SUPERNUS PHARMACEUTICALS INC
Form 10-K
March 12, 2015

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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, 2014

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

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, 2014, 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 $238,315,986.

The number of shares of the registrant's common stock outstanding as of March 11, 2015 was 44,089,023.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2015 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 2014 fiscal year end, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SUPERNUS PHARMACEUTICALS, INC.
FORM 10-K

For the Year Ended December 31, 2014

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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. We launched our first two products in neurology for the treatment of epilepsy, Oxtellar XR (oxcarbazepine extended release tablets) and Trokendi XR (topiramate extended release capsules), during 2013. We are also developing multiple product candidates in psychiatry to address the large unmet medical needs and market opportunities in impulsive aggression across several areas (such as attention deficit hyperactivity disorder ("ADHD"), autism and bipolar disorder), and ADHD. Our extensive expertise in product development has been built over the past 24 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 were 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 the immediate release products by offering convenient once-daily dosing and unique pharmacokinetic profiles that can be very important for patients with epilepsy. We believe a once-daily dosing regimen improves compliance allowing patients to benefit from their medications, and the unique smooth and steady pharmacokinetic profiles of once-daily dosing avoid the blood level fluctuations that are typically associated with immediate release products that can result in adverse events or decreased efficacy. 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.

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Underlying our net product revenues of $89.6 million in 2014 is strong growth in prescriptions for Oxtellar XR and Trokendi XR. Total prescriptions as reported by Wolter Kluwers or Symphony ("SHA") have shown a steady increase quarter over quarter as shown in the following graph.

Source: SHA Monthly Prescriptions

Given the large and growing base of prescriptions of immediate release products, we expect to continue to expand our revenues for Oxtellar XR and Trokendi XR for the foreseeable future. We believe these products have the potential for peak net sales in excess of $500 million based on a market of $1.3 billion for oxcarbazepine and $4.5 billion for topiramate, which accounts for all indications of corresponding molecules' total market.

Oxtellar XR is indicated for adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age and 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 adjunctive 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). SPN-810 is currently being developed for the treatment of impulsive aggression in patients with ADHD in conjunction with standard ADHD treatment. In August 2014, the Food and Drug Administration ("FDA") granted fast track designation for SPN-810 and in December 2014 we held an end of Phase II clinical meeting with the FDA. The Company is currently designing a Phase III protocol which will undergo a Special Protocol Assessment ("SPA"). We expect the program to enter Phase III testing in the fourth quarter of 2015. SPN-812 is being developed as a non-stimulant treatment for ADHD. During the second quarter of 2014, we completed a pharmacokinetic study evaluating extended release formulations for SPN-812. This study was successful and we have selected

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an extended release formulation that will be the basis of future clinical trials including a Phase IIb trial which we expect to initiate in the fourth quarter of 2015.

We have a successful track record of developing and launching 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 have been utilized to create nine marketed products, including both Trokendi XR and Oxtellar XR, 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	Impulsive Aggression*	Phase III in 2015
SPN-812	ADHD	Phase IIb in 2015
SPN-809	Depression	Active IND

* Initial program will be in ADHD, with a plan to follow on in autism and bipolar disorder.

We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies, products, and product candidates. We currently have four U.S. patents issued covering Oxtellar XR and five 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 will start trials for our product candidates in our psychiatry portfolio. SPN-810 is being developed as a treatment for impulsive aggression in patients with ADHD in conjunction with standard ADHD treatment. We expect the program to enter Phase III testing in the fourth quarter of 2015. SPN-812 is being developed as a non-stimulant treatment for ADHD. We expect to start a Phase IIb trial during 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, potential co-development partnerships on 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.

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Our Neurology Portfolio

Oxtellar XR and Trokendi XR are novel extended release formulations of two well known and approved anti-epileptic drugs ("AEDs"), oxcarbazepine and topiramate, respectively. Both formulations are designed to offer epilepsy patients effective therapy, the potential for reduced side effects and improved compliance with once-per-day dosing. We believe that by delivering more consistent plasma concentrations of oxcarbazepine and topiramate, Oxtellar XR and Trokendi XR can potentially reduce adverse side effects to improve tolerability and increase adherence, enabling patients to benefit from better seizure control and fewer breakthrough seizures as compared to immediate release products of oxcarbazepine and topiramate. Given that Oxtellar XR and Trokendi XR are based on different drug compounds and different mechanisms of action, they target different market segments and patient populations within the epilepsy market.

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 AED therapy is a serious issue and remains one of the most common causes 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 blood level concentrations as compared to immediate release products, potentially resulting in fewer side effects, better tolerability and efficacy. Improved tolerability can help patients improve their adherence, have fewer breakthrough seizures and, correspondingly, enjoy a better quality of life.

Trokendi XR

Trokendi XR is the first once-daily topiramate product indicated for epilepsy in the U.S. market and is designed to improve patient compliance and to have a better pharmacokinetic profile compared to the current immediate release products that are taken multiple times per day. Trokendi XR's pharmacokinetic profile results in lower peak plasma concentrations, higher trough plasma concentrations and slower input rate over an extended time period. This results in smoother and more consistent blood levels of topiramate as compared to immediate release topiramate. We believe that such a profile mitigates blood level fluctuations that are frequently associated with many of the side effects or breakthrough seizures that patients can suffer when taking immediate release products. Side effects can lead patients to skipping doses, and non-adherence could place them at higher risk for breakthrough seizures.

Oxtellar XR

Oxtellar XR is the only once-daily oxcarbazepine product indicated for the treatment of epilepsy in the U.S. as an adjunctive therapy. With its novel pharmacokinetic profile that delivers lower peak plasma concentrations, slower rate of input, higher trough plasma concentrations and smoother and more consistent blood levels concentrations compared to immediate release products, we believe Oxtellar XR has the potential to improve the tolerability of oxcarbazepine by reducing the side effects experienced by patients. This could enable more patients to tolerate higher doses of oxcarbazepine, which would permit them to benefit from the resulting improved efficacy and greater seizure control that have been previously reported in patients at higher doses. In addition, Oxtellar XR once-per-day dosing is

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designed to improve patient compliance compared to the current immediate release products that are taken multiple times per day.

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 seventeen geographically and clinically diverse sites across the U.S. to include non-academic and academic affiliated practices, general neurology, pediatric neurology, and epilepsy centers.

Sales and Marketing

We have established a commercial organization in the United States 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.

If we obtain FDA approval for any of our product candidates in our psychiatry portfolio, we anticipate adding additional sales representatives who will be dedicated to marketing our psychiatry products.

Manufacturing

We currently depend on third-party commercial manufacturing organizations ("CMOs"), for all of our required raw materials and drug substance for our preclinical research and clinical trials. We have entered into agreements with Patheon Pharmaceuticals Inc., PCI Inc., and Catalent Pharma Solutions, leading CMOs headquartered in North America, for the manufacture of the final commercial products Oxtellar XR and Trokendi XR. These CMOs offer a comprehensive range of contract manufacturing and packaging services.

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. For Trokendi XR, Oxtellar XR and our product candidates, we currently rely on single third-party suppliers for raw materials including drug substance and single manufacturers for the final commercial products. 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 and other anti-epileptic products. Oxtellar XR competes with all immediate release oxcarbazepine products including Trileptal and its related generics and other anti-epileptic products.

Our Psychiatry Portfolio

Our psychiatry portfolio includes three product candidates for the treatment of impulsive aggression in patients with ADHD, ADHD or its coexisting conditions, and depression, each of which is designed to bring important advancements in therapy.

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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 2014, according to data from SHA, the U.S. market for ADHD prescription drugs was $10 billion with 65.3 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 are treated for ADHD.

