2012—A Breakthrough Year For Su

Dear Supernus Stockholder,

2012 was an exciting breakthrough year for Supernus. We transitioned from a privately-held research and development company to a publicly-held fully integrated commercial pharmaceutical company on the verge of launching two products.

We raised $100 million in gross proceeds from our initial public offering in May 2012 and follow-on public offering in December 2012.

We also built our commercial organization including an experienced sales and marketing team in preparation for the launch of our lead epilepsy product, Oxtellar XR™ (extended-release oxcarbazepine), which was approved by the FDA in October, and for which we received confirmation from the FDA that it has been granted 3 years of marketing exclusivity. Oxtellar XR, a novel once-a-day treatment for epilepsy, is the first and only FDA approved once-a-day oxcarbazepine treatment indicated for adjunctive therapy in partial seizures in adults and children 6 to 17 years old.

In addition, we received tentative approval in June for Trokendi XR™ (extended-release topiramate), and later in October announced that the USPTO issued two patents covering the product.

Finally, in 2012, we continued to develop our pipeline through the successful completion of a Phase IIb trial with positive topline results on SPN 810, our novel treatment for impulsive aggression in ADHD patients.

These milestones in the aggregate represent a remarkable achievement for a company our size in the Central Nervous System ("CNS") specialty pharmaceutical sector.

At the time of writing this letter, we have just launched Oxtellar XR in epilepsy, our first product as a company. This represents a historic event for Supernus as it transitions to become a commercial company.

We believe the launch of Oxtellar XR and the upcoming launch of Trokendi XR in the third quarter of 2013 firmly establish Supernus as a major player in neurology with two novel and differentiated products, and serve as a solid foundation for future long term growth.

Focusing on Commercial Execution

Our specialty sales force continues to be focused on driving the trial and adoption of Oxtellar XR and is targeting the highest potential physicians who are current prescribers of oxcarbazepine for the treatment of epilepsy. In all, we have now deployed a sales force of approximately 75 professionals to call on physicians.

Our commercial team is focused on three strategic imperatives: increasing awareness of Oxtellar XR among high prescribers of oxcarbazepine, growing prescription volume, and ensuring patient access to Oxtellar XR. We have been encouraged by the positive feedback we have been receiving from the field and physicians regarding Oxtellar XR. We have also been able to secure early in the launch managed care coverage, with more than 127 million lives already covered. We expect more lives to be added on a state by state basis as the various states go through their approval process. The Company will continue its efforts to broaden patient access and managed care coverage for the product.

While we are early in the launch cycle, all indicators so far point to an excellent start. This will provide a strong platform from which to launch our second epilepsy product, Trokendi XR, in the third quarter of 2013.

Investing in our Pipeline

At Supernus, we believe we have an unparalleled pipeline in the CNS area. While we are launching two products in 2013, we already have lined up the next phase of growth by continuing to advance our psychiatry products in development. In November 2012 we announced encouraging phase IIb data on SPN 810, a novel product candidate for the treatment of impulsive aggression in ADHD. If approved, the product could be the first and only product available to treat this condition, which is prevalent in ADHD, autism, schizophrenia, and bipolar patients.

With no FDA-approved therapies to treat impulsive aggression, this represents a significant unmet medical need. We are pleased and very encouraged by the high level of interest in SPN 810 that has been shown in the psychiatry community.

Looking beyond SPN 810, we are also developing SPN 812 which has completed a phase IIa study in ADHD. Given the pharmacological properties of SPN 812, we believe it can be an efficacious non-stimulant treatment for ADHD with a better side effect profile as compared to existing non-stimulants.

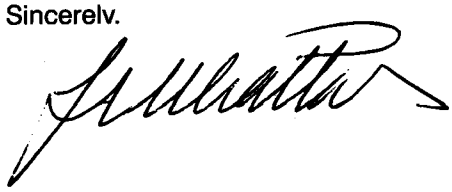
The Future: 2013 and Beyond

While our vision of becoming a CNS specialty pharmaceutical company developing and commercializing its own products has been realized in this first quarter of 2013, our journey of now becoming a leading and significant player in CNS has just begun. I can't be more excited by starting such a journey with the launch of two novel and differentiated products in neurology.

I see great opportunities to create significant shareholder value in the coming months and years by continuing our remarkable, proven and successful track record of execution. With an experienced commercial and clinical development team and our record of proven success, we expect to advance the commercialization of Oxtellar XR and Trokendi XR in the U.S. and continue the development of SPN 810 and SPN 812.

