Notes.

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Income Tax. During the year ended December 31, 2015, we recorded $1.0 million of current tax expense related primarily to an increase in our reserve for an uncertain tax position related to the Alternative Minimum Tax.

Net Income. We realized net income of $14.0 million during the year ended December 31, 2015, compared to a net income of $19.9 million during the year ended December 31, 2014, a decrease of $5.9 million. Excluding the one-time payment of $30 million received from HC Royalty during 2014, there would have been a net loss of $10.1 million at year ended December 31, 2014. This change was primarily due to the revenue generated from our two commercial products, Oxtellar XR and Trokendi XR, offset by increased expenses incurred in preparing for the late stage studies for two product candidates and an increase in marketing expenditures associated with ongoing support of Oxtellar XR and Trokendi XR.

Comparison of the year ended December 31, 2014 and December 31, 2013

	Year Ended December 31,		Increase/ (decrease)
	2014	2013	
	(in thousands)		
Revenues:			
Net product sales	$ 89,571	$ 11,552	78,019
Revenue from royalty agreement	30,000		30,000
Licensing revenue	2,474	467	2,007
Total revenues	122,045	12,019	
Costs and expenses			
Cost of product sales	5,758	1,104	4,654
Research and development	19,586	17,245	2,341
Selling, general and administrative	72,471	55,590	16,881
Total costs and expenses	97,815	73,939	
Operating loss	24,230	(61,920)	
Other income (expense)			
Interest income and other income (expense), net	387	400	(13)
Interest expense	(4,963)	(7,849)	2,886
Changes in fair value of derivative liabilities	2,809	(13,354)	16,163
Loss on extinguishment of debt	(2,592)	(9,550)	6,958
Total other expenses	(4,359)	(30,353)	
Net Income (loss)	$ 19,871	$ (92,273)	

Net Product Sales. Our net product sales of $89.6 million for the year ended December 31, 2014 are comprised of $24.7 million of revenue from Oxtellar XR and $64.9 million of revenue from Trokendi XR. Net product sales are based on gross revenue from shipments to distributors, less estimates for discounts, rebates, other sales deductions and returns. The increase in sales from 2013 to 2014 is driven primarily by increased prescriptions.

Our net product sales of $11.6 million for the year ended December 31, 2013 are comprised of $11.0 million of revenue from Oxtellar XR and $0.6 million of revenue from Trokendi XR. Net product sales for Oxtellar XR are based on gross revenue from shipments to distributors, less estimates for discounts, rebates, other sales deductions, and returns. Net product sales for Trokendi XR are based on prescriptions filled at the pharmacy level during the third quarter of 2013, net of sales deductions, rebates, and other sales deductions.

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Revenue from Royalty Agreement. In 2014, the Company entered into an agreement with HC Royalty, resulting in payment of $30 million for certain rights related to Orenitram.

Licensing Revenue. The licensing revenue for the year ended December 31, 2014 consisted primarily of the United Therapeutics Corporation milestone payment of $2.0 million under their license agreement with the Company. There was no revenue generated from the achievement of milestones in the year ended December 31, 2013.

Research and Development Expense. Research and development expenses during the year ended December 31, 2014 were $19.6 million as compared to $17.2 million for the year ended December 31, 2013, an increase of $2.4 million or 13.5%. This increase is due to preclinical trials, clinical trials and manufacturing scale up for both of our product candidates, SPN-810 and SPN-812.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses were $72.5 million during the year ended December 31, 2014 as compared to $55.6 million for the year ended December 31, 2013, an increase of $16.9 million or 30.4%. This increase was mainly due to increased compensation and travel expense due to the expansion of our sales force during the year ended December 31, 2014, coupled with increased marketing expenses such as sample distribution to support the growth of Oxtellar XR and Trokendi XR.

Interest Expense. Interest expense decreased from $7.8 million for the year ended December 31, 2013 to $5.0 million during the year ended December 31, 2014. The decrease of $2.8 million was primarily due to a decrease in the principal amount of our outstanding Notes, from $49.5 million at January 1, 2014 to $36.1 million at December 31, 2014.

Changes in Fair Value of Derivative Liability. During the year ended December 31, 2014, we recognized a non-cash gain of $2.8 million related to a change in estimated fair value of the interest make-whole derivative liability related to our Notes. This gain is primarily due to the passage of time and because our stock price remains above the $5.30 conversion price. We recognized a non-cash expense of $13.4 million associated with the interest make-whole derivative during the year ended December 31, 2013, due primarily to the effect of the increase in our stock price on the valuation of the derivative liability.

Loss on Extinguishment of Debt. During the year ended December 31, 2014, we recognized a non-cash loss on extinguishment of debt of $2.6 million related to the conversion of $13.4 million of our Notes. During the year ended December 31, 2013, we recognized a non-cash charge of $8.4 million related to the conversion of $40.5 million of our Notes and $1.2 million on extinguishment of our secured credit facility.

Net Income/(Loss). We realized net income of $19.9 million during the year ended December 31, 2014 as compared to a net loss of $92.3 million during the year ended December 31, 2013, a change of $112.2 million. Excluding the one-time payment of $30 million received from HealthCare Royalty during 2014, there would have been a net loss of $10.1 million at year ended December 31, 2014. This increase in net income was primarily due to revenue generated from our two commercial products, Oxtellar XR and Trokendi XR, partially offset by increased expenses incurred associated with the expansion of our sales force, higher marketing expenses, and increased research and development expenses.

Liquidity and Capital Resources

We believe our increasing levels of net product sales will be sufficient to finance our operations in 2016 and subsequent years, including the increased research and development expenses for our clinical trials. We expect to incur significantly increased R&D expenses in 2016 and in subsequent years to support

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the development of SPN-810 and SPN-812 including the Phase III trials for SPN-810, the Phase IIb trial for SPN-812, and follow on Phase III trials for SPN-812.

Our working capital at December 31, 2015 was $49.9 million, a decrease of $31.5 million compared to our working capital of $81.4 million at December 31, 2014. Our long term marketable securities at December 31, 2015 were $55.0 million, an increase of $35.2 million compared to our long term marketable securities of $19.8 million at December 31, 2014.

Our stockholders' equity increased by $47.5 million during the year ended December 31, 2015 primarily as a result of the issuance of shares related to the conversion of our Notes, coupled with net income of $14.0 million.

In July 2014, we entered into a Royalty Interest Acquisition Agreement with HC Royalty. Pursuant to this Interest Acquisition Agreement, HC Royalty paid us $30.0 million in consideration for acquiring certain royalty and milestone rights related to the commercialization of Orenitram (treprostinil) Extended-Release Tablets by United Therapeutics Corporation. Full ownership of the royalty rights will revert back to us after a certain threshold has been reached per the terms of the Agreement.

In addition to income from operations, we have historically financed our business through the sale of our debt and equity securities. Our most recent financing occurred May 3, 2013, when we issued $90.0 million aggregate principal amount of Notes to qualified institutional buyers, the initial purchasers of the Notes (Initial Purchasers).

As of December 31, 2015, holders of the Notes have converted a total of approximately $81.5 million of the Notes. Cumulatively, through December 31, 2015, we issued a total of approximately 15.4 million shares of common stock in conversion of the principal amount of the Notes and issued an additional 2.2 million shares of common stock and paid approximately $1.7 million cash in settlement of the interest make-whole provision related to the converted Notes.

Subsequent to December 31, 2015, holders of the Notes converted approximately $2.0 million of the Notes and we issued a total of approximately 0.4 million shares of common stock in conversion of the principal amount of the Notes and accrued interest thereon.

We believe our current working capital and long term marketable securities, along with increased revenues from increasing product sales, will be sufficient to finance the Company. We achieved positive cash flow and profitability from operations in each quarter of 2015. While we expect continued profitability in 2016 as we continue to increase sales while also increasing activities and spending to advance our clinical product candidates, we anticipate there may be significant variability from quarter to quarter in our level of profitability.

On December 17, 2014, the SEC declared effective our registration statement on Form S-3. We may offer and sell securities at a maximum aggregate offering price of up to $112.8 million. In addition, in this shelf registration statement we registered the resale of 12,749,328 shares of our common stock then held by two selling security holders. As these security holders have subsequently sold on the open market or distributed to their limited partners all of the shares, we will not resell any of these shares under this registration statement. While we have no current plans to do so, in the event that we need additional working capital, this registration statement provides an efficient manner for us to complete securities offering to raise such funds.

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Cash Flows

The following table sets forth the major sources and uses of cash for the periods set forth below summarized, in thousands:

	Year Ended December 31,		Increase/ (decrease)
	2015	2014	
Net cash provided by (used in):			
Operating activities	$ 32,123	$ 7,733	24,390
Investing activities	(36,234)	(4,887)	(31,347)
Financing activities	1,867	570	1,297
Net (decrease) increase in cash and cash equivalents	$ (2,244)	$ 3,416	

Operating Activities

Net cash provided by/used in operating activities is comprised of two components; cash provided by operating income/loss and cash provided by/used in changes in working capital. Results for the years ended December 31, 2015 and December 31, 2014 are summarized below, in thousands:

	Year Ended December 31,		Increase/ (decrease)
	2015	2014	
Cash provided by operating income	$ 22,061	$ 25,234	(3,173)
Cash provided by (used in) changes in working capital	10,062	(17,501)	27,563
Net cash provided by operating activities	$ 32,123	$ 7,733	

The increase in net cash provided by operating activities is primarily driven by increased revenue generated from the sale of Trokendi XR and Oxtellar XR. For the year ended 2014, operating income includes a one-time payment of $30.0 million in royalty revenue.

The increase in cash provided by changes in working capital is primarily driven by increased net sales deductions associated with our increased revenue.

The changes in certain operating assets and liabilities are, in thousands:

	Year Ended December 31,		
	2015	2014	Explanation of Change
Increase in accounts receivable	$ (8,638)	$ (12,216)	Shipment of additional product to wholesalers.
Decrease (increase) in inventory	854	(6,289)	Change in product inventory.
Increase in prepaid expenses and other assets	(1,582)	(1,144)	Increase in activity to support commercial products.
Increase in accounts payable and accrued expenses	18,790	9,036	Increase in net sales deductions.
Increase (decrease) in deferred product and licensing revenue	149	(8,086)	The 2014 change relates to the transition of Trokendi XR revenue recognition to be based on shipments to wholesalers.
Other	489	1,198	
	$ 10,062	$ (17,501)	

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Investing Activities

We invest excess cash in accordance with our investment policy. Marketable securities consist of investments which mature in four years or less, including United States Treasury and various government agency debt securities, as well as investment grade securities in industrial and financial institutions. Fluctuations in investing activities between periods relate exclusively to the timing of marketable security purchases and the related maturities of these securities.