Current Treatments for Impulsive Aggression in Patients with ADHD

Currently, we do not believe there are any approved medications for the treatment of impulsive aggression in patients with ADHD. Impulsive aggression is characteristic of individuals that spontaneously react to stimuli by committing verbal or physical acts against parents, peers, property, or themselves. The current treatment options for impulsive aggression 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 exhibited initial aggression still had what can be described as impulsive aggression 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.

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, and diabetes, which is of particular concern when treating pediatric populations.

SPN-810 (molindone hydrochloride)

We are developing SPN-810 (molindone hydrochloride) as a treatment for impulsive aggression in patients with ADHD in conjunction with standard ADHD treatment. The FDA has granted fast track designation for SPN-810 for the treatment of impulsive aggression in ADHD in conjunction with standard ADHD treatment. Fast track designation is for products that are being investigated for treatment of serious conditions, and for which nonclinical or clinical data suggest that they may address an unmet medical need. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the

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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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disease, if left untreated, will progress from a less severe condition to a more serious one. 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"). The Company intends to submit a request for a SPA to the FDA prior to commencing Phase III testing in the fourth quarter of 2015.

In preparation for our Phase III program, we have conducted technology transfer and completed scale-up at commercial manufacturing sites for both bulk active ingredient and dosage form manufacture. We met with the FDA during the third quarter of 2014 to discuss commercial manufacturing requirements for our extended release formulation. Also, in December 2014 we held an end-of-phase II meeting with the FDA where we discussed the development plan of SPN-810 and protocols for our studies. Based on the meeting we will expand the target patient population in our clinical program to include adolescents. This allows us to address a larger patient population and does not significantly alter our development plan and projected timeline. Finally, in 2014 we completed an intensive program to create and validate a new and specific outcomes and assessments scale for use in this unique development program for the treatment of impulsive aggression in patients with ADHD. We are making progress toward finalizing this scale in close cooperation with the FDA. We are targeting to meet with the FDA during the second quarter to review the scale and our request for a special protocol assessment.

Molindone hydrochloride was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. Dosing typically ranged from 50 mg/day to 225 mg/day. Moban has not been commercially available since 2010. The FDA has confirmed that this was not due to safety or efficacy. Molindone hydrochloride is unusual among anti-psychotics in that it is less likely to be associated with weight gain. In addition, we believe the lower doses (12mg/day - 36mg/day) tested for the proposed indication of impulsive aggression should be better tolerated than the higher doses approved to treat schizophrenia. The Phase IIb trial with SPN-810, which included 121 patients, indicated that at the doses studied in the trial, there was no difference in weight gain between patients treated with SPN-810 and placebo. Although initially we are developing SPN-810 as a treatment for impulsive aggression in patients with ADHD in conjunction with standard ADHD treatment, if we are successful in demonstrating the effectiveness of SPN-810, we may then develop the product candidate for the treatment of other patient populations that are characterized by impulsive aggression; e.g. patients with autism, bipolar disorder, schizophrenia, and some forms of dementia. In the aggregate, we believe the addressable market for SPN-810 is greater than $3 billion, including $1.5 billion in ADHD, $1.0 billion in autism and $0.6 billion in bipolar disorder. Our plans are to develop an intellectual property position around the novel synthesis process for this product candidate, its novel use in impulsive aggression, and its novel delivery system.

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 impulsive aggression that is not controlled by optimal stimulant and behavioral therapy. The primary objective of the study was to assess the effect of SPN-810 in reducing impulsive aggression as measured by the Retrospective-Modified Overt Aggression Scale ("R-MOAS") after at least three weeks of assigned treatment. Secondary endpoints included the rate of remission of impulsive aggression 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. We received preliminary results from this trial in November 2012. The final analysis provided here updates those preliminary results.

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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, treatment group means of the change form baseline at the end of 3 weeks of treatment in R-MOAS for each of the four dose groups (high, medium, low and placebo) are compared using the t-test. The non-parametric method does not assume that data are normally distributed. Under this method, treatment group medians of the change from baseline at the end of 3 weeks of treatment in R-MOAS for each of the four dose groups (high, medium, low and placebo) are compared using the Wilcoxon Rank-sum test. There was a statistically significant difference between the low dose and placebo ($p=0.064$ for t-test and $p=0.031$ for Wilcoxon test) and also between the medium dose and placebo ($p=0.027$ for t-test and $p=0.024$ for Wilcoxon test) at the $\alpha=0.05$ level. There was no statistically significant difference between the high dose and placebo. Both parametric and non-parametric results show that the medium dose and low dose are superior to placebo and this conclusion is not dependent on data distribution. These results indicated 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 statistical significance 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. 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 ("EPS") 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 adverse events, and no unexpected, life threatening, or dose-limiting safety issues.

SPN-812 (viloxazine hydrochloride)

We are developing SPN-812 as a novel non-stimulant for the treatment of ADHD. 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. We expect to start the Phase IIb trial during the fourth quarter of 2015.

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

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other non-stimulant therapies due to its different pharmacological profile. A Phase IIa trial, completed in 2011, showed that SPN-812 was effective in treating ADHD in adults.

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) 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 net product sales of approximately $700 million each. 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. We own all of the pending applications.

We expect SPN-812, if approved, to have five year market exclusivity given its new chemical entity status in the United States of America.

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. 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. 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 either treatment three times a day for a one-week titration followed by five weeks of maintenance therapy. SPN-812 was shown to be safe and well tolerated as indicated by the results of the primary safety endpoint. 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 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 plan to commence a Phase IIb trial during the fourth quarter of 2015.

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.

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(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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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; and Daytrana. 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 with the other seven being marketed by our partners. 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 our partner 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 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.

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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. 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 six U.S. patents, four 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, and Mexico. In addition, we have certain pending U.S. and foreign patent applications that cover various extended release formulations containing oxcarbazepine. The four 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 five U.S. patents that cover Trokendi XR. We have one patent issued each in Europe, Australia, Japan and Canada for extended release topiramate and have certain pending U.S. and foreign patent applications that relate to the U.S. patents that cover extended release formulations containing topiramate. The five 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 in the U.S. in one family, covering a process for preparing molindone. In another family we have one patent issued each in the U.S. and Australia, covering modified release formulations of molindone. 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. We own all of the issued patents and the pending applications.

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

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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 United States 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 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®," "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 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 five cases pending against third 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."

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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. Under the terms of the license agreements, we have paid Afecta $550,000 in license fees and milestone payments and may pay up to an additional $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 net sales worldwide in the low-single digits. Unless terminated by us or Afecta for material breach or bankruptcy, by Afecta for our discontinuation of development and commercialization activities, or by us for convenience, the license agreements will continue in full force and effect on a country-by-country basis until six months from the discontinuation of the commercial sale and collection of revenues for the Afecta product.

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. Under the terms of the agreement, we have paid Rune a £25,000 up-front fee. 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. Unless terminated by us or Rune for material breach, by Rune for our discontinuation of development or commercialization activities relating to a product based on the Rune product concept, we will be obligated to pay royalties to Rune on a country-by-country basis until the earlier of (a) ten years from the date of first commercial sale of a product covered by the agreement, or (b) the market entry in such country of any product utilizing the Rune product by any entity other than us, our affiliates or our licensees.

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, 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 United States.

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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 United States 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 $19.6 million and $17.2 million for each of 2014 and 2013, respectively.

Once a suitable product candidate is successfully created, a preliminary development strategy is determined. Usually, an Investigational 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.

Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRBs for approval. Protocols detail, among other

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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.

In addition, under the Pediatric Research Equity Act of 2003 ("PREA") which was reauthorized under the Food and Drug Administration Safety and Innovation Act of 2012, an NDA must contain, *a priori*,

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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 Syndrom from two years to less than six years of age. We expect to need a total of four pediatric studies to fulfill these deferred pediatric commitments for Trokendi XR.