In closing, I would like to recognize our entire team for its integrity, commitment and scientific excellence. Our success is due to our committed employees. On behalf of the whole team at Supernus, our board of directors, and more importantly, the patients we serve, I thank you for your continued support. You have put us in a position to deliver value to both our patients and our shareholders through innovative therapies.

Sincerely,



Jack A. Khattar,
President, Chief Executive Officer and Secretary of
Supernus Pharmaceuticals, Inc.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012

COMMISSION FILE NUMBER: 0-50440

or

☐ **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 ☐ No ☒

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

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

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

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

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 ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

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

As of June 30, 2012, 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 $19,554,538.

The number of shares of the registrant's common stock outstanding as of February 28, 2013 was 30,892,070.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2013 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 2012 fiscal year end, are incorporated by reference into Part III of this Annual Report on Form 10-K.

On the following pages, we have reproduced items one through fourteen of our annual report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2013. The Form 10-K has not been approved by the Securities and Exchange Commission, nor has the Commission passed upon the accuracy or adequacy of the data included therein. A copy of the complete Form 10-K, with exhibits, as filed with the Securities and Exchange Commission may be obtained without charge by writing to: Mr. Gregory Patrick, Chief Financial Officer, Supernus Pharmaceuticals, Inc., 1550 East Gude Drive, Rockville, MD 20850.

SUPERNUS PHARMACEUTICALS, INC.
FORM 10-K

For the Year Ended December 31, 2012

TABLE OF CONTENTS

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®," "Microtrol®," "Solutrol®," "ProScreen®," "OptiScreen®," "ProPhile®," "Trokendi XR™," "Oxtellar XR™," and the registered Supernus Pharmaceuticals logo.

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, or CNS, diseases. Our extensive expertise in product development has been built over the past 20 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 launched Oxtellar XR (extended release oxcarbazepine), our first epilepsy product, in the first quarter of 2013 and anticipate the launch of a second epilepsy product, Trokendi XR (extended release topiramate), in the third quarter of 2013, and are developing multiple product candidates in psychiatry to address the large market opportunity in the treatment of attention deficit hyperactivity disorder, or ADHD, including ADHD patients with impulsive aggression. We intend to market our products in the United States through our own focused sales force targeting specialty physicians, which include neurologists and psychiatrists; and to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

Our neurology portfolio consists of a marketed product and a tentatively approved product. On October 19, 2012, the Food and Drug Administration, or FDA, granted final approval of Oxtellar XR, as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age. On November 15, 2012, the FDA granted Oxtellar XR a three year marketing exclusivity. The commercial launch of Oxtellar XR occurred during the first quarter of 2013. On June 25, 2012, the FDA granted tentative approval of Trokendi XR, as 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. The final approval for Trokendi XR may not be made effective until the expiration of the marketing exclusivity period that Topamax's new drug application, or NDA, (currently held by Johnson & Johnson, Inc.) has regarding safety information in a specific pediatric population. This marketing exclusivity expires on June 22, 2013. In early December, 2012, the Company submitted to the FDA a request for final approval as an amendment to the NDA including a safety data update, a new package insert and packaging configurations for Trokendi XR and was informed that should the FDA approve such amendment, it will most likely be in the form of a tentative approval because the review period of such amendment would be expected to conclude in the second quarter prior to the June 22, 2013 expiration of the pediatric exclusivity. The Company

continues to expect getting the final approval and commercially launching Trokendi XR in the third quarter of 2013.

Our psychiatry product candidates include SPN-810 (molindone hydrochloride), which received positive topline results from its Phase IIb study for the treatment of impulsive aggression in ADHD patients, and SPN-812, which is also moving forward into later stage development, having successfully completed a Phase IIa trial as a novel non-stimulant treatment of ADHD.

We have several additional product candidates in various stages of development, including SPN-809 for which we submitted an investigational new drug application, or IND, in 2008. SPN-809 would represent a novel mechanism of action for the U.S. anti-depressant market. We believe our broad and diversified portfolio of product candidates provides us with multiple opportunities to achieve our goal of becoming a leading specialty pharmaceutical company focused on CNS diseases.