Net cash used in investing activities for the year ended December 31, 2015 of $36.2 million related to net purchase of marketable securities of $25.6 million, deferred legal fees of $8.5 million and property and equipment purchases of $2.1 million. Net cash used in investing activities for the year ended December 31, 2014 consisted of deferred legal fees of $4.5 million and property and equipment purchases of $0.6 million, offset by net sales and maturities of marketable securities of $0.2 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2015 was $1.9 million, resulting from proceeds received from stock option exercises. Net cash provided by financing activities for the year ended December 31, 2014 was $0.6 million, consisting primarily of proceeds received from stock option exercises.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2015 (except as noted below), in thousands:

Contractual Obligations	Less than 1 Year	1 - 3 Years	3 - 5 Years	Greater than 5 Years	Total
Convertible Senior Secured Notes	$	$	$ 8,537	$	$ 8,537
Interest on Convertible Notes	640	1,281	373		2,294
Operating leases(1)	1,430	2,604	1,795		5,829
Purchase obligations(2)	4,111				4,111
Total(3)	$ 6,181	$ 3,884	$ 10,705	$	$ 20,771

(1) Our commitments for operating leases relate to our lease of office equipment, fleet vehicles and office and laboratory space as of December 31, 2015.

(2) Relates primarily to agreements and purchase orders with contractors for the conduct of clinical trials, other research and development and sales and marketing activities.

(3) This table does not include (a) any milestone payments which may become payable to third parties under license agreements as the timing and likelihood of such payments are not known, (b) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known and (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

We have obtained exclusive licenses from third parties for proprietary rights to support the product candidates in our psychiatry portfolio. Under license agreements with Afecta, we have an exclusive option to evaluate Afecta's CNS pipeline and to obtain exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. We do not owe any future milestone payments for SPN-810. We will be obligated to pay royalties to Afecta based on net sales worldwide of our product candidates in the low-single digits.

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We have also entered into a purchase and sale agreement with Rune, where we obtained the exclusive worldwide rights to a product concept from Rune HealthCare Limited (Rune). There are no future milestone payments owing to Rune under this agreement. If we receive approval to market and sell any products based on the Rune product concept for SPN-809, we will be obligated to pay royalties to Rune based on net sales worldwide in the low single digits.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Recently Issued Accounting Pronouncements

For a discussion of new accounting pronouncements, see Note 2 in the notes to the consolidated financial statements in Part II, Item 8 of this report.

Jumpstart Our Business Startups Act of 2012

The JOBS Act permits an "emerging growth company" such as ours to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to "opt out" of this provision. As a result, we will continue to comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash, cash equivalents, marketable securities and long term marketable securities. As of December 31, 2015, we had unrestricted cash, cash equivalents, marketable securities and long term marketable securities of $117.2 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash, cash equivalents, marketable securities and long term marketable securities and because we hold these securities to maturity, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments. We do not have any currency or other derivative financial instruments other than the interest make-whole payment associated with our Notes.

We may contract with CROs and investigational sites globally. Currently, we do not have on-going trials outside of the U.S. We may be subject to fluctuations in foreign currency rates in connection with these agreements, primarily with respect to Euro denominated contracts. We do not hedge our foreign currency exchange rate risk. A hypothetical 10% appreciation in Euro exchange rates against the U.S. dollar from prevailing market rates would have decreased our net income by approximately $4,000 for the year ended December 31, 2015. Conversely, a hypothetical 10% depreciation in Euro exchange rates against the U.S. dollar from prevailing market rates would have increased our net income by approximately $4,000 for the year ended December 31, 2015. We do not believe that inflation and changing prices over the years ended December 31, 2015 and 2014 had a significant impact on our consolidated results of operations.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Supernus Pharmaceuticals, Inc.
Consolidated Financial Statements
Years ended December 31, 2015, 2014 and 2013

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Supernus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Supernus Pharmaceuticals, Inc. and subsidiary (the Company) as of December 31, 2015, and the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Supernus Pharmaceuticals, Inc. and subsidiary as of December 31, 2015, and the results of their operations and their cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Baltimore, Maryland
March 8, 2016

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Supernus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Supernus Pharmaceuticals, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Supernus Pharmaceuticals, Inc. at December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

McLean, Virginia
March 12, 2015

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Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 34,152	$ 36,396
Marketable securities	28,038	37,940
Accounts receivable, net	25,908	17,270
Inventories, net	12,587	13,441
Prepaid expenses and other current assets	5,292	3,845
Total current assets	105,977	108,892
Long term marketable securities	55,009	19,816
Property and equipment, net	3,874	2,448
Deferred legal fees	22,503	5,209
Intangible assets, net	976	225
Other non-current assets	391	918
Total assets	$ 188,730	$ 137,508
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,314	$ 1,863
Accrued sales deductions	26,794	8,461
Accrued expenses	24,813	17,026
Deferred licensing revenue	176	143
Total current liabilities	56,097	27,493
Deferred licensing revenue, net of current portion	1,390	1,274
Convertible notes, net of discount	7,189	26,947
Other non-current liabilities	4,325	3,876
Derivative liabilities	854	6,564
Total liabilities	69,855	66,154
Stockholders' equity:		
Common stock, $0.001 par value, 130,000,000 shares authorized at December 31, 2015 and 2014; 49,004,674 and 42,974,463 shares issued and outstanding at December 31, 2015 and 2014, respectively	49	43
Additional paid-in capital	263,955	230,122
Accumulated other comprehensive loss	(488)	(154)
Accumulated deficit	(144,641)	(158,657)
Total stockholders' equity	118,875	71,354
Total liabilities and stockholders' equity	$ 188,730	$ 137,508

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,		
	2015	**2014**	**2013**
Revenue			
Net product sales	$ 143,526	$ 89,571	$ 11,552
Revenue from royalty agreement		30,000	
Licensing revenue	901	2,474	467
Total revenue	144,427	122,045	12,019
Costs and expenses			
Cost of product sales	8,423	5,758	1,104
Research and development	29,135	19,586	17,245
Selling, general and administrative	89,204	72,471	55,590
Total costs and expenses	126,762	97,815	73,939
Operating income (loss)	17,665	24,230	(61,920)
Other income (expense)			
Interest income	643	348	299
Interest expense	(1,229)	(4,963)	(7,849)
Changes in fair value of derivative liabilities	193	2,809	(13,354)
Loss on extinguishment of debt	(2,338)	(2,592)	(9,550)
Other income	38	39	101
Total other expense	(2,693)	(4,359)	(30,353)
Earnings (loss) before income taxes	14,972	19,871	(92,273)
Income tax expense	956		
Net income (loss)	$ 14,016	$ 19,871	$ (92,273)
Income (loss) per common share:			
Basic	$ 0.30	$ 0.47	$ (2.90)
Diluted	$ 0.28	$ 0.32	$ (2.90)
Weighted-average number of common shares outstanding:			
Basic	47,485,258	42,260,896	31,848,299
Diluted	51,160,380	50,583,511	31,848,299

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Income (Loss)

(in thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Net income (loss)	$ 14,016	$ 19,871	$ (92,273)
Other comprehensive (loss) income:			
Unrealized net (loss) gain on marketable securities	(334)	(154)	57
Other comprehensive (loss) income:	(334)	(154)	57
Comprehensive income (loss)	$ 13,682	$ 19,717	$ (92,216)

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2012	30,621,869	$ 31	$ 143,851	$ (57)	$ (86,255)	$ 57,570
Exercise of over allotment from secondary offering	239,432		1,791			1,791
Share-based compensation			1,913			1,913
Issuance of employee stock purchase plan shares	81,370		444			444
Exercise of stock options	62,513		78			78
Equity conversion feature on issuance of convertible notes, less issuance costs of $869			21,467			21,467
Equity issued on conversion of convertible notes	8,978,253	9	42,408			42,417
Net loss					(92,273)	(92,273)
Other comprehensive income (loss)				57		57
Balance, December 31, 2013	39,983,437	40	211,952		(178,528)	33,464
Share-based compensation			2,716			2,716
Issuance of employee stock purchase plan shares	76,333		516			516
Exercise of stock options	17,627		54			54
Equity issued on conversion of convertible notes	2,897,066	3	14,884			14,887
Net income					19,871	19,871
Other comprehensive income (loss)				(154)		(154)
Balance, December 31, 2014	42,974,463	43	230,122	(154)	(158,657)	71,354
Share-based compensation			4,231			4,231
Issuance of employee stock purchase plan shares	98,986		930			930
Exercise of stock options	205,640		937			937
Equity issued on conversion of convertible notes	5,693,062	6	27,083			27,089
Exercise of warrants	32,523		652			652
Net income					14,016	14,016
Other comprehensive income (loss)				(334)		(334)
Balance, December 31, 2015	49,004,674	$ 49	$ 263,955	$ (488)	$ (144,641)	$ 118,875

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Cash flows from operating activities			
Net income (loss)	$ 14,016	$ 19,871	$ (92,273)
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Loss on extinguishment of debt	2,338	2,592	9,550
Change in fair value of derivative liability	(193)	(2,809)	13,354
Unrealized (loss) gain on marketable securities		(154)	57
Depreciation and amortization	921	928	742
Amortization of deferred financing costs and debt discount	748	2,090	3,033
Share-based compensation expense	4,231	2,716	1,913
Changes in operating assets and liabilities:			
Accounts receivable	(8,638)	(12,216)	(5,043)
Inventories	854	(6,289)	(6,000)
Prepaid expenses and other assets	(1,582)	(1,144)	(889)
Accounts payable	2,061	(1,279)	336
Accrued sales deduction	18,333	7,461	1,000
Accrued expenses	(1,604)	2,854	7,156
Deferred product revenue, net		(7,882)	7,883
Deferred licensing revenue	149	(204)	803
Other non-current liabilities	489	1,198	429
Net cash provided by (used in) operating activities	32,123	7,733	(57,949)
Cash flows from investing activities			
Purchases of marketable securities	(63,205)	(53,262)	(85,567)
Sales and maturities of marketable securities	37,581	53,473	75,806
Purchases of property and equipment	(2,104)	(593)	(1,646)
Deferred legal fees	(8,506)	(4,505)	(705)
Net cash used in investing activities	(36,234)	(4,887)	(12,112)
Cash flows from financing activities			
Proceeds from issuance of common stock	1,867	571	2,437
Proceeds from convertible debt issuance			90,000
Cash settlement of debt to equity conversion		(1)	(1,727)
Repayment of secured notes payable			(24,344)
Financing costs and underwriters discounts			(3,627)
Net cash provided by financing activities	1,867	570	62,739
Net change in cash and cash equivalents	(2,244)	3,416	(7,322)
Cash and cash equivalents at beginning of year	36,396	32,980	40,302
Cash and cash equivalents at end of year	$ 34,152	$ 36,396	$ 32,980

Supplemental cash flow information:			
Cash paid for interest	$ 825	$ 2,854	$ 4,313
Noncash financial activity:			
Conversion of convertible notes and interest make-whole	$ 27,089	$ 14,887	$ 42,417
Initial value of interest make-whole derivative issued in connection with the convertible debt	$	$	$ 9,270
Initial value of conversion option reported in equity	$	$	$ 22,336
Exercise of warrants	$ 652	$	$
Deferred legal fees included in accrued expenses	$ 9,392	$	$

See accompanying notes.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

Years ended December 31, 2015, 2014 and 2013

1. Organization and Nature of Operations

Supernus Pharmaceuticals, Inc. (the Company) was incorporated in Delaware on March 30, 2005, and commenced operations on December 22, 2005. The Company is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, including neurological and psychiatric disorders. The Company markets two epilepsy products, Oxtellar XR and Trokendi XR, and has several proprietary product candidates in clinical development that address the psychiatry market.