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 candidates successfully, and to attract commercialization partners for our 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 Affordability Reconciliation Act of 2010, which we refer to collectively as the Health Care 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 health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care 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 HeatlhCare 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 Health Care 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 Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. 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. 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 predict whether any proposed cost-containment measures will be adopted or otherwise implemented in

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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 the Centers for Medicare and Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. 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 Health Care 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, 2014, we employed 309 full-time employees. 56 employees are engaged in research and development activities and 253 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 successfully commercialize Oxtellar XR and Trokendi XR 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 for Oxtellar XR and Trokendi XR;
- 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 build commercial 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 the product by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements;
- manage our growth and spending as costs and expenses increase due to commercialization;
- establish collaborations with third parties for the commercialization of our products in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- 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 of our products, as well as the emergence of new or existing products as competition, which may be

proven to be more clinically effective and cost-effective.

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 support of our sales of Oxtellar XR and Trokendi XR. In addition, we have certain revenue expectations with respect to the sale of Oxtellar XR and Trokendi XR. If we cannot continue to

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achieve those revenue expectations with respect to Oxtellar XR and Trokendi XR, this would result in a material adverse impact on our anticipated revenue, earnings and liquidity.

The ability to produce Oxtellar XR and Trokendi XR will be largely dependent on the ability of third-party manufacturers and collaborators. If they do not deploy the resources we would like them to, our revenue could then suffer. In addition, we could become embroiled in disputes with these parties regarding the terms of any agreements, their performance or intellectual property rights. Any dispute could disrupt the sales of our products and adversely affect our reputation and revenue. In addition, if any of our manufacturing or collaboration partners fail to effectively perform under our arrangements for any reason, or cannot perform as a result of circumstances beyond their control, we may not be able to find a suitable replacement partner on a timely basis, or at all, or on acceptable terms.

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 additional 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;
- availability of alternative treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing capability and strategies; and
- ability to obtain sufficient third-party coverage or reimbursement.

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 dependent on the continued increase in sales of Oxtellar XR and Trokendi XR and the ability of our product candidates to receive regulatory approval.

A substantial majority of our resources are focused on continuing to increase sales of our products Oxtellar XR and Trokendi XR in the United States. We also expect to continue to expend significant time, resources and effort on the development of our product candidates. All of our product candidates are in development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully increase sales of Oxtellar XR and Trokendi XR.

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Our ability to successfully commercialize any of our product candidates will depend on, among other things, our ability to:

- successfully complete our clinical trials;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- 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 launch commercial sales of our product candidates;
- establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- 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 to increase the growth of our business. In addition, if we experience unanticipated delays or problems, development costs could substantially increase and our business, financial condition and results of operations will be adversely affected.

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

We have built our sales and marketing capabilities in the United States to commercialize Oxtellar XR and Trokendi XR. We have built such capabilities by investing significant amounts of financial and management resources. We have committed and will commit additional resources to develop and maintain our internal sales and marketing capabilities. Further, we could face a number of additional risks in maintaining our internal sales and marketing capabilities, including:

- we may not be able to continue to attract and retain talented and qualified personnel to maintain effective marketing or sales capability;
- the cost of establishing and maintaining marketing and sales capability may not be justifiable in light of the revenues generated by Oxtellar XR, Trokendi XR, or any of our product candidates if approved by the FDA; and
- our direct sales and marketing efforts may not continue to be successful.

If we are unable to establish 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 and that may prevent us from maintaining profitability.

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The commercial success of our products and product candidates, once approved, depends upon achieving and maintaining market acceptance by physicians, patients, third-party payors and the medical community.

Physicians may not prescribe Oxtellar XR, Trokendi XR or any of our product candidates if approved by the FDA at the levels which we anticipate, in which case we would not generate the revenues we anticipate. Market acceptance of any of our products or product candidates by physicians, patients, third-party payors and the medical community depends on, among other things:

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of each product or product candidate as a safe and effective treatment;
- perceived advantages of our products or product candidates over alternative treatments;
- relative convenience and ease of administration of our products or product candidates compared to existing treatments;
- any labeling restrictions placed upon each product or product candidate in connection with its approval;
- the prevalence and severity of the adverse side effects of each of our products or product candidates;
- the clinical indications for which each of our products or product candidates are approved, including any potential additional restrictions placed upon each product or product candidate in connection with its approval;
- prevalence of the disease or condition for which each product or product candidate is approved;
- the cost of treatment in relation to alternative treatments, including competitors and generic products;
- the extent to which each product or product candidate is approved for inclusion on formularies of hospitals and managed care organizations and the level of reimbursement;
- any negative publicity related to our or our competitors' products or product candidates, including as a result of any related adverse side effects;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness; and
- the availability of adequate reimbursement by third parties.

For example, new AEDs that were introduced in the market as NCEs historically have not quickly gained significant market share against existing molecules in the epilepsy market because physicians are often reluctant to change a patient's existing therapy (even for an NCE) and risk a breakthrough seizure or exacerbate tolerability issues in their patients. Although Oxtellar XR and Trokendi XR are not NCEs, they are subject to the risk that they will not be able to gain significant market share against existing or new AEDs, particularly since their markets are

dominated by low cost generic product offerings. If our products or product candidates do not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenues from these products or product candidates to remain profitable.

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Final marketing approval of any of our product candidates 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 products and 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.

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

could 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;

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 used in our product candidates, wherein those deficiencies may result in interruption in the ability to supply product;

may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;

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

may change its approval policies or adopt new regulations; or

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

Notwithstanding the approval of many products by the FDA pursuant to 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 Section505(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

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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 and product candidates, including Oxtellar XR and Trokendi XR, 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 have been 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 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 generally 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 to a smaller set than we believe they are effective in treating.

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 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.

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In addition, many managed care organizations negotiate the price of products and develop 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 the potential healthcare reforms discussed elsewhere in this Annual Report on Form 10-K, as well as the trend toward programs aimed at reducing health care costs and the increasing influence of health maintenance organizations and additional legislative proposals.

Our failure to successfully develop and market products or 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, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license 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 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;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

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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.

Our 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.

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.

Our products and product candidates may cause undesirable side effects or have other properties 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 sales of the products. Undesirable side effects that are caused by any of our products or product candidates could have a material adverse effect on our business as a whole.

Immediate release oxcarbazepine and topiramate, drug compounds upon which Oxtellar XR and Trokendi XR are based, respectively, 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 these 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 these 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;

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- we may be required to modify the product in some way;
- 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.

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 may and have received 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 in the market Qudexy XR (extended release topiramate) and its own authorized generic, both of which compete with Trokendi XR. SinceTrokendi XR was not granted any 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 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 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

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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.

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 clinical research organizations ("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 initiated 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

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

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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.

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 officers 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.

We also have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

We expect intense competition and, 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 or product candidates that are commercialized unless 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 impulsive aggression 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 for impulsive aggression symptoms observed in patients with ADHD.

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In addition, several companies have various product candidates they are developing for ADHD and which may compete with our SPN-812 product candidate. Non-stimulant ADHD products in Phase III 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 Phase III data in adults 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 plans additional Phase III work in adults in 2015 and has an ongoing Phase II study in adolescents.

Further, new developments, including the development of other drug technologies, may render our 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 any commercialized product.

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 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, if they receive regulatory approval, may be subject to restrictions or withdrawal from the market and 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 post-market information. In addition, manufacturers of drug products and their facilities are

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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, such as side effects of unanticipated severity or frequency, or 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, and our product candidates upon FDA approval, 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. Physicians may nevertheless prescribe our products and, upon receiving FDA approval, our product candidates to their patients in a manner that is inconsistent with the approved label. 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.

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.

We do not currently 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 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 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 on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

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

Manufacturers of pharmaceutical products need to comply with cGMP requirements and other requirements as enforced by the FDA, including for electronic tracking and submission. These requirements include, among other things, 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 or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates. 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 or product candidates, 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 and permanently 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

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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. While we intend 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 of the United States, who may fail to effectively commercialize our products and product candidates.