We use our proprietary technologies to enhance the therapeutic benefits of approved drugs through advanced extended release formulations. Oxtellar XR and Trokendi XR are novel oral once-daily extended release formulations of oxcarbazepine and topiramate, respectively, for the treatment of epilepsy. Oxtellar XR is the first and only extended release formulation of oxcarbazepine available in the U.S. We believe that Trokendi XR will be the first extended release formulation of topiramate for the treatment of epilepsy in the U.S. Immediate release formulations of oxcarbazepine and topiramate are available in generic form and are marketed by Novartis and Johnson & Johnson under the brand names of Trileptal and Topamax, respectively. According to IMS Health, peak sales of Trileptal and Topamax represented an estimated 8.1% and 25.8% of the total seizure disorder market in 2006 and 2008, respectively. We pursued a Section 505(b)(2) regulatory strategy for Oxtellar XR, which allowed us to rely on the existing data from the NDA of Trileptal. The formulations allowing once-per-day dosing of Oxtellar XR and Trokendi XR are designed to improve patient compliance and to possibly provide a better tolerability profile compared to the current immediate release anti-epileptic drugs, or AEDs, that must be taken multiple times per day to maintain therapeutic drug concentrations over the dosing interval. We believe there is a significant unmet need for extended release products, such as Oxtellar XR and Trokendi XR, for the treatment of epilepsy. Extended release products have been shown to improve compliance, increase seizure control, reduce side effects and improve tolerability(1) as compared to immediate release products.(2) We have two U.S. patents issued covering Oxtellar XR and two U.S. patents issued covering Trokendi XR.

(1) Miller, A.D., *Improved CNS tolerability following conversion from immediate-to extended-release carbamazepine*, published June 2004 in *Acta Neurologica Scandinavia*.

(2) Balzac, F., *Medication Noncompliance in Epilepsy*, published March 2006 in *Neurology Reviews*.

Our development portfolio also includes treatments for new indications in diseases such as ADHD and its coexisting disorders. We are developing SPN-810, which completed a Phase IIb trial for which we received positive topline results in November 2012, as a novel treatment for impulsive aggression in patients with ADHD. Since we issued the topline results, we have been analyzing the full dataset and working on putting together a package that outlines our development plan including a proposed Phase III design to discuss in detail with the FDA later this year. If approved by the FDA, SPN-810 could be the first product available to address this serious, unmet medical need. SPN-810 is based on molindone hydrochloride, which was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. In addition, SPN-812, which completed a Phase IIa trial, is being developed as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. In addition, because the active ingredient of SPN-812 has demonstrated efficacy as an anti-depressant in Europe, this product candidate, if studied in that specific patient population and shown to be effective, may provide increased benefit to an estimated 40% of ADHD patients who suffer from depression.(3)

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

Product	Indication	Status
Oxtellar XR	Adjunctive therapy for epilepsy	Launched
Trokendi XR	Epilepsy	Tentative approval by FDA
SPN-810	Impulsive aggression in ADHD	Phase IIb completed
SPN-812	ADHD	Phase IIa completed
SPN-809	Depression	IND filed

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. We have a broad portfolio of drug development technologies consisting of six platforms that include the following: Microtrol (multiparticulate delivery platform), Solutrol (matrix delivery platform) and EnSoTrol (osmotic delivery system). Our proprietary technologies have been used in the following approved products: Carbatrol (carbamazepine), Adderall XR (mixed amphetamine salts), and Intuniv (guanfacine), marketed by Shire; Equetro (carbamazepine), marketed by Validus Pharmaceuticals Inc.; Sanctura XR (trospium chloride), marketed by Allergan, Inc.; and Oracea (doxycycline), marketed by Galderma Laboratories, L.P. We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies and our product candidates. Throughout our 20 year history, we have continued our commitment to innovation with a focus for the past seven years on successfully developing our own product candidates in neurology and psychiatry.

Our Strategy

Our goal 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 goal are to:

- *Build in-house sales and marketing capabilities, focused on specialty markets in the United States, to promote Oxtellar XR and Trokendi XR.* We have built our sales and marketing capabilities in the United States to launch Oxtellar XR and, assuming receipt of final approval from the FDA, Trokendi XR. Additionally, there are plans to further expand our sales and marketing capabilities later this year.

(3) 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*.

- *Continue to advance our product candidates in our psychiatry portfolio, including SPN-810 and SPN-812.* As part of our longer term strategy, we intend to further develop our product candidates in our psychiatry portfolio to enable further diversification of our pipeline and future growth. We completed a Phase IIb trial of SPN-810 for impulsive aggression in ADHD patients for which we received positive topline results in November 2012. We are planning to meet with the FDA to discuss next steps in the development program and the design and protocol for Phase III clinical trials.
- *Continue to develop differentiated products by applying our technologies to known drug compounds.* We intend to continue our development activities on known drug compounds and compounds with established mechanisms of action thereby reducing the risks, costs and time typically associated with pharmaceutical product development. We intend to leverage our proprietary and in-licensed technologies, to expand our patent portfolio and further develop and protect our diverse pipeline of product candidates.
- *Establish strategic partnerships to accelerate and maximize the potential of our product candidates worldwide.* We intend to continue to seek strategic collaborations with other pharmaceutical companies to commercialize our products outside the United States. We believe that we are an attractive collaborator for pharmaceutical companies due to our broad portfolio of proprietary technologies and our proven product development track record.
- *Leverage our management team's expertise to develop and commercialize our broad portfolio of product candidates.* We intend to leverage the expertise of our executive management team in developing and commercializing innovative therapeutic products. 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 or, wherever appropriate, external collaborations.