The Company commenced the commercialization of Oxtellar XR and Trokendi XR in 2013.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements include the accounts of Supernus Pharmaceuticals, Inc. and Supernus Europe Ltd., collectively referred to herein as "Supernus" or "the Company." All significant intercompany transactions and balances have been eliminated in consolidation. The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP).

The Company, which is primarily located in the United States, operates in one operating segment.

Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, accrued sales deductions, fair value of financial assets and liabilities, derivative liabilities, common stock options, income taxes, preclinical study and clinical trial accruals, and other contingencies. Management bases its estimates on historical experience or on various other assumptions, including information received from its service providers and independent valuation consultants, which it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

Cash and Cash Equivalents

The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less to be cash equivalents.

Marketable Securities

Marketable securities consist of investments in U.S. Treasuries, various U.S. governmental agency debt securities, corporate bonds and other fixed income securities. The Company's investments are classified as available for sale. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive income,

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

which is a separate component of stockholders' equity. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in 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, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income is recognized when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with government, industrial, or financial 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 as non-current assets.

The Company established the Supernus Supplemental Executive Retirement Plan (SERP) for the sole purpose of receiving funds for executives from a previous SERP and providing a continuing deferral program under the Supernus SERP. As of December 31, 2015 and 2014, the estimated fair value of the mutual fund investment securities within the SERP was approximately $263,000 and $305,000, respectively. The fair value of these assets is included within other non-current assets on the consolidated balance sheets. A corresponding noncurrent liability is also included in the consolidated balance sheets to reflect the Company's obligation for the SERP. The Company has not made, and has no plans to make, contributions to the SERP. The securities are restricted in nature and can only be used for purposes of paying benefits under the SERP.

Accounts Receivable, net

Accounts receivable are reported on the consolidated balance sheets at outstanding amounts, less an allowance for doubtful accounts and discounts. The Company extends credit without requiring collateral. The Company writes off uncollectible receivables when the likelihood of collection is remote. The Company evaluates the collectability of accounts receivable on a regular basis. An allowance, when needed, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts, and economic factors or events expected to affect future collections experience. No accounts have been written off in 2015 and 2014. No allowance for uncollectible receivables is recorded at December 31, 2015 or December 31, 2014. The Company recorded an allowance of approximately $3.8 million and $4.1 million for expected sales discounts as of December 31, 2015 and December 31, 2014, respectively. The following table includes those customers that represent more than 10% of total net product sales for 2015 and more than 10% of the accounts receivable balance on the consolidated balance sheet as of December 31, 2015:

	Percent of Net Product Sales	Percent of Accounts Receivable, net
Customer A	26%	40%
Customer B	32%	28%
Customer C	38%	29%
	96%	97%

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, accounts receivable and marketable securities. The counterparties are various corporations and financial institutions of high credit standing.

Substantially all of the Company's cash and cash equivalents are maintained with well known, U.S. and non U.S. financial institutions, government agencies, and corporations. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, management believes they bear minimal risk.

Inventory

Inventories, which are recorded at the lower of cost or market, include materials, labor, and other direct and indirect costs and are valued using the first-in, first-out method. The Company capitalizes inventories produced in preparation for commercial launches when it becomes probable that the related product candidates will receive regulatory approval and that the related costs will be recoverable through the commercial sale of the product.

Property and Equipment

Property and equipment are stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are computed using the straight-line method over the following average useful lives:

Computer equipment	3 years
Software	3 years
Lab equipment and furniture	5 - 10 years
Leasehold improvements	Shorter of lease term or useful life

Deferred Legal Fees

Deferred legal fees have been incurred in connection with legal proceedings related to patents for Oxtellar XR and Trokendi XR (see Note 6). Amortization of the deferred legal fees will begin upon successful outcome of the on-going litigation. Deferred legal fees will be charged to expense in the event of an unsuccessful outcome of the on-going litigation.

Intangible Assets

Intangible assets consist primarily of purchased patents and deferred legal fees. Patents are carried at cost less accumulated amortization, which is calculated on a straight-line basis over the estimated useful lives of the patents, generally estimated to be ten years. The carrying value of the patents is assessed for impairment annually during the fourth quarter of each year, or more frequently if impairment indicators exist. There were no indicators of impairment identified at December 31, 2015, 2014 or 2013.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

Impairment of Long-Lived Assets

Long-lived assets consist primarily of purchased patents, deferred legal fees, and property and equipment. The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. Evaluating for impairment requires judgment, including the estimation of future cash flows, future growth rates and profitability and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of the long-lived assets over its estimated fair value. For the years ended December 31, 2015, 2014, and 2013, the Company determined that there was no impairment of the Company's long-lived assets.

Deferred Financing Costs

Deferred financing costs consist of financing costs incurred by the Company in connection with the closing of the Company's 7.50% Convertible Senior Secured Notes and Secured Notes Payable (see Note 8). The Company amortizes deferred financing costs over the term of the related debt using the effective interest method. When extinguishing debt, the related deferred financing costs are written off.

Preclinical Study and Clinical Trial Accruals

The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions, investigators, and clinical research organizations (CROs) that conduct these activities on our behalf. In recording service fees, the Company estimates the time period over which the related services will be performed and compares the level of effort expended through the end of each period to the cumulative expenses recorded and payments made for such services and, as appropriate, accrues additional service fees or defers any non-refundable advance payments until the related services are performed. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust its accrual or deferred advance payment accordingly. If the Company later determines that it no longer expects the services associated with a nonrefundable advance payment to be rendered, the advance payment will be charged to expense in the period that such determination is made.

Revenue Recognition

Revenue from product sales is recognized when persuasive evidence of an arrangement exists; delivery has occurred and title to the product and associated risk of loss has passed to the customer; the price is fixed or determinable; collection from the customer has been reasonably assured; all performance obligations have been met; and returns and allowances can be reasonably estimated. Product sales are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions as well as estimated product returns (collectively, "sales deductions").

Our products are distributed through wholesalers and pharmaceutical distributors. Each of these wholesalers and distributors will take title and ownership to the product upon physical receipt of the

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

product and then distribute our products to pharmacies. Beginning in the fourth quarter of 2013, the Company began recognizing revenue for Oxtellar XR, net of estimated sales deductions, at the time of shipment to wholesalers. Prior to this time, the Company recognized revenue for Oxtellar XR upon fulfillment of prescriptions, net of all known or estimated sales deductions.

Beginning in the second quarter of 2014, the Company began recognizing revenue for Trokendi XR, net of estimated sales deductions, at the time of shipment to wholesalers. Prior to this time, the Company recognized revenue for Trokendi XR upon fulfillment of prescriptions to patients, net of all known or estimated sales deductions. For the year ended December 31, 2015, the revenue for Oxtellar XR and Trokendi XR was recognized contemporaneously upon shipment of finished products to wholesalers, net of allowances for estimated sales deductions and returns.

During the year ended December 31, 2015, the Company recorded a $2.9 million reduction to net revenue related to a change in estimate associated with its accrued sales deductions of $26.8 million at December 31, 2015. The change in estimate reflects returns experience associated with our initial launch shipments, which have now passed their expiry dating.

Revenue from Product Sales

The Company launched Oxtellar XR on February 4, 2013 and launched Trokendi XR on August 26, 2013. During the fourth quarter of 2013, we began to recognize revenue for Oxtellar XR contemporaneously upon shipment of finished product to wholesalers less allowances for estimated sales deductions and, during the second quarter of 2014, we began to recognize revenue for Trokendi XR contemporaneously upon shipment of finished product to wholesalers less allowances for estimated sales deductions.

Through December 31, 2013, the Company recorded shipments of Trokendi XR to wholesalers as deferred revenue i.e., sales price net of known sales deductions (e.g. prompt pay discounts and other similar charges defined below). At the time, we lacked the experiential data which would allow us to estimate all remaining sales rebates, allowances and returns. Accordingly, when this data became available to the Company, we moved to contemporaneous revenue recognition in the second quarter of 2014.

Sales Deductions

Allowances for estimated sales deductions are provided for the following:

Rebates. Rebates include mandated discounts under the Medicaid Drug Rebate Program, the Medicare coverage gap program, as well as negotiated discounts with commercial healthcare providers. Rebates are amounts owed after the final dispensing of products to a benefit plan participant and are based upon contractual agreements or legal requirements with the public sector (e.g. Medicaid) and with private sector benefit providers. The allowance for rebates is based on statutory and contractual discount rates and expected claimed rebates paid based on a plan provider's utilization. Rebates are generally invoiced and paid quarterly in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known or estimated prior quarters' unpaid

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks. Chargebacks are discounts that occur when contracted customers purchase directly from an intermediary distributor or wholesaler. Contracted customers, which currently consist primarily of Public Health Service institutions and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The distributor or wholesaler, in turn, charges back the difference between the price initially paid by the distributor or wholesaler and the discounted price paid to the distributor or wholesaler by the customer. The allowance for distributor/wholesaler chargebacks is based on known sales to contracted customers.

Distributor/Wholesaler deductions and discounts. U.S. specialty distributors and wholesalers are offered various forms of consideration including allowances, service fees and prompt payment discounts as consideration for distributing our products. Distributor allowances and service fees arise from contractual agreements with distributors and are generally a percentage of the purchase price paid by the distributors and wholesalers. Wholesale customers are offered a prompt pay discount for payment within a specified period.

Co-pay assistance. Patients who pay in cash or have commercial insurance and meet certain eligibility requirements may receive co-pay assistance from the Company. The intent of this program is to reduce the patient's out of pocket costs.

Liabilities for co-pay assistance are based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Returns. Sales of our products are not subject to a general right of return; however, the Company will accept product that is damaged or defective when shipped directly from our warehouse and expired product six months prior and up to 12 months subsequent to its expiry date. Product that has been used to fill patient prescriptions is no longer subject to any right of return.