Outside of the United States, we utilize strategic partners where appropriate, to assist in the commercialization of our products and product candidates, if approved. We currently possess limited resources and may not be successful in establishing collaborations or co-marketing arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promotion 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 and product candidates 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 product candidates outside of 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 product candidates, 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 candidates. 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 be uncertain. 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

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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.

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 on the merits, which may not occur for several years.

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

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

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

- a court prohibiting us from selling 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

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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.

We may become 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 Approved Drug Product List (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 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 patents 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 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 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 ("PAH"), as well as for other indications. On December 20, 2013, United Therapeutics Corporation announced that the FDA had approved Orenitram (treprostinil). United Therapeutics Corporation launched this product 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 threshold payment to Health Care Royalty Partners has been reached. We are entitled to receive milestones and royalties for use of this formulation in

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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.

We also have license agreements with Especificos Stendhal, S.A., DE C.V. and we may enter into additional collaborations in the future. 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 or product candidates for any of these reasons, we may not be able to replace the collaboration partner with another partner to develop and commercialize the product or product candidate 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 continue development and commercialization of the product candidate on our own, which could adversely affect our results of operations.

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

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obligations in an effective and timely manner. Our reliance on third parties, including third-party 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 costly or 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 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 or projected timelines and necessary quality standards for successful manufacture of the various required lots of material for our development and commercialization efforts 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. 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.

We have in-licensed or acquired a portion of our intellectual property necessary to develop certain of our psychiatry product candidates, and 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.

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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.

In order 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 product candidates 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 or product candidates.

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 exposes 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 or product candidate 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;

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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 product candidates 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 any 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 and, 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 and other 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 United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce healthcare costs may adversely affect our ability to set prices for any approved product or our product candidates which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In both the United 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 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 legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010. These laws and their regulations, which we refer to collectively as the Health Care 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 government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care 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.

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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. 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. 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 candidates. The Drug Quality and Security Act ("DQSA") became law on November 27, 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 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 adversely affected by the Health Care 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 Health Care 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 Health Care Reform Law was signed into law in 2010. The Health Care Reform Law is multi-faceted and is being implemented in phases. The financial impact of all of the provisions of the Health Care Reform Law on our business is unclear, and there can be no assurance that our business will not be materially harmed by future implementation of the Health Care Reform Law. In addition, if we are found not to be in full compliance with the Health Care Reform Law, we could face enforcement action, fines and other penalties and we could receive adverse publicity.

The Health Care Reform Law also includes various provisions designed to strengthen significantly 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 of this statute or specific intent to violate it.

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.

The risk of our being found in violation of the Health Care Reform Law, its underlying regulations, or other laws impacted by its implementation is increased 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 federal and state healthcare laws and regulations pertaining to patients' rights to privacy fraud and abuse are and will be applicable to our business. We could be

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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 also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the Health Care 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 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 2014, we increased from 235 employees to 309 employees and increased revenues to $122.0 million in 2014 from $12.0 million in 2013. Our need to effectively execute our growth strategy requires that we:

- manage our regulatory approvals and clinical trials effectively;

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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.

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.

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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 and 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.

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

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. We have in the past been required to change a proposed product name. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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 incurred significant operating losses in the years prior to 2014.

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 primarily through the following transactions:

- private placements of convertible preferred stock;
- our collaboration and license arrangements;
- the monetization of certain future royalty streams under our existing licenses for Orenitram, Oracea, Sanctura XR, and Intuniv;
- the sale of our subsidiary, Royalty Sub, which held the license rights to Oracea and Sanctura XR;
- borrowing via secured loans;
- 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.

We have incurred significant operating losses since our inception in 2005. We incurred net losses of approximately $33.5 million, $38.5 million, $46.3 million and $92.3 million in the years ended December 31, 2008, 2010, 2012 and 2013, respectively. We realized net income of approximately $0.5 million, $53.8 million and $19.9 million in the years ended December 31, 2009, 2011 and 2014 respectively, due to one-time, non recurring items. As of December 31, 2014, we had an accumulated deficit of approximately $158.7 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 be substantial as we continue to support the ongoing commercialization of our products.

Our prior losses have had an adverse effect on our stockholders' equity and working capital. While we anticipate maintaining profitability in 2015 and beyond, we cannot be certain that we will do so and any potential future losses, if and when they occur, could also 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. As a result, we expect to continue to incur significant operating expenses for the foreseeable future.

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.

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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;
- the actions of our competitors and their success in selling competitive product offerings; and
- the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

Additional financing may not be available when we need it or may not be available on terms that are favorable to us, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to delay, reduce the scope of or eliminate 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, particularly Oxtellar XR and Trokendi XR, and our product candidates once approved by the FDA. 2013 was the first year in which we generated revenue from our first commercial products, Oxtellar XR and Trokendi XR. Prior to the commercial launch of these products, our historical revenues have been generated through fees for development services and payment for the achievement of specified development, regulatory and sales milestones, as well as royalties on product sales of Orenitram, Oracea, Sanctura XR and Intuniv licensed products and the sale or license of certain of our assets.

Our operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly and annual fluctuations. We expect that any revenues we generate will fluctuate from quarter to quarter and year to year as a result of revenue from approved products, our license agreements, the amount of 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:

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

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

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;

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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 or new products that may emerge;

regulatory developments affecting our products and product candidates; and

changes in reimbursement environment and regulatory changes.

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 all of 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 compliance cost. We anticipate that these costs will further increase when we are no longer an "emerging growth company", which we anticipate occurring on December 31, 2017. Beginning in 2015, we are transitioning from being a "smaller reporting company" to an "accelerated filer" status which will lead 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 and 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, and 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.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. 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 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 occur 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 increase 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, 2014, we had U.S. Federal and state net operating loss carryforwards of $31.8 million and research and development tax credit carryforwards of $0.6 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.

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Risks Related to Our Indebtedness

Our significant level of indebtedness could adversely affect our business, financial condition and results of operations and prevent us from fulfilling our obligations under the Notes.

We have a significant amount of indebtedness and consequentially substantial debt service requirements. As of December 31, 2014, we have issued and outstanding convertible notes in the aggregate principal amount of $36.1 million. Subject to certain conditions and limitations in the Indenture governing the Notes, we may also incur additional indebtedness, including secured debt, to meet future financing needs.

Our substantial indebtedness could have important and significant effects on our business, financial condition and results of operations. For example, it could:

- make it more difficult for us to satisfy our financial obligations, including with respect to the Notes;
- result in an event of default if we fail to comply with the covenants contained in the Indenture governing the Notes and any agreement governing our existing or future indebtedness. An event of default could result in all of our debt becoming immediately due and payable;
- increase our vulnerability to general adverse economic, industry and competitive conditions;
- reduce the availability of our cash flow to fund working capital, capital expenditures, acquisitions and other general corporate purposes because we will be required to dedicate a substantial portion of our cash flow from operations to the payment of principal and interest on our indebtedness;
- subject us to increased sensitivity to interest rate increases on our existing and future indebtedness, if any, with variable interest rates;
- limit our flexibility in planning for, or reacting to, and increasing our vulnerability to changes in our business, the industry in which we operate and the general economy;
- prevent us from raising funds necessary to repurchase Notes tendered to us if there is a "fundamental change" or pay the interest make-whole payment that may be due in cash in connection with certain conversions of the Notes under the Indenture governing the Notes;
- place us at a competitive disadvantage compared to our competitors that have less indebtedness or are less highly leveraged and that, therefore, may be able to take advantage of opportunities that our debt levels or leverage prevent us from exploiting; and
- limit our ability to obtain additional financing.

Each of these factors may have a material and adverse effect on our business, financial condition and results of operations and our ability to meet our payment obligations under the Notes and our future indebtedness, if any.