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 or physical abilities. Epilepsy, which is typically diagnosed by a neurologist, is estimated to affect 50 million people worldwide(4) and 2 million people in the United States.(5) According to IMS Health, U.S. sales of AEDs were approximately $4.0 billion in 2011. The annual cost of epilepsy to the healthcare system is estimated to be $12.5 billion.(6)

(4) Bialer, M., *Key factors in the discovery and development of new antiepileptic drugs*, published January 2010 in *Nature*.

(5) U.S. Centers for Disease Control and Prevention, *Epilepsy Self-Management Tools* (citing DiIorio, C., *The Prevention Research Centers' Managing Epilepsy Well Network*, published September 2010 in *Epilepsy & Behavior*).

(6) Epilepsy Foundation, *Cost Study Shows Divide in Treatment Effects*, published April 2000.

Epileptic seizures can cause a person to experience severe muscle jerking, to lose consciousness and fall, or to suffer from distorted vision, all potentially leading to physical injuries or hospitalization. Until reliable seizure control has been achieved, patients are forced to adjust their lifestyles to avoid activities that a seizure can significantly disrupt or render life threatening. A breakthrough seizure is a sudden, unexpected seizure experienced by a patient who previously had achieved reliable seizure control. Even when no physical injury occurs, breakthrough seizures often result in significant social, legal and developmental consequences for patients such as loss of driver's license, loss of employment, disruption of school attendance, academic underachievement, and disruption of social networks. In addition, a single breakthrough seizure can lead to permanent loss or reduction in overall seizure control. Data suggest that a significant proportion of patients who experience a breakthrough seizure have a lower chance of achieving reliable seizure control.(7) In certain cases, a single breakthrough seizure can develop into *status epilepticus*, a prolonged seizure or series of repeated seizures, and eventually result in brain damage or death. Data indicate that the risk of sudden unexpected death in epilepsy was 23 times higher in patients who had at least one breakthrough seizure compared to patients who had achieved seizure control.(8)

Current Treatment Options

Once a patient is diagnosed with epilepsy, the goal of the neurologist is to find the particular drug or combination of drugs, and appropriate dosing, that will lead the patient to reliable seizure control while minimizing side effects. There are currently over 15 approved AEDs marketed in the United States. Side effects play a major role in altering treatment in epilepsy as they can limit the usefulness of AEDs. AEDs are generally associated with the incidence of numerous side effects that can adversely impact the quality of life for patients with epilepsy. Such side effects may include dizziness, paresthesia, headaches, cognitive deficiencies such as memory loss and speech impediment, digestive problems, somnolence, double vision, gingival enlargement, nausea, weight gain, and fatigue. To address these side effects and help patients better tolerate their AEDs, neurologists typically initiate treatment with a single AED as monotherapy at a low dose and then increase the dose to a higher level until the patient reaches the most efficacious dose with an acceptable tolerance of side effects.

Many patients develop refractory epilepsy, which refers to inadequate control of seizures despite treatment, thereby requiring treatment with multiple AEDs. Patients taking more than one AED at a time are susceptible to side effects associated with each of the multiple drugs and with drug interactions. Despite the introduction of new AEDs in the past few years, drug therapy remains ineffective for seizure control in up to 30% of patients with epilepsy.(9) Many patients fail drug therapy either because the drugs do not control their seizures or because they cannot tolerate the side effects.

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(7) Citizen Petition of UCB, Inc. to U.S. Food and Drug Administration, submitted October 3, 2006 (citing Schmidt, D., *Uncontrolled epilepsy following discontinuation of antiepileptic drugs in seizure-free patients: a review of current clinical experience*, published December 2005 in *Epilepsia*).

(8) Citizen Petition of UCB, Inc. to U.S. Food and Drug Administration, submitted October 3, 2006 (citing Tomson, T., *Sudden unexpected death in epilepsy: a review of incidence and risk factors*, published May 2005 in *Acta Neurologica Scandinavia*).

(9) World Health Organization, *Epilepsy: aetiogy, epidemiology and prognosis*, Fact Sheet No. 165, revised February 2001.