Revenue from Royalty Agreement

In the third quarter of 2014, the Company recognized $30.0 million in revenue from a royalty agreement related to HealthCare Royalty Partners III, L.P.'s purchase of certain of the Company's rights under the Royalty Interest Acquisition Agreement with United Therapeutics Corporation related to the commercialization of Orenitram. The Company determined to recognize this revenue immediately because (1) the executed contract constituted persuasive evidence of an arrangement, (2) the delivery of the license occurred and the Company has no current or future performance obligations, (3) the total consideration for the license agreement was fixed and known at the time of its execution and there were no rights of return, and (4) the cash was received and is non-refundable.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

Revenue Recognition of License Revenue

License and Collaboration Agreements

We have entered into collaboration agreements to have both Oxtellar XR and Trokendi XR commercialized outside of the U.S. These agreements generally include an up-front license fee and ongoing milestone payments upon the achievement of specific events. We believe the milestones meet all of the necessary criteria to be considered substantive and therefore should be recognized as revenue when achieved. For up-front license fees, we have estimated the service period of the contract and are recognizing this payment as revenue on a straight-line basis over the respective service period.

Milestone Payments

Milestone payments on licensing agreements are recognized as revenue when the collaborative partner acknowledges completion of the milestone and substantive effort was necessary to achieve the milestone. Management may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved only if the milestone meets all the criteria to be considered substantive. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive effort on the partner's part is involved in achieving the milestone; and
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and amortized over the appropriate period.

The Company recorded milestone revenues of $0.8 million and $2.0 million during the years ended December 31, 2015 and 2014, respectively. There was no revenue generated from the achievement of milestones in the year ended December 31, 2013.

Cost of Product Sales

The cost of product sales consist primarily of materials, third-party manufacturing costs, freight and distribution costs, allocation of labor, quality control and assurance, and other manufacturing overhead costs.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs primarily consist of employee-related expenses, including salaries and benefits; share-based compensation

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

expense; expenses incurred under agreements with clinical research organizations (CROs), investigative sites, and consultants that conduct the Company's clinical trials; the cost of acquiring and manufacturing clinical trial materials; the cost of manufacturing materials used in process validation, to the extent that those materials are manufactured prior to receiving regulatory approval for those products and are not expected to be sold commercially, facilities costs that do not have an alternative future use; related depreciation and other allocated expenses; license fees for and milestone payments related to in-licensed products and technologies; and costs associated with animal testing activities and regulatory approvals.

Advertising Expense

The Company records the cost of its advertising efforts when services are performed or goods are delivered. The Company incurred approximately $19.3 million, $14.8 million, and $14.6 million in advertising costs for the years ended December 31, 2015, 2014, and 2013, respectively and are recorded in the sales, general and administrative expense line of the Statement of Operations.

Share-Based Compensation

Employee share-based compensation is measured based on the estimated fair value on the grant date. The grant date fair value is calculated using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility, expected term, risk-free rate, and the fair value of the underlying common stock. The Company recognizes expense using the straight-line method less estimated forfeitures.

The Company records the expense for stock option grants to non-employees based on the estimated fair value of the stock option using the Black-Scholes option-pricing model. The fair value of non-employee awards is re-measured at each reporting period. As a result, stock compensation expense for non-employee awards with vesting is affected by subsequent changes in the fair value of the Company's common stock.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established to reduce deferred tax assets to the amounts expected to be realized.

The Company accounts for uncertain tax positions in its consolidated financial statements when it is more-likely-than-not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. The Company's policy is to recognize any interest and penalties related to income taxes in income tax expense.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

Recently Issued Accounting Pronouncements

In November 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes". The standard requires that deferred tax assets and liabilities be classified as noncurrent on the balance sheet rather than being separated into current and noncurrent. ASU 2015-17 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted and the standard may be applied either retrospectively or on a prospective basis to all deferred tax assets and liabilities. We early adopted ASU 2015-17 during our fourth quarter of fiscal year 2015 on a prospective basis. Accordingly, we reclassified the current deferred taxes to noncurrent on our December 31, 2015 Consolidated Balance Sheet, eliminating the presentation of the offsetting $0.2 million current deferred tax asset and non-current deferred tax liability.

In July 2015, the FASB issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory." Under this new guidance, entities that measure inventory using any method other than last-in, first-out or the retail inventory method will be required to measure inventory at the lower of cost and net realizable value. The amendments in this ASU, which should be applied prospectively, are effective for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2015-11 on our consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-05, "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." This ASU provides guidance about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the software license element of the arrangement is consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, then it should account for the arrangement as a service contract. The amendments in this ASU are effective for financial statements issued for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. The Company has elected to adopt the amendment early. The adoption of this standard had no impact on the Company's financial results.

In April 2015, the FASB issued ASU No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs." This ASU more closely aligns the treatment of debt issuance costs with debt discounts and premiums and requires debt issuance costs be presented as a direct deduction from the carrying amount of the related debt. The amendments in this ASU are effective for financial statements issued for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. This guidance should be applied on a retrospective basis and the Company will be required to comply with the applicable disclosures for a change in accounting principle. Presently, the Company does not expect the adoption of ASU 2015-03 to have a material impact on our consolidated financial statements and accompanying notes.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern". The new standard requires management to perform interim and annual assessments of an entity's ability to continue to meet its obligations as they become due within one year after the date that the financial statements are issued. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

2. Summary of Significant Accounting Policies (Continued)

permitted. We do not believe the adoption of the new standard will have a significant impact on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers". ASU 2014-09 will eliminate transaction-and industry-specific revenue recognition guidance under current U.S. GAAP and replace it with a principles-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. The FASB has voted to approve a one-year deferral, changing the effective date to annual reporting periods beginning after December 15, 2017, with early adoption being permitted for periods ending after December 15, 2016. Entities can transition to the standard either retrospectively or as a cumulative effect adjustment as of the date of adoption. Presently, the Company is assessing what effect the adoption of ASU 2014-09 will have on our consolidated financial statements and accompanying notes and has not yet selected a method of adoption.

The Company has evaluated all other ASUs issued through the date the consolidated financials were issued and believes that no other ASU will have a material impact on the Company's consolidated financial statements.

3. Fair Value of Financial Instruments

The fair value of an asset or liability should represent the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal or most advantageous market for the asset or liability. Accordingly, fair value is determined based on a hypothetical transaction at the measurement date, considered from the perspective of a market participant rather than from a reporting entity's perspective.

The Company reports assets and liabilities that are measured at fair value using a three level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1 Inputs are unadjusted quoted prices in active markets for identical assets that the Company has the ability to access at the measurement date.

Level 2 Inputs are quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 Unobservable inputs that reflect the Company's own assumptions, based on the best information available, including the Company's own data.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

3. Fair Value of Financial Instruments (Continued)

In accordance with the fair value hierarchy described above, the following tables show the fair value of the Company's financial assets and liabilities that are required to be measured at fair value, in thousands:

	Fair Value Measurements at December 31, 2015			
	Total Carrying Value at December 31, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 34,152	$ 34,152	$	$
Marketable securities	28,038		28,038	
Long term marketable securities	55,009		55,009	
Marketable securities restricted (SERP)	263		263	
Total assets at fair value	$ 117,462	$ 34,152	$ 83,310	$
Liabilities:				
Derivative liabilities	$ 854	$	$	$ 854

	Fair Value Measurements at December 31, 2014			
	Total Carrying Value at December 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 36,396	$ 36,396	$	$
Marketable securities	37,940		37,940	
Long term marketable securities	19,816		19,816	
Marketable securities restricted (SERP)	305		305	
Total assets at fair value	$ 94,457	$ 36,396	$ 58,061	$
Liabilities:				
Derivative liabilities	$ 6,564	$	$	$ 6,564

The fair value of the restricted marketable securities is included within other non-current assets in the consolidated balance sheets.

The Company's Level 1 assets include cash held with banks and money market funds.

Level 2 assets include the SERP (Supplemental Executive Retirement Plan) assets, commercial paper and investment grade corporate bonds and other fixed income securities. Level 2 securities are valued using third-party pricing sources that apply applicable inputs and other relevant data into their models to estimate fair value.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

3. Fair Value of Financial Instruments (Continued)

Level 3 liabilities include the estimated fair value of the interest make-whole liability associated with the Company's 7.50% Convertible Senior Secured Notes due 2019 (the Notes) and the outstanding warrants to purchase Common Stock, which are recorded as derivative liabilities. As of December 31, 2015, no warrants remained outstanding.

The fair value of the interest make-whole liability of the Notes was calculated using a binomial-lattice model with the following key assumptions as of December 31 2015:

Volatility	45%
Stock Price as of December 31, 2015	$13.44 per share
Credit Spread	2363 bps
Term	1.33 years
Dividend Yield	0.0%

Significant changes to these assumptions could result in increases/decreases to the fair value of the derivative liabilities.

Changes in the fair value of the warrants and the interest make-whole liability are recognized as a component of Other Income (Expense) in the Consolidated Statements of Operations. The following table presents information about the Company's Level 3 liabilities as of December 31, 2014 and December 31, 2015 that are included in the Non-Current Liabilities section of the Consolidated Balance Sheets, in thousands:

	Year Ended December 31, 2014 and 2015
Balance at December 31, 2013	$ 12,644
Changes in fair value of derivative liabilities included in earnings	(2,809)
Reduction due to conversion of debt to equity	(3,271)
Balance at December 31, 2014	6,564
Changes in fair value of derivative liabilities included in earnings	(193)
Reduction due to conversion of debt to equity	(4,865)
Cashless exercise of common stock warrants	(652)
Balance at December 31, 2015	$ 854

The carrying value, face value and estimated fair value of the Notes was approximately $7.2 million, $8.5 million and $22.6 million, respectively, as of December 31, 2015. The fair value was estimated based on actual trade information as well as quoted prices provided by bond traders, which would be characterized within Level 2 of the fair value hierarchy. This fair value amount gives recognition to the value of the interest make-whole liability and the value of the conversion option. These items have been accounted for as derivative liabilities and additional paid-in-capital, respectively.

The carrying amounts of other financial instruments, including accounts receivable, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

3. Fair Value of Financial Instruments (Continued)

Unrestricted marketable securities held by the Company were as follows, in thousands:

At December 31, 2015:

Available for Sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	$ 83,535	5	(493)	$ 83,047

At December 31, 2014:

Available for Sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	$ 57,910	4	(158)	$ 57,756

The contractual maturities of the unrestricted available for sale marketable securities held by the Company were as follows, in thousands:

	December 31, 2015
Less Than 1 Year	$ 28,038
1 - 5 years	55,009
Greater Than 5 Years	
Total	$ 83,047

The Company has not experienced any other-than-temporary losses on its marketable securities and restricted marketable securities. The cost of securities sold is calculated using the specific identification method.