Our ability to make payments with respect to the Notes and to satisfy any other debt obligations will depend on our future operating performance and our ability to generate significant cash flow in the future, which will be affected by prevailing economic conditions and financial, business, competitive, legislative and regulatory factors as well as other factors affecting our company and industry, many of which are beyond our control.

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Servicing our indebtedness requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial indebtedness.

As of December 31, 2014, we have issued and outstanding convertible notes in the aggregate principal amount of $36.1 million, bearing an interest rate of 7.5% per annum. Servicing our indebtedness will require the dedication of a portion of our expected cash flow from operations, thereby reducing the amount of our cash flow available for other purposes. In addition, our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive, regulatory and other factors beyond our control. We expect to continue to incur significant and increasing operating expenses for the foreseeable future. Accordingly, the cash flow from operations in the future may be insufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. If we raise additional debt, it could increase our interest expense, leverage and operating financial costs. In addition, the terms of the Indenture governing the Notes and the agreements governing our future indebtedness may restrict us from adopting any of these alternatives. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. Our lack of cash resources or failure to generate sufficient cash flow or to affect any of these alternatives could significantly and adversely affect our ability to pay amounts due under the Notes.

The Indenture governing the Notes contains restrictions that will limit our operating flexibility, and we may incur additional debt in the future that may include similar or additional restrictions.

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;
- make investments in our foreign subsidiaries; and
- enter into mergers, consolidations or sales or leases of all or substantially all of our assets.

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

A breach of any of these covenants or other provisions in our debt agreements could result in an event of default, which if not cured or waived, could result in such debt becoming immediately due and payable. This, in turn, could cause our other debt to become due and payable as a result of cross-default or cross-acceleration provisions contained in the agreements governing such other debt. In the event that some or all of our debt is accelerated and becomes immediately due and payable, we may not have the funds to repay, or the ability to refinance, such debt.

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 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

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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).

We may not have the ability to raise the funds necessary to pay the interest on our Notes, the principal amount of the Notes when due at maturity, redemption or otherwise, the amount of cash due upon conversion of the Notes, if relevant, or the fundamental change purchase price due when a holder submits its Notes for purchase upon the occurrence of a fundamental change, and the agreements governing our existing and future indebtedness may contain limitations on our ability to pay certain of such cash obligations.

Our Notes bear interest annually at a rate of 7.50% per year which interest is payable semi-annually on May 1 and November 1. In addition, in certain circumstances, we are obligated to pay additional interest on the Notes. At maturity or on the redemption date, if any, the entire outstanding principal amount of the Notes will become due and payable by us with respect to Notes that have not been previously converted or purchased by us. In addition, upon the occurrence of an event of default, we may be required to repay the principal amount of Notes, or upon the occurrence of a fundamental change, holders may require us to purchase, for cash, all or a portion of their Notes at a fundamental change purchase price. We at our election may elect to settle conversions of the Notes partially or entirely in cash.

Such payments could be significant, and there can be no assurance that we will have sufficient financial resources, or will be able to arrange financing, so that we can make such payments when due. The terms of the Indenture that govern the Notes may limit our ability to obtain such financing. In addition, the occurrence of a fundamental change may cause an event of default under agreements governing our or our existing or future subsidiaries' indebtedness. Agreements governing any future debt may also restrict our ability to make certain of the required cash payments even if we have sufficient funds to make them. Furthermore, our ability to satisfy such cash obligations may be limited by law or regulatory authority. In addition, if we fail to pay such cash obligations, we will be in default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our indebtedness, which in turn may result in the acceleration of other indebtedness we may then have. If the repayment of the other indebtedness were to be accelerated, we may not have sufficient funds to repay that indebtedness and to make such payments.

The fundamental change provisions of the Notes may delay or prevent an otherwise beneficial takeover attempt of us.

The fundamental change purchase rights, which will allow holders to require us to purchase all or a portion of their Notes upon the occurrence of a fundamental change, and the provisions requiring an increase to the conversion rate for conversions in connection with a make-whole fundamental change may in certain circumstances delay or prevent a takeover of us and the removal of incumbent management that might otherwise be beneficial to investors.

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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 and the trading price of our Notes.

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, 2014, we had outstanding 42,974,463 shares of common stock, of which approximately 15,346,863 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, 2014, we had outstanding options to purchase 2,080,749 shares of common stock and warrants to purchase 42,083 shares of common stock that, if exercised, would result in these additional shares becoming available for sale. A large portion of these shares, options and warrants are held by a small number of persons and investment funds. 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 2,254,948 and 305,570 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, 2014, 5,108,212 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. Also, 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 also registered the resale of 12,749,328 shares of our common stock that may be sold by two selling security holders.

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, 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. In the event we obtain securities or industry analyst coverage, 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.

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The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit your ability to influence certain corporate matters.

Our directors and their affiliated entities, and our executive officers beneficially own, in the aggregate, approximately 28.8% of our outstanding common stock. As a result, these stockholders are collectively able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets. The concentration of ownership may delay, prevent or deter a change in control of our Company even when such a change may be in the best interests of some stockholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our Company or our assets and might adversely affect the prevailing market price of our common stock.

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.

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

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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.

There was no public market for our common stock prior to the closing of our initial public offering in May 2012. 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 or warrants are exercised, there will be dilution to new investors.

As of December 31, 2014, we had options to purchase 2,080,749 shares of common stock outstanding, with exercise prices ranging from $0.40 to $12.92 per share and a weighted average exercise price of $7.93 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. Dilution could also be experienced if we issue additional shares of common stock under the warrants that we issued to our lenders. As of December 31, 2014, the lender warrants to purchase 18,750 shares of common stock at an exercise price of $4.00 per share and 23,333 shares of common stock at an exercise price of $5.00 per share remain outstanding.

The price of our common stock may fluctuate substantially.

The market price for our common stock is likely to be volatile, in part because our common stock has been traded publicly for less than three years. 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;
- 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;

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

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

The realization of any of the risks described in these "Risk Factors" could have a dramatic and material 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.

The number of shares of our common stock that may be issued upon conversion of the Notes may have an adverse effect on our stock price.

As of March 11, 2014 the holders of $23.5 million of Notes have the right to convert the Notes into an aggregate of 4,424,717 shares of our common at any time. In addition, in certain instances we may issue additional shares of our common stock to holders who convert their Notes in order to satisfy our obligation to pay an interest make-whole payments to these note holders or who those holder that convert their Notes in connection with a transaction that constitutes a "make-whole fundamental change" under the Indenture governing the Notes. The possibility that we may issue a substantial number of shares of common stock to the holders of Notes in connection with conversions and thus substantially increase the number of issued shares of our common stock outstanding may have an adverse effect on our stock price for as long as the Notes remain outstanding.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

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

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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 our 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 a fourth Orange Book patent, United States Patent No. 8,821,930. Our United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930 generally cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. The FDA Orange Book lists all four 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 generic version of Oxtellar XR prior to the expiration of our patents. Filing its August 7, 2013 Complaint within 45 days of receiving Actavis's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Actavis's ANDA for 30 months from the date of our receipt of the first Paragraph IV certification notice. On September 25, 2013, Actavis answered the August 7, 2013 complaint, denying the substantive allegations of that Complaint. One defendant, Actavis Labs FL, asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity of United States Patent Nos. 7,722,898 and 7,910,131. On October 30, 2013, we filed a Reply, denying the substantive allegations of those Counterclaims. On April 30, 2014, Actavis answered the March 28, 2014 complaint, denying the substantive allegations of that Complaint. Actavis Labs FL also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity of United Sates Patent No. 8,617,600. On June 4, 2014, we filed our Reply, denying the substantive allegations of those Counterclaims. On June 4, 2014, the District Court issued a consolidated scheduling order for both cases. This consolidated case is proceeding through fact discovery.

We received a third Paragraph IV Notice from Actavis Labs FL against United States Patent No. 8,821,930 on February 21, 2015.