Dynamics of the Epilepsy Market

There are several important dynamics that play a major role in the treatment of epilepsy and that differentiate epilepsy from many other diseases:

- *Compliance is Critical to the Reduction in Breakthrough Seizures*

Compliance with drug treatment regimens is critically important to achieving effective therapy for patients with epilepsy where the consequences of non-compliance can be life threatening. 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 is also important. Typically, non-compliance is caused by frequent or multiple dosing, serious side effects, or a lack of tolerability. A 2002 survey undertaken by neurologists in the United States found that, at least once per month, 71% of patients with epilepsy forgot to take their AED, and it was evident that the chances of a patient missing a dose increased with the number of tablets prescribed.(10) Of patients that missed a dose, 45% reported a breakthrough seizure. Patients taking a larger number of tablets/capsules further increased their odds of having a breakthrough seizure by 43% after a missed dose. Other studies also have shown reduced rates in breakthrough seizures as a result of improved compliance with AED treatment regimens. In addition, a non-compliant patient can cost the healthcare system approximately an additional $16,300 per year when compared to a compliant patient.(11)

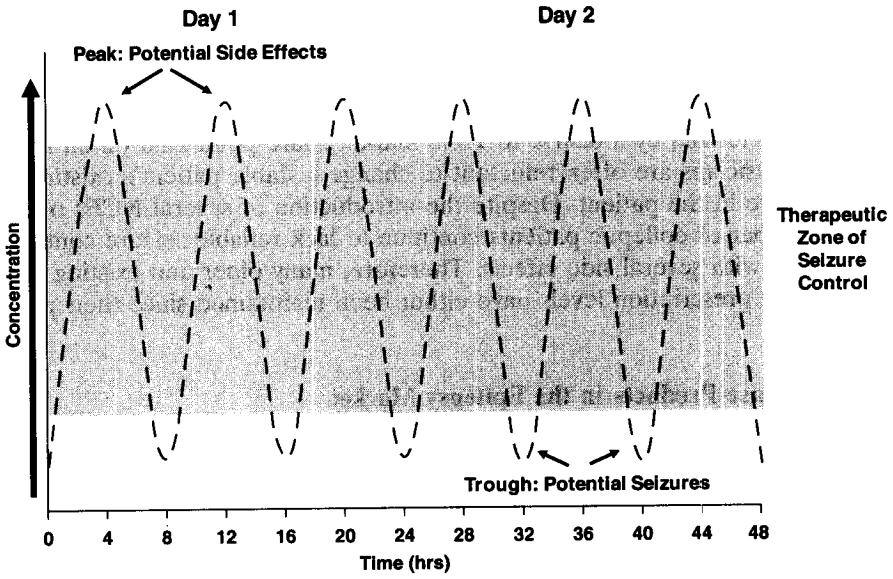
(10) Cramer, J.A., *The relationship between poor medication compliance and seizures*, published August 2002 in *Epilepsy & Behavior.*

(11) Faught, R.E., Weiner, J.R., Guérin, A. et al., *Impact of nonadherence to antiepileptic drugs on healthcare utilization and costs: Findings from RANSOM study*, published March 2009 *Epilepsia*; 50:501-9.

- *Immediate Release Products Have Serious Side Effects and Lack of Tolerability*

The FDA has recognized AEDs as being "critical dose drugs," or drugs in which a comparatively small difference in dose or concentration may lead to serious therapeutic failures and/or serious side effects. Immediate release formulations of AEDs necessitate frequent administration to maintain appropriate plasma concentrations. However, these immediate release formulations cause wide fluctuations of blood levels of the active drug during the day, with peak concentrations when the drug is released and potentially sub-therapeutic concentrations thereafter. At least one study has shown that complaints of side effects typically occur when blood levels exceed certain concentrations, particularly at high doses, and the risk of breakthrough seizures can occur when blood levels are below certain minimum effective levels, as indicated in the chart below.

Simulated Plasma Concentration-Time Curve at Steady State of Immediate Release Anti-Epileptic Drug Administered Over Two Days



Source: Pellock, JM et al, Epilepsy & Behavior 5 (2004), 302

- *Generic Substitution Can Cause an Increase in Breakthrough Seizures*

Patients today are most typically switched from branded drugs to generics, or from one generic drug to another, mainly to reduce cost. In most states, unless a physician explicitly writes "dispense as written" or "no substitution," pharmacists can switch a patient to a lower-cost generic drug without the consent of either the patient or the physician. Epilepsy patients are particularly vulnerable to changes in their drugs or formulations because slight variations in the blood concentrations of these drugs could lead to the occurrence of breakthrough seizures. Accordingly, despite existing regulatory criteria to ensure the bioequivalence of generic drugs, the "switch-back" rates of AEDs (that is, the frequency of an individual being returned to his or her previous branded product under a physician's guidance) is much higher than for many other drug products. For example, the rates of patients switching back from generics to branded drugs because of adverse events were found to be 20.8% to 44.1% for AEDs compared to 7.7% to 9.1% for non-AEDs.(12)

(12) J. LeLorier, *Clinical consequences of generic substitution of lamotrigine for patients with epilepsy*, published October 2008 in *Neurology*.