4. Inventories

Inventories consist of the following, in thousands:

	December 31, 2015	December 31, 2014
Raw materials	$ 2,887	$ 2,491
Work in process	3,946	6,328
Finished goods	5,754	4,622
	$ 12,587	$ 13,441

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

5. Property and Equipment

Property and equipment consist of the following, in thousands:

	December 31, 2015	December 31, 2014
Computer equipment	$ 1,112	$ 862
Software	307	254
Lab equipment and furniture	5,667	5,194
Leasehold improvements	2,642	2,428
Construction in progress	1,114	
	10,842	8,738
Less accumulated depreciation and amortization	(6,968)	(6,290)
	$ 3,874	$ 2,448

Depreciation and amortization expense on property and equipment was approximately $678,000, $699,000, and $512,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

6. Intangible Assets

The Company purchased certain patents from Shire Laboratories, Inc. pursuant to a 2005 purchase agreement. These patents are being amortized over the weighted average life of the patents purchased in that transaction. Deferred legal fees have been incurred in connection with litigation related to patents for Oxtellar XR and Trokendi XR. The following sets forth the gross carrying amount and related accumulated amortization of these intangible assets, in thousands:

		December 31, 2015		December 31, 2014	
	Weighted-Average Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Purchased patents	10.0	$ 2,292	$ 2,292	$ 2,292	$ 2,067
Capitalized patent defense costs	9.5	$ 994	$ 18	$	$

Deferred legal fees will be capitalized as part of the patents upon successful outcome of the on-going litigation related to these patents, at which point amortization of those costs will begin. The Company reached an agreement to settle certain litigation related to Trokendi XR in October 2015, at which time the Company capitalized the costs associated with that litigation and began amortization.

The net book value of intangible assets was $1.0 million as of December 31, 2015 and was $0.2 million as of December 31, 2014. Amortization expense on intangible assets was approximately $243,000, $229,000, and $229,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

There were no indicators of impairment identified at December 31, 2015 or December 31, 2014.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

7. Accrued Expenses

Accrued expenses are comprised of the following, in thousands:

	December 31, 2015	December 31, 2014
Accrued compensation	$ 7,519	$ 5,784
Accrued professional fees	10,057	2,049
Accrued clinical trial and clinical supply costs	3,677	2,942
Accrued sales and marketing expenses	434	1,017
Accrued product costs	113	3,014
Accrued interest expense	295	639
Other accrued expenses	2,718	1,581
	$ 24,813	$ 17,026

8. Convertible Senior Secured Notes

On May 3, 2013, the Company issued $90.0 million aggregate principal amount of Notes. The Company completed this private placement offering in reliance on Section 4(a)(2) under the Securities Act of 1933, as amended (the Securities Act). The notes were available for resale in transactions exempt from the registration requirements of the Securities Act to persons reasonably believed by the initial purchasers to be "qualified institutional buyers" as defined in Rule 144A under the Securities Act.

Aggregate offering expenses in connection with the transaction, including the underwriters' fee of $3.0 million, were approximately $3.5 million, resulting in net proceeds of approximately $86.5 million. The Company used approximately $19.6 million to repay in full its borrowings under and terminate its then existing secured credit facility.

The Company issued the Notes under an Indenture, dated May 3, 2013 (the Indenture), between the Company and U.S. Bank National Association, as Trustee and Collateral Agent. The Notes provide for 7.50% interest per annum on the principal amount of the Notes, payable semi-annually in arrears on May 1 and November 1 of each year, beginning on November 1, 2013. Interest will accrue on the Notes from and including May 3, 2013 and the Notes will mature on May 1, 2019, unless earlier converted, redeemed or repurchased by the Company. The Notes are convertible into the Company's common stock (Common Stock) as described below.

The Notes are the Company's senior secured obligations and (i) rank senior in right of payment to any of the indebtedness that is expressly subordinated in right of payment to the Notes; (ii) rank effectively senior to any of the unsecured indebtedness to the extent of the value of the collateral securing the Notes; (iii) rank equal in right of payment with all of the Company's indebtedness that is not subordinated to the Notes; and (iv) are structurally subordinated to all indebtedness and liabilities, including trade payables, of the Company's existing and future subsidiaries.

The Notes are secured by a first-priority lien, other than customary permitted liens, on substantially all of the Company's and its domestic subsidiaries' assets, whether now owned or hereafter acquired, including license agreements, general intangibles, accounts, instruments, investment property, intellectual property and any proceeds of the foregoing pursuant to that certain Security and Pledge Agreement, dated May 3, 2013 (the Security Agreement), between the Company and U.S. Bank

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

8. Convertible Senior Secured Notes (Continued)

National Association, as Collateral Agent. The Indenture restricts the ability of the Company and its existing and future subsidiaries to make investments, including transfers of the Company's assets that constitute collateral securing the Notes, in its existing and future foreign subsidiaries. The Company is entitled to the release of property and other assets constituting collateral from the liens securing the Notes and the obligations thereunder (i) to enable the Company to consummate the sale, transfer, license, monetization or other disposition of such property or assets; (ii) with the consent of the holders of at least $66^{2}/_{3}\%$ of the aggregate principal amount of the Notes then outstanding and affected; or (iii) pursuant to a modification or amendment of the Indenture, the Notes or the Security Agreement.

Prior to the close of business on the business day immediately preceding November 1, 2018, a holder of Notes may convert all or a portion of its Notes, in principal amounts equal to $1,000 or an integral multiple thereof, only if one or more of the following conditions has been satisfied: (1) if, for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading day period ending within five trading days prior to a conversion date, the last reported sale price of the Company's Common Stock exceeds the conversion price on each such trading day; (2) during the five consecutive business day period immediately following any five consecutive trading day period (the Measurement Period), in which, for each trading day of that Measurement Period, the trading price (as defined in the Indenture) per $1,000 principal amount of Notes for such trading day was less than 98% of the product of the last reported sale price of the Company's Common Stock on such trading day and the applicable conversion rate on such trading day; (3) upon the occurrence of specified corporate transactions; or (4) if the Company calls the Notes for redemption, at any time prior to the close of business on the business day immediately preceding the redemption date. On and after November 1, 2018, a holder of Notes may convert all or a portion of its Notes, in principal amounts equal to $1,000 or an integral multiple thereof, at any time prior to the close of business on the business day immediately preceding the maturity date of the Notes, regardless of the foregoing circumstances. The Company will settle conversion of the Notes through payment or delivery, as the case may be of cash, shares of Common Stock or a combination thereof, at its election.

The conversion rate for the Notes is equal to 188.7059 shares of Common Stock per $1,000 principal amount of notes (which is equivalent to an initial conversion price of approximately $5.30 per share of Common Stock). The conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. In addition, upon the occurrence of a "make-whole fundamental change" (as defined in the Indenture), the Company will, in certain circumstances, increase the conversion rate by a number of additional shares for a holder that elects to convert its notes in connection with such make-whole fundamental change as described in the Indenture.

Effective November 1, 2013, if, for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading day period ending within five trading days prior to a conversion date, the last reported sale price of the Company's common stock exceeds the conversion price on each such trading day, the Company became required, in certain circumstances, to make an interest make-whole payment to converting holders equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the Notes to be converted had such notes remained outstanding until May 1, 2017 computed using a discount rate equal to 2%. The Company may pay an interest make-whole payment either in cash or in Common Stock, at its election. If the Company elects to pay

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

8. Convertible Senior Secured Notes (Continued)

an interest make-whole payment in Common Stock, then the stock will be valued at 95% of the simple average of the daily volume- weighted average price (VWAP) per share for the 10 trading days ending on and including the trading day immediately preceding the conversion date. Notwithstanding the foregoing, the number of shares the Company may deliver in connection with an interest make-whole payment and repayment of principal will not exceed 221.7294 shares per $1,000 principal amount of Notes, subject to adjustment. If, pursuant to its election to deliver Common Stock in connection with the payment of the interest make-whole amount, the Company would be required to deliver a number of shares of Common Stock in excess of such threshold, the Company would deliver cash in lieu of shares otherwise deliverable upon conversions in excess thereof (based on the simple average of the daily VWAP for the 10 trading days ending on and including the trading day immediately preceding the conversion date).

Upon (i) the occurrence of a fundamental change (as defined in the Indenture) or (ii) if the Company calls the Notes for redemption as described below (either event, a "make-whole fundamental change") and a holder elects to convert its Notes in connection with such make-whole fundamental change, the Company will, in certain circumstances, increase the conversion rate by a number of additional shares (the "Additional Shares") as described below. The Company will notify holders within one business day after the first public announcement by it or a third party of an event or transaction that the Company reasonably determines would, if consummated, constitute a make-whole fundamental change. Upon receiving notice or otherwise becoming aware of a potential make-whole fundamental change described, the Company will use commercially reasonable efforts to announce or cause the announcement of such potential make-whole fundamental change in time to deliver such notice at least 50 scheduled trading days prior to the anticipated effective date for such transaction. The Company will notify the Trustee and holders of the effective date of any make-whole fundamental change no later than one business day after such effective date.

The number of additional shares by which the Company will increase the conversion rate will be determined based on the date on which the make-whole fundamental change occurs or becomes effective (the Effective Date) and the price (the Stock Price) paid (or deemed paid) per share of the Company's Common Stock in the fundamental change. If the holders of the Company's common stock receive only cash in a make-whole fundamental change (i) the Stock Price shall be the cash amount paid per share and (ii) the Company will satisfy its conversion obligation to a holder that converts its Notes any time after such make-whole fundamental change by delivering to such holder, on the third business day immediately following the relevant conversion date, an amount of cash, for each $1,000 principal amount of Notes converted, equal to the product of (x) the conversion rate in effect on the relevant conversion date (as increased by the Additional Shares, if any) and (y) the Stock Price. Otherwise, (i) the Stock Price will equal the average of the last reported sale prices of the Company's Common Stock over the five trading day period ending on, and including, the trading day immediately preceding the Effective Date of the make-whole fundamental change and (ii) the Company will satisfy its conversion obligation to a holder that converts its Notes in connection with such make-whole fundamental change based on the conversion rate as increased by the number of Additional Shares. In connection with a make-whole fundamental change triggered by redemption of the Notes, the Effective Date of such make-whole fundamental change will be the date on which the Company delivers notice of the redemption. Notwithstanding the foregoing, in no event will the conversion rate exceed the

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

8. Convertible Senior Secured Notes (Continued)

maximum conversion rate, which is 221.7294 shares per $1,000 principal amount of Notes, which amount is inclusive of repayment of the principal of the Notes.

If a fundamental change occurs at any time, holders will have the right, at their option, to require the Company to purchase for cash any or all of the Notes, or any portion of the principal amount thereof, that is equal to $1,000 or an integral multiple of $1,000 in excess thereof, on a date of the Company's choosing that is not less than 20 calendar days nor more than 35 calendar days after the date on which it delivers a fundamental change notice. The price the Company is required to pay for a Note is equal to 100% of the principal amount of such Note plus accrued and unpaid interest, if any, to, but excluding, the fundamental change purchase date. Any Notes purchased by the Company will be paid for in cash.