***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. Our United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930 generally cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. The FDA Orange Book lists all four of our Oxtellar XR patents as expiring on April 13, 2027.

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. asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity of United States Patent Nos. 7,722,898 and 7,910,131. This case is in its early stages, and the Court has not yet issued a Scheduling Order.

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

We received a Paragraph IV Notice Letter against three Trokendi XR Orange Book patents (United States Patent Nos. 8,298,576, 8,298,580, and 8,663,683) from generic drug maker Actavis Labs FL, Inc. on August 20, 2014. On October 1, 2014, we filed a lawsuit against Actavis, Actavis, Inc., Actavis plc, Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc. alleging infringement of United States Patent Nos. 8,298,576, 8,298,580, and 8,663,683, which cover once-a-day topiramate formulations and methods of treating seizures using those formulations. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on March 18, 2029 and United States Patent Nos. 8,298,580, 8,663,683, 8,877,248, and 8,889,191 as expiring on November 16, 2027. Supernus has not received a Paragraph IV Notice Letter from Actavis against United States Patent Nos. 8,877,248 and 8,889,191.

The Complaint filed in the U.S. District Court for the District of New Jersey alleges that the defendants infringed our 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 our patents. Filing its October 1, 2014 Complaint within 45 days of receiving the Actavis Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Actavis's ANDA for 30 months from the date of our receipt of the Actavis Paragraph IV certification notice. This case is in its early stages, and the Court has not yet issued a Scheduling Order.

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

We received a Paragraph IV Notice Letter against three Trokendi XR Orange Book patents (United States Patent Nos. 8,298,576, 8,298,580, and 8,663,683) from generic drug maker Zydus Pharmaceuticals (USA) Inc. ("Zydus") on or about October 13, 2014. On November 21, 2014, we filed a lawsuit against Zydus and Cadila Healthcare Limited, alleging infringement of these three patents. We received a second Paragraph IV Notice Letter from Zydus dated February 19, 2015 against two other Trokendi XR Orange Book patents (United States Patent Nos. 8,877,248 and 8,889,191). On February 27, 2015, we filed an Amended Complaint against Zydus and Cadila Healthcare Limited, alleging infringement of all five patents listed in the Orange Book for Trokendi XR, namely United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, 8,877,248, and 8,889,191, which cover once-a-day topiramate formulations and methods of treating seizures using those formulations. The FDA Orange Book currently lists U.S. Patent No. 8,298,576 as expiring on March 18, 2029 and U.S. Patent Nos. 8,298,580, 8,663,683, 8,877,248, and 8,889,191 as expiring on November 16, 2027.

The Complaint and the Amended Complaint filed in the U.S. District Court for the District of New Jersey allege that the defendants infringed our 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 our patents. Filing its November 21, 2014 Complaint within 45 days of receiving the Zydus Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Zydus's ANDA for 30 months from the date of our receipt of the first Zydus Paragraph IV certification notice. This case is in its early stages, and the Court has not yet issued a Scheduling Order.

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

We received a Paragraph IV Notice Letter against four Trokendi XR Orange Book patents (United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, and 8,877,248) from generic drug maker Par Pharmaceutical, Inc. ("Par") on or about December 8, 2014. On January 16, 2015, we filed a lawsuit against Par and Par Pharmaceutical Companies, Inc. alleging infringement of United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, and 8,877,248. We received a second Paragraph IV Notice Letter

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from Par dated January 28, 2015 against one other Trokendi XR Orange Book patent (United States Patent No. 8,889,191). On February 23, 2015, we filed an Amended Complaint against Par and Par Pharmaceutical Companies, Inc. alleging infringement of all five patents listed in the Orange Book for Trokendi XR, namely United States Patent Nos. 8,298,576, 8,298,580, 8,663,683, 8,877,248, and 8,889,191, which cover once-a-day topiramate formulations and methods of treating seizures using those formulations. The FDA Orange Book currently lists U.S. Patent No. 8,298,576 as expiring on March 18, 2029 and U.S. Patent Nos. 8,298,580, 8,663,683, 8,877,248, and 8,889,191 as expiring on November 16, 2027.

The Complaint and the Amended Complaint filed in the U.S. District Court for the District of New Jersey allege that the defendants infringed our 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 our patents. Filing its January 16, 2015 Complaint within 45 days of receiving the Par Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Par's ANDA for 30 months from the date of our receipt of the first Par Paragraph IV certification notice. This case is in its early stages, and the Court has not yet issued a Scheduling Order.

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
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
2013		
First Quarter	$ 8.08	$ 4.90
Second Quarter	$ 7.20	$ 4.45
Third Quarter	$ 8.40	$ 6.10
Fourth Quarter	$ 9.05	$ 5.84

On December 31, 2014, the closing price of our common stock on The NASDAQ Global Market was $8.30 per share. As of December 31, 2014, we had 28 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.

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ITEM 6. SELECTED FINANCIAL DATA.

The following table sets forth selected consolidated financial data that is qualified in its entirety by and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. The consolidated financial data as of December 31, 2014 and 2013 and for the fiscal years ended December 31, 2014, 2013 and 2012 are derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of future operating results. You should read the selected consolidated financial data in conjunction with the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, all included elsewhere in this Annual Report on Form 10-K.

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Supernus Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,		
	2014	**2013**	**2012**
Revenue			
Net product sales	$ 89,571	$ 11,552	$
Revenue from royalty agreement	30,000		
Licensing revenue	2,474	467	1,480
Total revenue	122,045	12,019	1,480
Costs and expenses			
Cost of product sales	5,758	1,104	
Research and development	19,586	17,245	23,517
Selling, general and administrative	72,471	55,590	20,132
Total costs and expenses	97,815	73,939	43,649
Operating income (loss)	24,230	(61,920)	(42,169)
Other income (expense)			
Interest income	348	299	120
Interest expense	(4,963)	(7,849)	(3,575)
Changes in fair value of derivative liabilities	2,809	(13,354)	(710)
Loss on extinguishment of debt	(2,592)	(9,550)	
Other income	39	101	50
Total other income (expense)	(4,359)	(30,353)	(4,115)
Net income (loss)	19,871	(92,273)	(46,284)
Cumulative dividends on Series A convertible preferred stock			(1,143)
Net income (loss) attributable to common stockholders	$ 19,871	$ (92,273)	$ (47,427)
Income (loss) per common share:			
Basic	$ 0.47	$ (2.90)	$ (2.72)
Diluted	$ 0.32	$ (2.90)	$ (2.72)
Weighted-average number of common shares:			
Basic	42,260,896	31,848,299	17,440,910
Diluted	50,583,511	31,848,299	17,440,910

	Year Ended December 31,	
	2014	**2013**
	(in thousands)	
Consolidated Balance Sheet Data:		

Cash and cash equivalents and marketable securities	$ 74,336	$ 82,191
Long term marketable securities	19,816	8,756
Working capital	81,399	70,761
Total assets	137,508	110,995
Convertible notes, net of discount	26,947	34,393
Accumulated deficit	(158,657)	(178,528)
Total stockholders' equity	71,354	33,464

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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.

In addition, we are developing multiple product candidates in psychiatry to address the large market opportunity in the treatment of attention deficit hyperactivity disorder ("ADHD") including the unmet clinical need in impulsive aggression in patients who have ADHD in conjunction with standard ADHD treatment.

Oxtellar XR and Trokendi XR are the first once-daily extended release oxcarbazepine and topiramate products, respectively, indicated for epilepsy in the U.S. market. Total revenues from these products reached $89.6 million in 2014 representing significant growth compared to the $11.6 million in product revenue in 2013.

We expect the number of prescriptions filled for Oxtellar XR and Trokendi XR to increase throughout 2015 and in later years. Data from Wolters-Kluwer/Symphony show 70,739 prescriptions filled for both drugs during the three months ended December 31, 2014, representing a growth of 22.4% as compared to the three months ended September 30, 2014, which totaled 57,776 prescriptions filled.