A number of epilepsy advocacy groups such as the Epilepsy Foundation of America, the American Academy of Neurology, the Centers for Medicare and Medicaid Services and several regulatory agencies around the world, including the UK National Institute for Health and Clinical Excellence, or NICE, Sweden's Medical Products Agency, or MPA, and other European agencies, have all acknowledged that AED generic substitutions for non-therapeutic reasons can be harmful and should either be limited or not permitted, and have issued guidelines, recommendations or taken affirmative steps to limit such substitutions. Additionally, approximately 88% of physicians indicate that they are concerned with the increase in breakthrough seizures resulting from switching from branded drugs to generics.(13) While we are not aware of any well-controlled studies conducted to establish unequivocal scientific evidence that generic substitutions cause increased incidence of breakthrough seizures, the FDA is currently considering stricter standards of bioequivalence for generics and its Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted 11-2 that the current bioequivalence standards are insufficient for critical dose drugs such as AEDs.

- *Physicians are Reluctant to Switch to New Chemical Entities*

In the epilepsy market, new chemical entities, or NCEs, generally lack the same appeal that would typically be associated with a new drug for other indications. Based on IMS Health prescription data from 1994 to 2005 for NCE launches for seizure disorders, such NCEs, on average, experienced slow market penetration, characterized by a 0.58% to 1.1% market share point gain on an annual basis. We believe this is because physicians are often reluctant to change a stable patient's existing therapy and risk a breakthrough seizure in the patient. Despite the introduction of several NCEs over the past decade, a significant number of epileptic patients continue to lack reliable seizure control. Many NCEs continue to be associated with several side effects. Therefore, many older and existing drugs continue to be prescribed and their prescription levels have either been maintained since their peak or declined very slowly.

Benefits of Extended Release Products in the Epilepsy Market

- *Extended Release Products Improve Compliance and Reduce Breakthrough Seizures*

Achieving reliable seizure control for patients and avoiding the serious health and life dangers that can be associated with breakthrough seizures depends on patients being compliant and diligent in taking their medications. Frequent and multiple dosing, side effects and lack of tolerability of the immediate release products can significantly contribute to patients forgetting doses or skipping them. Even taking a second or third dose later than the scheduled time may place a patient at an increased risk of a breakthrough seizure because the drug level in the patient's blood could drop below the minimum effective therapeutic level that prevents such seizures. We believe increased patient compliance can be achieved with extended release products that offer once-daily dosing, reduced side effects and improved tolerability. We believe physicians understand that the release profiles of extended release products can produce more consistent and steadier blood levels as compared to immediate release products, resulting in fewer side effects and better tolerability that further help patients to be compliant, have fewer breakthrough seizures and, correspondingly, enjoy a better quality of life.

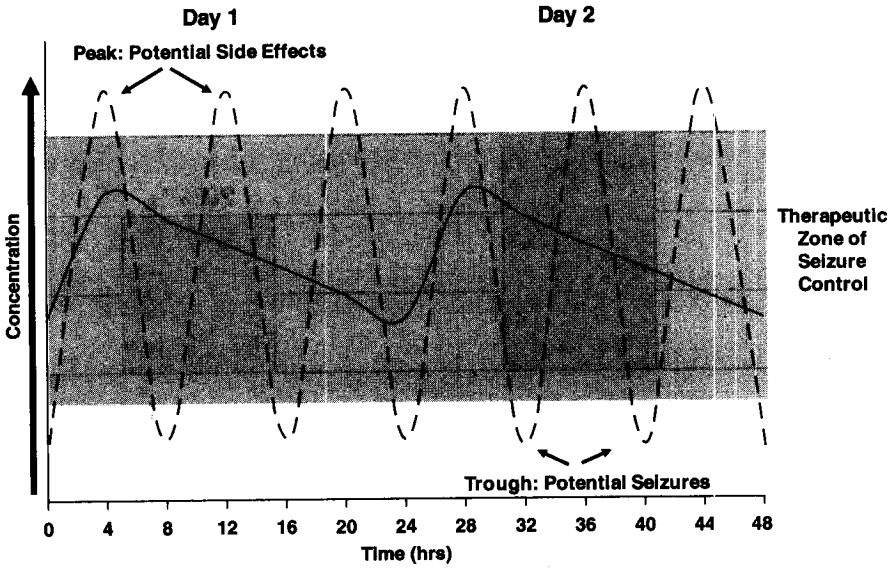
- *Extended Release Products Reduce Side Effects and Improve Tolerability*