The Company may not redeem the Notes prior to May 1, 2017. On or after May 1, 2017, the Company may redeem for cash all, but not less than all, of the Notes if the last reported sale price of the Company's Common Stock equals or exceeds 140% of the applicable conversion price for at least 20 trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date the Company delivers written notice of the redemption. The redemption price will be equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. If the Company calls the Notes for redemption, a make- whole fundamental change will be deemed to occur and the Company will, in certain circumstances, increase the conversion rate for holders who convert their notes in connections with such make-whole fundamental change as described in the Indenture.

The Company incurred approximately $3.5 million of financing costs (including the underwriters' fee) in connection with the issuance of the Notes. Approximately $0.9 million of this amount was allocated to additional paid-in capital and the remaining $2.6 million is recorded as a deferred cost being amortized over the term of the Notes. As of December 31, 2015, approximately $0.1 million remained unamortized, of which $0.03 million is current and $0.07 million is long term.

The table below summarizes activity related to the Notes from issuance on May 3, 2013 through December 31, 2015, in thousands:

Gross proceeds	$	90,000
Initial value of interest make-whole derivative reported as debt discount		(9,270)
Conversion option reported as debt discount and APIC		(22,336)
Conversion of debt to equity principal		(53,941)
Conversion of debt to equity accretion of debt discount		17,926
Accretion of debt discount		4,568
December 31, 2014 carrying value		26,947
Conversion of debt to equity principal		(27,522)
Conversion of debt to equity accretion of debt discount		7,077
Accretion of debt discount		687
December 31, 2015 carrying value	$	7,189

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

8. Convertible Senior Secured Notes (Continued)

During the year ended December 31, 2015, approximately $27.5 million of the Notes were presented to the Company for conversion. Accordingly, the Company issued approximately 5.2 million shares of common stock in conversion of the principal amount of the Notes. The Company issued an additional 0.5 million shares of common stock in settlement of the interest make-whole provision related to the converted Notes. As a result of the conversions, the Company incurred a loss on extinguishment of debt of approximately $2.3 million during the period ended December 31, 2015.

During the year ended December 31, 2014, approximately $13.4 million of the Notes were presented to the Company for conversion. Accordingly, the Company issued approximately 2.5 million shares of common stock in conversion of the principal amount of the Notes. The Company issued an additional 0.4 million shares of common stock in settlement of the interest make-whole provision related to the converted Notes. As a result of the conversions, the Company incurred a loss on extinguishment of debt of approximately $2.6 million during the period ended December 31, 2014.

Secured Notes Payable

In January 2011, the Company entered into a secured credit facility pursuant to a loan and security agreement with certain lenders, which was subsequently amended in December 2011, providing for term loans of up to an aggregate of $30.0 million. On January 26, 2011 and December 30, 2011, the Company drew down $15.0 million and $15.0 million, respectively, of term loans under this secured credit facility. The Company used approximately $19.6 million of the Convertible Note proceeds to repay in full its borrowings under and terminate this secured credit facility in May 2013. Upon repayment of the secured notes payable, the Company incurred an approximately $1.2 million loss on extinguishment of debt during the period ended December 31, 2013.

9. Stockholders' Equity

Common Stock

The holders of the Common Stock are entitled to one vote for each share of Common Stock held. On May 1, 2012, the Company completed its IPO, in which 10 million shares of the Company's Common Stock were sold at a price of $5 per share. Additionally, the underwriters of the Company's IPO exercised the full amount of their over-allotment option resulting in the sale of an additional 449,250 shares of the Company's Common Stock at a price of $5 per share, resulting in cash proceeds to the Company of $52.3 million. The Company realized net proceeds of $47.6 million from the IPO, after issuance costs of approximately $4.7 million.

On December 5, 2012, the Company completed a follow-on offering, in which 6 million shares of the Company's Common Stock were sold at a price of $8 per share. Additionally, the underwriters of the Company's follow-on offering exercised their over-allotment options in January 2013 resulting in the sale of an additional 239,432 shares of the Company's Common Stock at a price of $8 per share, resulting in total cash proceeds to the Company of $49.9 million. The Company realized net proceeds of $46.6 million from the follow-on offering, after issuance costs of approximately $3.3 million.

During the period from November 1, 2013 through December 31, 2015, the Company issued 15,372,477 shares of common stock as a result of the conversion of approximately $81.5 million of Convertible

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

9. Stockholders' Equity (Continued)

Notes and approximately 2,195,904 shares of common stock in settlement of the interest-make whole associated with those conversions.

10. Share-Based Payments

Stock Option Plans

The Company has adopted the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan (the 2012 Plan), which is stockholder approved, and provides for the grant of stock options and certain other awards, including stock appreciation rights (SAR), restricted and unrestricted stock, stock units, performance awards, cash awards and other awards that are convertible into or otherwise based on the Company's common stock, to the Company's key employees, directors, and consultants and advisors. The 2012 Plan is administered by the Company's Board of Directors and provides for the issuance of up to 4,000,000 shares of the Company's Common Stock. Option awards are granted with an exercise price equal to the estimated fair value of the Company's Common Stock at the grant date; those option awards generally vest in four annual installments, starting on the first anniversary of the date of grant and have ten-year contractual terms. Share-based compensation recognized related to the grant of employee and non-employee stock options, SAR, potential Employee Stock Purchase Plan (ESPP) awards and non-vested stock was as follows, in thousands:

	Year Ended December 31,		
	2015	2014	2013
Research and development	$ 874	$ 728	$ 493
Selling, general and administrative	3,357	1,988	1,420
Total	$ 4,231	$ 2,716	$ 1,913

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model using the assumptions in the following table:

	Year Ended December 31,		
	2015	2014	2013
Fair value of common stock	$9.13 - $21.21	$7.63 - $10.02	$5.40 - $7.90
Expected volatility	60.9% - 64.6%	64.5% - 68.3%	69.5% - 70.9%
Dividend Yield	0%	0%	0%
Expected term	6.25 years	6.25 years	6.25 - 9.60 years
Risk-free interest rate	1.54% - 1.74%	1.67% - 1.97%	1.20% - 2.94%
Expected forfeiture rate	5%	5%	5%

Fair Value of Common Stock For option grants that occurred after the Company's IPO on May 1, 2012, the fair value of the Common Stock underlying the option grants was determined based on observable market prices of the Company's Common Stock.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

10. Share-Based Payments (Continued)

Expected Volatility Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company has identified several public entities of similar size, complexity, and stage of development and, accordingly, historical volatility has been calculated using the volatility of these companies, as well as taking into consideration the Company's actual volatility since our IPO. As our historical experience is not sufficient to calculate volatility for our option grants, the Company will continue to use guideline peer group volatility information until the historical volatility of its own Common Stock is sufficient on its own to measure expected volatility for future option grants.

Dividend Yield The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Expected Term This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years. The Company determines the average expected life of stock options according to the "simplified method" as described in Staff Accounting Bulletin 110, which is the mid-point between the vesting date and the end of the contractual term. Over time, management will track estimates of the expected life of the option term so that estimates will approximate actual behavior for similar options.

Risk-Free Interest Rate This is the U.S. Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected term of the option.

Expected Forfeiture Rate The forfeiture rate is the estimated percentage of options granted that are expected to be forfeited or canceled on an annual basis before becoming fully vested.

The following table summarizes stock option and SAR activity:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding, December 31, 2013	1,463,043	$ 7.27	8.51
Granted	686,235	$ 9.20	
Exercised	(17,627)	$ 3.08	
Forfeited	(50,902)	$ 7.79	
Outstanding, December 31, 2014	2,080,749	$ 7.93	8.04
Granted	971,500	$ 10.12	
Exercised	(205,640)	$ 4.56	
Forfeited	(147,602)	$ 8.60	
Outstanding, December 31, 2015	2,699,007	$ 8.94	7.92
As of December 31, 2015:			
Vested and expected to vest	2,654,381	$ 8.93	7.90
Exercisable	901,672	$ 7.95	6.86

The aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable as of December 31, 2015 is approximately $12.6 million, $12.4 million and $5.0 million, respectively. The

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

10. Share-Based Payments (Continued)

aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable as of December 31, 2014 is approximately $2.0 million, $2.0 million and $1.5 million, respectively. The aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable as of December 31, 2013 is approximately $1.4 million, $1.4 million and $1.0 million, respectively.

The weighted-average, grant-date fair value of options granted for the years ended December 31, 2015, 2014, and 2013 was $6.05, $5.79, and $4.98 per share, respectively.

The total fair value of the underlying Common Stock related to shares that vested during the years ended December 31, 2015, 2014, and 2013 was approximately $2.6 million, $1.9 million, and $0.5 million, respectively.

The total intrinsic value of options exercised amounted to approximately $1.6 million, $0.1 million, and $0.4 million, respectively, during the years ended December 31, 2015, 2014, and 2013.

As of December 31, 2015 and 2014, the total unrecognized compensation expense, net of estimated forfeitures, was approximately $7.2 million, and $5.9 million, respectively, which the Company expects to recognize over a weighted-average period of 2.54 and 2.56 years, respectively.

11. Earnings per Share

Basic income (loss) per common share is determined by dividing income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted income (loss) per share is computed by dividing the income (loss) attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants, SAR, and potential Employee Stock Purchase Plan (ESPP) awards, and the if-converted method is used to determine the dilutive effect of the Company's Notes.