We achieved positive cash flows from operations during the fourth quarter of 2014. We expect the business to be cash flow positive and profitable in 2015 and beyond. We believe our working capital and long term marketable securities balance of $101.2 million as of December 31, 2014, along with increased revenues from increasing product sales, will be sufficient to finance the Company.

We are progressing with our Phase IV post-marketing commitments for Oxtellar XR and Trokendi XR. The work we are completing to meet the Food and Drug Administration ("FDA"), commitments may also have applicability in life-cycle management.

We entered into a Royalty Interest Acquisition Agreement in July 2014 with HealthCare Royalty Partners III, L.P. ("HC Royalty"). Pursuant to the Royalty Interest Acquisition 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 by the Company's partner United Therapeutics Corporation. We will retain full ownership of the royalty rights after a certain threshold has been reached per the terms of the Agreement.

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 filed several complaints against these third parties alleging infringement of our intellectual property rights. We intend to

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vigorously defend our intellectual property rights in each of these cases and we anticipate continuing to incur increasing amounts of legal fees and related expenses for these cases as they progress through discovery. (See Part I, Item 3 Legal Proceedings for additional information.)

We are developing SPN-810 (molindone hydrochloride) as a treatment for impulsive aggression in patients who have ADHD in conjunction with standard ADHD treatment and SPN-812 for the treatment of ADHD. We expect to progress SPN-810 into Phase III testing in the fourth quarter of 2015 and SPN-812 into Phase IIb trials in the fourth quarter of 2015.

We expect to incur significant research and development expenses related to the continued development of each of our product candidates. These expenses are expected to be funded by cash flows from operations.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis 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 in our financial statements. Actual results could differ from those estimates.

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

Inventories and Cost of Product Sales

We carry inventories at the lower of cost or market using the first-in, first-out method. Inventory values include materials, labor, and direct and indirect overhead. Inventory is evaluated for impairment through consideration of factors such as net realizable value, obsolescence and expiry. The value of our inventories does not exceed either replacement cost or net realizable value. We believe Oxtellar XR and Trokendi XR have limited risk of obsolescence or expiry based on current demand, our projection for future demand, and product dating.

The cost of product sales consists primarily of materials, third-party manufacturing costs, freight and distribution costs, allocation of labor, quality control and assurance, and other manufacturing overhead costs associated with the sales of Oxtellar XR and Trokendi XR.

Revenue Recognition

Revenue from product sales is recognized when persuasive evidence of an arrangement exists; delivery has occurred and title of 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 (collectively, "sales deductions") as well as estimated product returns.

Our products are distributed through wholesalers and pharmaceutical distributors. Each of these wholesalers and distributors will take title and ownership of the product upon physical receipt of the product and then distribute our products to pharmacies. Beginning in the fourth quarter of 2013, we began recognizing revenue for Oxtellar XR, net of estimated sales deductions, at the time of shipment to wholesalers. Beginning in the second quarter of 2014, we began recognizing revenue for Trokendi XR, net of estimated sales deductions, at the time of shipment to wholesalers.

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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.

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 HC Royalty's purchase of certain of the Company's rights under the license 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 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.

Deferred Legal Fees

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

Deferred legal fees will be capitalized as part of the patents upon successful outcome of the on-going litigation and we will begin amortization at that time. 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 contract research organizations, 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.

Share-Based Compensation

Employee share-based compensation is measured based on the estimated fair value of the award on the grant date. The grant date fair value of options granted 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 has awarded non-vested stock that vests based on service conditions. The Company recognizes the expense for stock options over the vesting period 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.

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Results of Operations

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 income (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 based on $24.7 million of revenue from shipments of Oxtellar XR to distributors, less estimates for discounts, rebates, other sales deductions and returns, and $64.9 million of revenue for Trokendi XR, primarily from shipment to distributors, less estimates for discounts, rebates, other sales deductions and returns.

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

Revenue from Royalty Agreement. The revenue for the year ended December 31, 2014 resulted from the Royalty Interest Acquisition Agreement that we entered into with HC Royalty for Orenitram, which is marketed by United Therapeutics Corporation. We received a one-time payment of $30.0 million upon execution of that Agreement.

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,

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2013, an increase of $2.4 million or 13.5%. This increase is due to preclinical and 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 the increase in compensation and travel due to the expansion of our sales force during the year ended December 31, 2014 and an increase in marketing expenses such as sample distribution to support the growth of Oxtellar XR and Trokendi XR.

Interest Expense. Interest expense was $5.0 million during the year ended December 31, 2014 as compared to $7.8 million for the year ended December 31, 2013. The decrease of $2.8 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 $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. This change was primarily due to the revenue generated from our two commercial products, Oxtellar XR and Trokendi XR, and $30 million in revenue associated with the HC Royalty Interest Acquisition Agreement, partially offset by increased expenses incurred associated with the expansion of our sales force as well as an increase in marketing expenditures associated with ongoing support of Oxtellar XR and Trokendi XR.

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Comparison of the year ended December 31, 2013 and December 31, 2012

	Year Ended December 31,		Increase/ (decrease)
	2013	2012	
	(in thousands)		
Revenues:			
Net product sales	$ 11,552	$	11,552
Licensing revenue	467	1,480	(1,013)
Total revenues	12,019	1,480	
Costs and expenses			
Cost of product sales	1,104		1,104
Research and development	17,245	23,517	(6,272)
Selling, general and administrative	55,590	20,132	35,458
Total costs and expenses	73,939	43,649	
Operating loss	(61,920)	(42,169)	
Other income (expense)			
Interest income and other income (expense), net	400	170	230
Interest expense	(7,849)	(3,575)	(4,274)
Changes in fair value of derivative liabilities	(13,354)	(710)	(12,644)
Loss on extinguishment of debt	(9,550)		(9,550)
Total other expenses	(30,353)	(4,115)	
Net loss	$ (92,273)	$ (46,284)	

Revenues. Our net product sales of $11.6 million for the year ended December 31, 2013 are based on $11.0 million of revenue from shipments of Oxtellar XR to distributors in 2013, less estimates for discounts, rebates, other sales deductions and returns, and $0.6 million of revenue on Trokendi XR prescriptions filled at the pharmacy level during the third quarter of 2013, net of sales deductions. There were no product sales in the year ended December 31, 2012.

Licensing revenue decreased by $1.0 million due to receipt of a milestone payment in 2012 related to the approval of Oxtellar XR.

Research and Development Expense. Research and development expenses during 2013 were $17.2 million as compared to $23.5 million in 2012, a decrease of $6.3 million or 26.7%. In 2013, our research and development expense was primarily focused on preparation for future clinical trials for the product candidates, SPN-810 and SPN-812. During the year ended December 31, 2012, research and development expense included outside services spending on contract research organizations ("CROs") related to ongoing clinical trials, mainly due to the completion of our Phase IIb study for SPN-810. No new trials were commenced in 2013.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses were $55.6 million in 2013 as compared to $20.1 million in 2012, an increase of $35.5 million or 176.1%. This increase was mainly due to hiring and training our sales force which consisted of approximately 110 sales representatives as of December 31, 2013, and an $8.8 million increase in advertising expenses focused on creating promotional and marketing related programs in support of the launch and commercialization activities for Oxtellar XR and Trokendi XR in 2013.

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Interest Expense. Interest expense was $7.8 million in 2013 as compared to $3.5 million in 2012. The increase of $4.3 million was primarily due to the interest relating to the $90.0 million of Convertible Debt which was issued in May 2013.

Changes in Fair Value of Derivative Liability. We recognized a non-cash charge of $13.4 million associated with the interest make-whole derivative liability related to our Convertible Debt during 2013, primarily due to the passage of time as our stock price remained above the $5.30 conversion price.