When extended release formulations are used appropriately, drug levels remain within the patient's therapeutic zone, thereby reducing patient exposure to fluctuating drug levels, which may exacerbate side effects or induce breakthrough seizures. Because extended release formulations can reduce peak concentrations, it may also be possible to adjust doses upward to a more efficacious level without exacerbating side effects associated with peak concentrations. Extended release formulations can also

(13) Dalia Buffery, MA, ABD, *Switching to Generics Antiepileptic Drugs: Growing Concerns*, published September 2008 in *American Health & Drug Benefits.*

reduce the frequency and the extent of the troughs, or lower concentrations of the drug in the blood, thereby avoiding concentrations below the minimum effective concentrations that can increase the risk of breakthrough seizures.

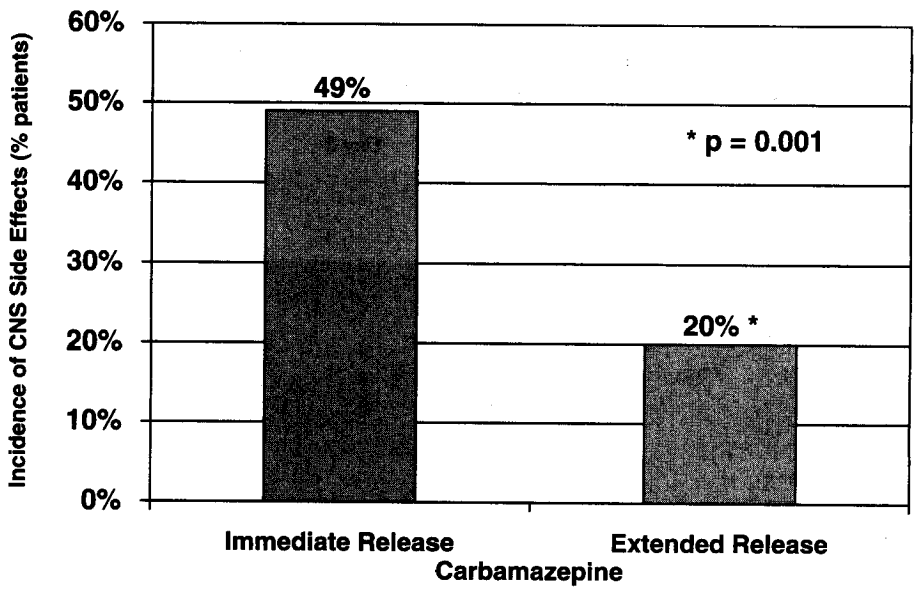
Simulated Plasma Concentration-Time Curve at Steady State of Immediate Release and Extended Release Anti-Epileptic Drug Administered Over Two Days



Source: Pellock, JM et al, Epilepsy & Behavior 5 (2004), 302

The enhanced safety profile of extended release products as compared to similar immediate release products has been supported by several studies. For example, in a 2004 published trial conducted by physicians at Johns Hopkins, Carbatrol, an anti-epileptic extended release carbamazepine product that uses our Microtrol technology, and Tegretol XR, another extended release carbamazepine product, demonstrated better tolerability and side effect profiles than comparable immediate release products. The trial reported that 49% of patients had side effects during treatment with immediate release carbamazepine such as sedation, double-vision, confusion, ataxia, dizziness or poor coordination, whereas with extended release carbamazepine treatments, only 20% of patients reported these side effects.

Reduction in CNS Side Effects Following Conversion to Carbamazepine Extended Release from Immediate Release Preparation



Source: Miller AD et al., Acta Neurol. Scand 2004: 109: 374-377

Equally as important, the patients in the trial tolerated high doses of extended release carbamazepine significantly better than high doses of immediate release carbamazepine. Specifically, 63% of patients treated with 1200 mg or more per day of immediate release carbamazepine developed side effects, yet only 12% of patients experienced side effects while taking similar doses of extended release carbamazepine. The investigators surmised that the improved tolerability of extended release carbamazepine at high doses may provide a treatment option for patients previously discontinuing immediate release carbamazepine because of dose-limiting side effects.