The following common stock equivalents were excluded in the calculation of diluted loss per share because their effect would be anti-dilutive as applied to the loss from continuing operations applicable to common stockholders for the years ended December 31, 2015, 2014, and 2013:

	Year Ended December 31,		
	2015	2014	2013
Shares underlying Convertible Senior Secured Notes			6,219,782
Warrants to purchase common stock			13,388
Stock options, stock appreciation rights, non-vested stock options and ESPP awards			151,737

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

11. Earnings per Share (Continued)

The following table sets forth the computation of basic and diluted net income per share for the years ended December 31, 2015, 2014, and 2013, in thousands, except share and per share amounts:

	Year ended December 31,		
	2015	2014	2013
Numerator, in thousands:			
Net income (loss) used for calculation of basic EPS	$ 14,016	$ 19,871	$ (92,273)
Interest expense on convertible debt	1,229	4,963	
Changes in fair value of derivative liabilities	(589)	(2,809)	
Loss on extinguishment of debt	2,338	2,592	
Loss on extinguishment of outstanding debt, as if converted	(2,494)	(8,315)	
Total adjustments	484	(3,569)	
Net income used for calculation of diluted EPS	$ 14,500	$ 16,302	$ (92,273)
Denominator:			
Weighted average shares outstanding, basic	47,485,258	42,260,896	31,848,299
Effect of dilutive potential common shares:			
Shares underlying Convertible Senior Secured Notes	2,459,009	7,090,722	
Shares issuable to settle interest make-whole derivatives	804,507	904,618	
Warrants to purchase common stock		20,499	
Stock options, stock appreciation rights, and non-vested stock options	411,606	306,776	
Total potential dilutive common shares	3,675,122	8,322,615	
Weighted average shares outstanding, diluted	51,160,380	50,583,511	31,848,299
Net income (loss) per share, basic	$ 0.30	$ 0.47	$ (2.90)
Net income (loss) per share, diluted	$ 0.28	$ 0.32	$ (2.90)

12. Income Taxes

The components of the income tax expense/ (benefit) for the years ended December 31, 2015, 2014, and 2013 were as follow, in thousands:

	Year Ended December 31,		
	2015	2014	2013
Current			
Federal	$ 914	$	$
State	42		
Deferred			
Federal			

State

Total	$	956	$	$

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

12. Income Taxes (Continued)

For the years ended December 31, 2015, the expense (benefit) for US. Federal or state income taxes was $1.0 million. For the years ended December 31, 2014, and 2013, there was no expense (benefit) for U.S. Federal or state income taxes based on continuing operations, net operating loss carryforwards and the Company's valuation allowance against its deferred income tax asset. A reconciliation of the expected income tax expense/(benefit) computed using the U.S. Federal statutory income tax rate to the Company's effective income tax rate is as follows, in thousands:

	Year Ended December 31,		
	2015	2014	2013
Income tax expense/(benefit) computed at U.S. Federal statutory tax rate	$ 5,240	$ 6,955	$ (32,286)
Permanent items	601	610	340
State income taxes	50	627	(4,772)
Change in valuation allowance	(4,849)	(10,604)	31,526
Uncertain income tax position	833	(960)	5,411
Research and development credits	(979)	(535)	(156)
Other	60	(125)	(63)
Deferred rate change		4,032	
Income tax expense (benefit)	$ 956	$	$

The Company recorded a change in our deferred income tax rate due to changes in state apportionment factors. The deferred income tax expense/(benefit) have been entirely offset by the net change in valuation allowances. The significant components of the Company's deferred income tax assets (liabilities) were as follow, in thousands:

	As of December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforward	$ 34,676	$ 42,800
Deferred rent credit	532	506
Accrued compensation and non-qualified stock options	5,891	3,392
Deferred financing costs	188	244
Depreciation and amortization	291	474
Research and development credits	5,529	4,725
Capitalized overhead into inventory (UNICAP §263A)	543	675
Other	495	552
Valuation allowance	(47,526)	(49,914)
Net deferred tax asset	619	3,454
Deferred tax liability:		
Debt discount on convertible notes	(509)	(3,454)
Depreciation	(110)	
Net deferred taxes	$	$

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

12. Income Taxes (Continued)

In assessing the realizability of deferred income tax assets, management considers whether it is more likely than not that some or all of the deferred income tax assets will not be realized. The ultimate realization of the deferred income tax assets is dependent upon the generation of future taxable income during the periods in which the net operating loss (NOL) and tax credit carryforwards are available. Management considers projected future taxable income, the scheduled reversal of deferred income tax liabilities, and available tax planning strategies that can be implemented by the Company in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the NOL and credit carryforwards are available to reduce income taxes payable, management has established a full valuation allowance as the Company is not more likely than not to realize such net deferred tax assets.

The net decrease during the year ended December 31, 2015 in total valuation allowance of approximately $2.5 million is due to the pretax book income which was generated in the current year and an adjustment in the Company's deferred income tax rate.

As of December 31, 2015, the US Federal and state NOL carryforwards amounted to approximately $91.8 million ($34.6 million tax effected) and will expire in various years beginning in 2030. As of December 31, 2015, the Company has available research and development credit carryforwards of approximately $5.5 million, which expire, if unused, starting in 2026. The use of the Company's U.S. Federal and state NOL carryforwards and research and development credits are restricted in annual use due to changes in the Company's ownership. For the year ended December 31, 2015, the Company utilized NOL's of approximately $18.5 million and expects the remaining $91.8 million of NOL carryforwards to become available over the years from 2016 to 2020, in amounts ranging from $7.8 million to $20.3 million per year. In addition, the Company has available research and development credits of approximately $5.5 million expected to become available in 2020 to 2021. The Company's state NOL's will have a similar limitation to the amount noted for US Federal. Additionally, despite the NOL carryforwards, the Company may have a future tax liability due to state and local income tax requirements. The Company paid no Federal income taxes in the years ended December 31, 2015, 2014, or 2013.

The Company accounts for uncertain income tax positions pursuant to the guidance in FASB ASC Topic 740, *Income Taxes*. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2015, the Company accrued interest of a nominal amount and penalties of $0.1 million related to uncertain tax positions. The Company's income taxes have not been subject to examination by any tax jurisdictions since its inception in 2005. Due to NOL and research and development credit carryforwards, all U.S. Federal and state income tax returns filed by the Company are subject to examination by the taxing jurisdictions. Any uncertain income tax position liability has been recorded to the Company's deferred income tax assets to offset such tax attribute carryforwards.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

12. Income Taxes (Continued)

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows, in thousands:

	Year Ended December 31,		
	2015	2014	2013
Balance as of January 1	$ 8,342	$ 9,828	$ 688
Gross (decreases) increases related to prior-year tax positions	(5)	(1,040)	23
Gross increases related to current-year tax positions	984	80	9,117
Gross decreases related to current-year tax positions	(244)		
Change in tax rates	(21)	(526)	
Balance as of December 31	$ 9,056	$ 8,342	$ 9,828

The Company believes that most of its uncertain income tax positions would not result in adjustments to its effective income tax rate because a corresponding adjustments to deferred income tax assets would be offset by adjustments to recorded valuation allowances. As of December 31, 2015, the Company recorded $1.0 million of current tax expense on setting up an uncertain tax position related to the Alternative Minimum Tax. The Company does not anticipate a significant increase or decrease in the uncertain income tax benefits within the next 12 months.

13. Commitments and Contingencies

The Company has concurrent leases for office and lab space that extend through April 2020. The Company may elect to extend the term of the leases for an additional five-year term. The leases provide for a tenant improvement allowance of approximately $2.1 million in aggregate. During December 31, 2015, 2014, and 2013, approximately $0.2 million, $0.1 million, and $0.5 million, respectively, of the allowance was utilized and is included in fixed assets and deferred rent. As of December 31, 2015, $0.5 million is available for tenant improvements. Rent expense for the leased facilities and leased vehicles for the years ended December 31, 2015, 2014, and 2013 was approximately, $2.6 million, $2.3 million, and $1.6 million, respectively.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2015 are as follows, in thousands:

Year ending December 31:	
2016	$ 1,430
2017	1,290
2018	1,314
2019	1,341
Thereafter	454
	$ 5,829

The Company has obtained exclusive licenses from third parties for proprietary rights to support the product candidates in the Company's psychiatry portfolio. Under license agreements with Afecta, the

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

13. Commitments and Contingencies (Continued)

Company has an exclusive option to evaluate Afecta's CNS pipeline and to obtain exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. The Company does not owe any future milestone payments for SPN-810. The Company is obligated to pay royalties to Afecta based on worldwide net product sales in the low-single digits.

The Company has also entered into a purchase and sale agreement with Rune, where the Company obtained the exclusive worldwide rights to a product concept from Rune. There are no future milestone payments due to Rune under this agreement. If the Company receives approval to market and sell any products based on the Rune product concept for SPN-809, the Company is obligated to pay royalties to Rune based on net sales worldwide in the low single digits.

14. Employee Benefit Plan

On January 2, 2006, the Company established the Supernus Pharmaceuticals, Inc. 401(k) Profit Sharing Plan (the 401(k) Plan) for its employees under Section 401(k) of the Internal Revenue Code (Code). Under the 401(k) Plan, all full-time employees who are at least 21 years old are eligible to participate in the 401(k) Plan. Employees may participate starting on the first day of the month following employment. Employees may contribute up to the lesser of 90% of eligible compensation or the applicable limit established by the Code.

Employees are 100% vested in their contributions to the 401(k) Plan. The Company matches 100% of a participant's contribution for the first 3% of their salary deferral and matches 50% of the next 2% of their salary deferral. As determined by the Board, the Company may elect to make a discretionary contribution not exceeding 60% of the annual compensation paid to all participating employees. The Company's contributions to the 401(k) Plan approximated $1.4 million, $1.1 million, and $0.6 million for the years ended December 31, 2015, 2014, and 2013, respectively.

15. Collaboration Agreements

The Company has a license agreement with United Therapeutics Corporation to use one of its proprietary technologies for an oral formulation of Remodulin for the treatment of pulmonary arterial hypertension and potentially for additional indications. The revenue generated in the year ended December 31, 2014 was $2.0 million for a milestone payment. During 2014, we entered into a Royalty Interest Acquisition Agreement with HC Royalty. Pursuant to this Agreement, HC Royalty made a $30.0 million cash payment to the Company in consideration for acquiring from the Company certain royalty and milestone rights related to the commercialization of Orenitram (treprostinil) Extended-Release Tablets. We will retain full ownership of the royalty rights after a certain threshold has been reached per the terms of the Agreement. Prior to that time, we will receive no revenue under this license agreement.

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Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2015, 2014 and 2013

16. Quarterly Financial Information (unaudited)

Quarterly financial information for fiscal 2015 and 2014 are presented in the following table, in thousands, except per share data, unaudited:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2015				
Revenue	$ 28,133	$ 35,052	$ 38,587	$ 42,655
Total costs and expenses	24,703	31,976	34,277	35,806
Operating income	3,430	3,076	4,310	6,849
Net income	917	2,005	4,222	6,872
Net income per share, basic	0.02	0.04	0.09	0.14
Net income per share, diluted	0.02	0.03	0.08	0.14
2014				
Revenue	$ 9,081	$ 29,675(2)	$ 52,488(1)	$ 30,801
Total costs and expenses	22,503	25,919	23,321	26,072
Operating loss	(13,422)	3,756	29,167	4,729
Net loss	(15,543)	3,202	27,858	4,354
Net loss per share, basic	(0.38)	0.08	0.65	0.10
Net loss per share, diluted	(0.38)	0.08	0.39	0.10

(1) The Company's results for the third quarter of 2014 include $30.0 million in revenue upon entering into a Royalty Interest Acquisition Agreement.

(2) The Company's results for the second quarter of 2014 include the change in accounting estimate regarding revenue recognition on product sales for Trokendi XR from prescriptions filled to shipments to wholesalers.

17. Subsequent Events

Subsequent to December 31, 2015, holders of the Notes converted approximately $2.0 million of the Notes.We issued a total of approximately 0.4 million shares of common stock in conversion of the principal amount of the Notes and accrued interest thereon resulting in a remaining outstanding balance of $6.6 million.