Loss on Extinguishment of Debt. In 2013, we recognized a non-cash loss on extinguishment of debt of $8.4 million related to the conversion of $40.5 million of our Convertible Debt. In addition, we recognized $1.2 million of loss related to the prepayment and settlement fees of our secured credit facility in May 2013.

Net Loss. We incurred a net loss of $92.2 million in 2013 as compared to net loss of $46.2 million in 2012, a decrease of $46.0 million or 99.3%. This increase was primarily due to the hiring of our sales force as well as an increase in marketing costs associated with the launch and commercialization activities for Oxtellar XR and Trokendi XR. In addition, increased interest expense and the change in fair value of our derivative liabilities and loss on extinguishment of debt contributed to a year to year increase in net loss.

Liquidity and Capital Resources

Our working capital at December 31, 2014 was $81.4 million, an increase of $10.6 million compared to our working capital of $70.8 million at December 31, 2013. This increase was primarily attributable to the increase in accounts receivable related to increased sales of both Oxtellar XR and Trokendi XR.

We expect to continue to incur significant sales and marketing expenses related to the commercial support of Oxtellar XR and Trokendi XR. In addition, we expect to incur substantial expenses related to our research and development efforts, primarily related to development of SPN-810 and SPN-812 as we continue to advance these clinical programs.

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 our partner United Therapeutics Corporation. We will retain full ownership of the royalty rights after a certain threshold has been reached per the terms of the Agreement.

In addition to revenues, we have historically financed our business through the sale of our debt and equity securities. On May 3, 2013, we issued $90.0 million aggregate principal amount of Notes to qualified institutional buyers, the initial purchasers of the Notes or the Initial Purchasers. We issued the Notes under an Indenture, dated May 3, 2013. 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. 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 secured by a first-priority lien, other than customary permitted liens, on substantially all of our and our domestic subsidiaries' assets, whether now owned or hereafter acquired. For a full description of the Notes and the Indenture, see Note 8 to the Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

As of December 31, 2014, holders of the Notes have converted a total of approximately $53.9 million of the Notes. Cumulatively, through December 31, 2014, we issued a total of approximately 10.2 million shares of common stock in conversion of the principal amount of the Notes and issued an additional

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1.7 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.

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 during the fourth quarter of 2014 and expect continued profitability in 2015 as we continue to increase sales while also increasing activities and spending to advance our clinical product candidates. 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 that may be sold by two selling security holders that held contractual rights to have the resale of their common stock registered. 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.

During the period from January 1, 2015 to March 11, 2015 holders of the Notes converted approximately $12.6 million of the Notes and we issued a total of approximately 2.4 million shares of common stock in conversion of the principal amount of the Notes and accrued interest thereon, and issued an additional 0.3 million shares of common stock in settlement of the interest make-whole provision related to the converted Notes.

Cash Flows

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

	Year Ended December 31,		Increase/ (decrease)
	2014	**2013**	
Net cash provided by (used in):			
Operating activities	$ 7,733	$ (57,949)	65,682
Investing activities	$ (4,887)	$ (12,112)	7,225
Financing activities	$ 570	$ 62,739	(62,169)
Net increase (decrease) in cash and cash equivalents	$ 3,416	$ (7,322)	

Operating Activities

Net cash provided by/used in operating activities is comprised of two components; cash provided by/used in operating income/loss and cash provided by/used in changes in working capital. Results for the years ended December 31, 2014 and December 31, 2013 are summarized below, in thousands:

	Year Ended December 31,		Increase/ (decrease)
	2014	**2013**	
Cash provided by (used in) operating income (loss)	$ 25,234	$ (63,624)	88,858
Cash (used in) provided by in changes in working capital	(17,501)	5,675	(23,176)
Net cash provided by (used in) operating activities	$ 7,733	$ (57,949)	

The increase in net cash provided by operating activities is primarily driven by increased revenue for Trokendi XR and Oxtellar XR and the receipt of $30.0 million from HC Royalty.

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

	Year Ended December 31,		
	2014	2013	Explanation of Change
Increase in accounts receivable	$ (12,216)	$ (5,043)	Shipment of additional product to wholesalers.
Increase in inventory	(6,289)	(6,000)	Build up of inventory for product sales.
Increase in prepaid expenses and other assets	(1,144)	(889)	
Increase in accounts payable and accrued expenses	9,036	8,492	Increase in activity to support both products.
(Decrease) increase in deferred product and licensing revenue	(8,086)	8,686	Transition of Trokendi XR revenue recognition to be based on shipments to wholesalers.
Other	1,198	429	
	$ (17,501)	$ 5,675	

Investing Activities

Our investing activities are principally driven by cash provided by our financing activities. We invest excess cash in accordance with our investment policy. Marketable securities consist of investments which generally mature in fifteen months or less, including U.S. 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, 2014 of $4.9 million related to deferred legal fees of $4.5 million and property and equipment purchases of $0.6 million, offset by net sales of marketable securities of $0.2 million. Net cash used in investing activities for the year ended December 31, 2013 consisted of $12.1 million related to the increase in marketable securities holdings by $9.8 million, property and equipment purchases of $1.6 million and deferred legal fees of $0.7 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2014 was $0.6 million, primarily the result of proceeds received from stock option exercises and cash settlement of debt to equity conversions of our Notes. Net cash provided by financing activities for the year ended December 31, 2013 were $62.7 million primarily the result of $86.5 million of net proceeds from the issuance of the Notes, offset by $24.3 million for the repayment of outstanding secured notes payable.

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Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2014 (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	$	$	$ 36,059	$	$ 36,059
Interest on Convertible Notes	2,704	5,409	3,606		11,719
Operating leases(1)	1,758	2,557	2,655	454	7,424
Purchase obligations(2)	3,959				3,959
Total(3)	$ 8,421	$ 7,966	$ 42,320	$ 454	$ 59,161

(1) Our commitments for operating leases relate to our lease of office equipment, fleet vehicles and office and laboratory space as of December 31, 2014.

(2) Relates primarily to agreements and purchase orders with contractors for the conduct of clinical trials and 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 Pharmaceuticals, Inc. ("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. 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.

Recent Accounting Pronouncements

In July 2013, the FASB issued Accounting Standards Update ("ASU") No. 2013-11, which amended ASC Topic 740 regarding presentation of an unrecognized tax benefit when a net operating loss ("NOL") carryforward, a similar tax loss, or a tax credit carryforward exists. The amendments in ASU No. 2013-11 require an entity to present an unrecognized tax benefit as a reduction of a deferred tax asset for an NOL carryforward, or similar tax loss or tax credit carryforward, rather than as a liability when (1) the uncertain tax position would reduce the NOL or other carryforward under the tax law of

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the applicable jurisdiction and (2) the entity intends to use the deferred tax asset for that purpose. The ASU does not require new recurring disclosures. This amendment was effective prospectively for fiscal years beginning after December 15, 2013, and did not have a material impact on the Company's financial statements.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers.* ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current 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. Early adoption is not permitted. 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.

In August 2014, the FASB issued Accounting Standards Update 2014-15 "Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15".) 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 permitted. We do not believe the adoption of the new standard will have a significant impact on our operations.

The Company has evaluated all other ASUs issued through the date the consolidated financials were issued and believes that the adoption of these will not have a material impact on the Company's consolidated financial statements.

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 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.

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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, 2014, we had unrestricted cash, cash equivalents, marketable securities and long term marketable securities of $94.2 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 and 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 outstanding warrants to purchase common stock and the interest make-whole payment associated with our Notes.

We contract with contract research organizations and investigational sites globally. 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 $2,000 for the year ended December 31, 2014. 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 $2,000 for the year ended December 31, 2014. We do not believe that inflation and changing prices over the years ended December 31, 2014 and 2013 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, 2014, 2013 and 2012

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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)