As of February 5, 2016, litigation with respect to Oxtellar XR was decided in favor of the Company pending appeal when a federal court ruled that three of our patents were found to be valid, and that Actavis infringed two of these three patents.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

CEO/CFO Certifications

Attached to this Annual Report on Form 10-K as Exhibits 31.1 and 31.2, there are two certifications, or the Section 302 certifications, one by each of our Chief Executive Officer (CEO) and our Chief Financial Officer (CFO). This Item 9A contains information concerning the evaluation of our disclosure controls and procedures and internal control over financial reporting that is referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Evaluation of Disclosure Controls and Procedures

Our management, including our CEO and CFO, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this Annual Report on Form 10-K has been appropriately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, to allow timely decisions regarding required disclosure. Based on that evaluation, our CEO and CFO have concluded that our disclosure controls and procedures are effective at the reasonable assurance level to ensure that material information relating to the company and our consolidated subsidiaries is made known to management, including the CEO and CFO, on a timely basis and during the period in which this Annual Report on Form 10-K was being prepared.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and our CFO, as appropriate, to allow timely decisions regarding required disclosures.

We conducted an evaluation, and under the supervision and with the participation of our management, including the CEO and CFO, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-15(b) and 15d-15(b) under the Exchange Act. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2015.

Our management, including the CEO and CFO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed 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 our company have been detected.

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Changes in Internal Control over Financial Reporting

Our management, including our CEO and CFO, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2015, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, our CEO and CFO and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP and includes those policies and procedures that:

- pertain to the management of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- 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 the Company are being made only in accordance with authorizations of management and directors of the Company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework that was published in 2013.

Based on our assessment, management believes that, as of December 31, 2015, the Company's internal control over financial reporting is effective based on those criteria.

As an Emerging Growth Company, as defined under the terms of the JOBS Act of 2012, the Company's independent registered public accounting firm is not required to issue a report on the internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Not applicable.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2016 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2015.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2016 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2015.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by Item 201(d) of Regulation S-K is set forth below. The remainder of the information required by this Item 12 is incorporated by reference from our definitive proxy statement for our 2016 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2015.

The following table shows the number of securities that may be issued pursuant to our equity compensation plans (including individual compensation arrangements) as of December 31, 2015:

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)	Weighted-average exercise price of outstanding options, warrants and rights(1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column(2))
Equity compensation plans approved by security holders	2,699,007	$ 8.94	1,330,973
Equity compensation plans not approved by security holders			
Total	2,699,007	$ 8.94	1,330,973

(1) The securities that may be issued are shares of the Company's Common Stock, issuable upon conversion of outstanding stock options.

(2) The securities that remain available for future issuance are issuable pursuant to the 2012 Equity Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2016 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2015.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2016 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2015.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a)(1) Index to consolidated Financial Statements

The Financial Statements listed in the Index to Consolidated Financial Statements are filed as part of this Annual Report on Form 10-K. See Part II, Item 8, "Financial Statement and Supplementary Data."

(a)(2) Financial Statement Schedules

Other financial statement schedules for the years ended December 31, 2015 and 2014 have been omitted since they are either not required, not applicable, or the information is otherwise included in the consolidated financial statements or the notes to consolidated financial statements.

(a)(3) Exhibits

The Exhibits listed in the accompanying Exhibit Index are attached and incorporated herein by reference and filed as part of this report.

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SIGNATURES

Pursuant to the requirements of Securities 13 or 15(d) of the Securities and Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SUPERNUS PHARMACEUTICALS, INC.
By: /s/ JACK A. KHATTAR

Name: Jack A. Khattar
Title: *President and Chief Executive Officer*

Date: March 8, 2016

Pursuant to the requirements of the Securities Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and the dates indicated below:

Signature	Title	Date
/s/ JACK A. KHATTAR	President and Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2016
/s/ GREGORY S. PATRICK	Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 8, 2016
/s/ M. JAMES BARRETT, PH.D.	Director and Chairman of the Board	March 8, 2016
/s/ GEORGES GEMAYEL	Director	March 8, 2016
/s/ FREDERICK M. HUDSON	Director	March 8, 2016
/s/ CHARLES W. NEWHALL, III	Director	March 8, 2016
/s/ WILLIAM A. NUERGE	Director	March 8, 2016
/s/ JOHN M. SIEBERT, PH.D.	Director	March 8, 2016

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EXHIBIT INDEX

Exhibit Number	Description
3.1*	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1, File No. 333-184930, as amended on November 28, 2012.)
3.2*	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1, File No. 333-184930, as amended on November 28, 2012.)
4.1*	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012.)
4.2*	Indenture dated as of May 3, 2013 by and between the Company and U.S. Banks National Associates, as Trustee and Collateral Agent (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on May 9, 2013, File No. 001-35518).
4.3*	Form of 7.50% Convertible Senior Secured Note due 2019 (incorporated by reference to Exhibit 4.2 to the Form 8-K filed on May 9, 2013, File No. 001-35518).
4.4*	Security and Pledge Agreement dated as of May 3, 2013 between the Company and U.S. Bank National Association, as Collateral Agent (incorporated by reference to Exhibit 4.2 to the Form 8-K filed on May 9, 2013, File No. 001-35518).
4.5*	First Supplemental Indenture dated as of October 24, 2013 by and between the Company and U.S. Bank National Association as Trustee and Collateral Agent (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on October 24, 2013, File No. 001-35518).
10.1*	2005 Stock Plan and form agreements there under (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.2*	Supplemental Executive Retirement Plan (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.3*	Employment Agreement, dated as of December 22, 2005, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.4*	Stock Restriction Agreement, dated December 22, 2005, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.5*	Lease, dated as of April 19, 1999, by and between ARE Acquisitions, LLC and Shire Laboratories Inc. (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.6*	First Amendment to Lease, dated as of November 1, 2002, by and between ARE Acquisitions, LLC and Shire Laboratories Inc. (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).

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Exhibit Number		Description
10.7*		Second Amendment to Lease, dated as of December 22, 2005, by and among ARE-East Gude Lease, LLC, Shire Laboratories Inc. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.8*		Third Amendment to Lease, dated as of November 24, 2010, by and between ARE-East Gude Lease, LLC and the Registrant (successor-in-interest to Shire Laboratories Inc.) (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.9*		Investor Rights Agreement, dated as of December 22, 2005, by and among the Registrant and the holders of shares of Series A convertible preferred stock identified therein, as amended (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2011).
10.10	*	Asset Purchase and Contribution Agreement, dated as of December 22, 2005, by and among the Registrant, Shire Laboratories Inc. and Shire plc (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.11	*	Guanfacine License Agreement, dated as of December 22, 2005, by and among the Registrant, Shire LLC and Shire plc, as amended (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.12	*	Exclusive License Agreement, dated as of June 6, 2006, by and between the Registrant and United Therapeutics Corporation (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.13	*	Exclusive Option and License Agreement, dated as of April 27, 2006, by and between the Registrant and Afecta Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.14	*	Purchase and Sale Agreement, dated as of June 9, 2006, by and between the Registrant and Rune HealthCare Limited (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.15	*	Exclusive License Agreement, dated as of November 2, 2007, by and between the Registrant and Afecta Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.16*		Form of Indemnification Agreement (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on February 14, 2012.
10.17*		Offer Letter, dated June 10, 2005, to Dr. Padmanabh P. Bhatt from the Registrant (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).

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Exhibit Number	Description
10.18*	Amended and Restated Employment Agreement, dated February 29, 2012, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.19*	Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on April 11, 2012).
10.20*	Form of Time-Based Incentive Stock Option Agreement under the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on April 11, 2012).
10.21*	Form of Non-Statutory Time-Based Stock Option Agreement under the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on April 11, 2012).
10.22*	Supernus Pharmaceuticals, Inc. 2012 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on April 11, 2012).
10.23*	Amendment No. 2 to Investor Rights Agreement dated April 6, 2012 by and among the Registrant and the holders of shares of Series A convertible preferred stock identified therein (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on April 11, 2012).
10.24*	Offer letter to Stefan K.F. Schwabe dated June 25, 2012 (incorporated by reference to Exhibit 10.1 to the Company's quarterly report filed on Form 10-Q, File No. 001-35518, on November 2, 2012).
10.25 *	Commercial Supply Agreement, dated August 23, 2012, by and among Patheon, Inc. and the Company (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 7, 2013, File No., 333-171375).
10.26*	Lease Agreement, dated February 6, 2013, by and among ARE-1500 East Gude, LLC and the Company.
10.27 *	Commercial Supply Agreement dated December 5, 2012 by and among Catalent Pharma Solutions, LLC and the Company (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 13, 2013, File No. 001-35518).
10.28*	Compensatory Arrangements of Certain Executive Officers for 2016 (incorporated by reference to the Form 8-K filed on March 4, 2016, File No. 001-35518).
10.29*	Royalty Interest Acquisition Agreement, dated July 1, 2014, by and between Supernus Pharmaceuticals, Inc. and HealthCare Royalty Partners III, L.P. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on July 8, 2014, File No. 001-35518).
10.30*	Security Agreement, dated July 1, 2014, by and between Supernus Pharmaceuticals, Inc. and HealthCare Royalty Partners III, L.P. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on July 8, 2014, File No. 001-35518).
10.31*	Form of Executive Retention Agreement (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 18, 2014, File No. 001-35518).

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Exhibit Number	Description
10.32*	Amendment to Amended and Restated Employment Agreement, dated August 8, 2014, by and between Supernus Pharmaceuticals, Inc. and Jack Khattar (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on August 11, 2014, File No. 001-35518).
10.33*	Fourth Amendment to Lease Agreement, dated October 20, 2014, by and between ARE-Acquisitions, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 24, 2014, File No. 001-35518).
10.34*	First Amendment to Lease Agreement, dated October 20, 2014, by and between ARE-1500 East Gude, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on October 24, 2014, File No. 001-35518).
10.35*	Second Amendment to Amended and Restated Employment Agreement, dated March 2, 2016, by and between Supernus Pharmaceuticals, Inc. and Jack Khattar (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on March 4, 2016, File No. 001-35518).
10.36 **	Settlement Agreement, dated October 14, 2015, by and between Supernus Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical, Inc.
14*	Code of Ethics.
21*	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1, File No. 333-184930, as amended on November 28, 2012).
23.1**	Consent of Ernst & Young LLP
23.2**	Consent of KPMG LLP
31.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 INS**	XBRL Instance Document.
101 SCH**	XBRL Taxonomy Extension Schema Documents.
101 CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101 DEF**	XBRL Taxonomy Extension Definition Linkbase Document.
101 LAB**	XBRL Taxonomy Extension Label/Linkbase Document.
101 PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.

Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the **Confidential Treatment Request.**

*

Previously filed.

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Filed herewith.