Other products where reductions in side effects were reported by patients when switching from immediate release to extended release formulations include Depakote ER (divalproex sodium extended release) and Keppra XR (levetiracetam extended release).

- *Managed Care Does Not Limit Success of Extended Release Products*

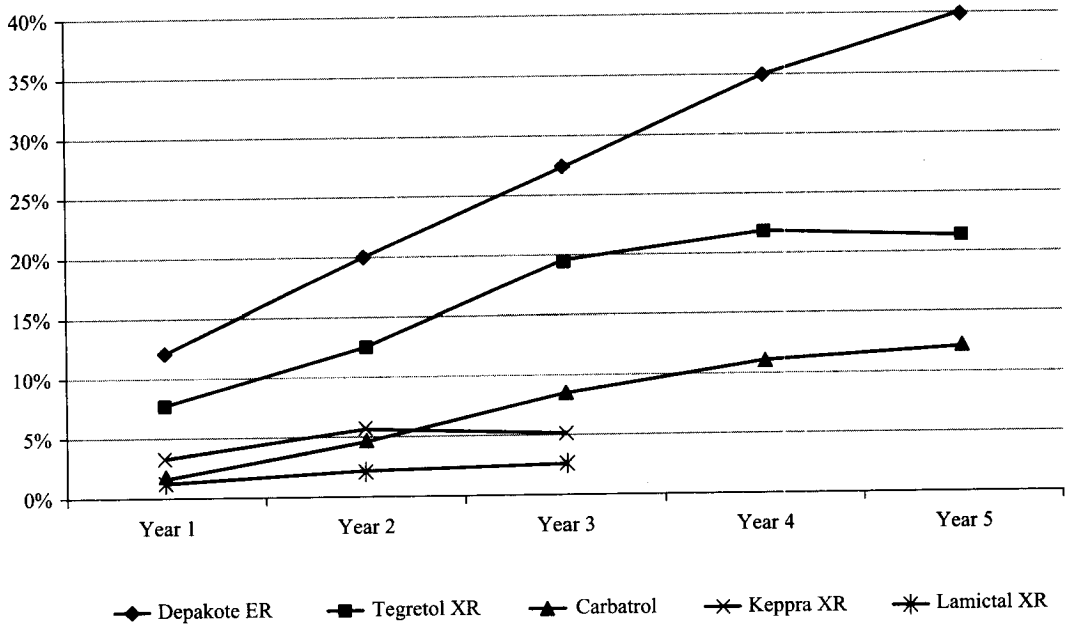
Given the serious nature of epilepsy and the key dynamics in the epilepsy market, we believe managed care plans acknowledge the important benefits of extended release AED products and, therefore, have not limited the success of such products even when lower cost generic immediate release products are available. For example, according to industry data, the recent commercial launches of extended release products Keppra XR and Lamictal XR have enjoyed acceptance rates by managed care plans that are similar to those of the corresponding immediate release products. Most managed care plans also acknowledge the position of several patient advocacy groups and the American Academy of Neurology regarding the risks of generic substitution of AEDs, including potential for breakthrough seizures. Although switching to a low-cost generic AED may initially offer some cost savings, we believe they also recognize that the risk and cost of one breakthrough seizure outweighs the potential savings from generics. For example, the healthcare costs associated with the treatment of patients who experience breakthrough seizures, which may run in excess of $26,000 per patient on an annual basis, is significantly greater than any cost savings per patient that may be achieved through switching to a low-cost generic AED. According to a 2009 survey, the total healthcare costs for patients using branded

topiramate products were approximately 20% lower than for patients using multiple generic topiramate products.(14)

- *Extended Release Products Perform Well in the Market*

Extended release products have generally performed well in the epilepsy market, even in the face of immediate release generic products. Moreover, IMS Health prescription data for seizure disorder drugs from 1994 to 2005 shows that extended release products perform better than NCEs during the first five years of their commercial launch. Currently, there are five extended release AEDs on the market (Tegretol XR, Carbatrol, Depakote ER, Lamictal XR, Keppra XR), as reflected in the chart below, with Depakote ER gaining almost 40% of all divalproex prescriptions, including immediate release versions of Depakote and generic divalproex, in its fifth year after commercial launch. We believe that the modest conversion of the corresponding molecule prescriptions of the recent commercial launches of Keppra XR and Lamictal XR are due to limited promotional support behind both products.

Comparison of Molecule Conversion of Extended Release Anti-Epilepsy Drugs (measured as percentage of total prescriptions for each individual molecule)



Source: IMS Health

Our Neurology Portfolio

We have developed a promising epilepsy product portfolio consisting of Oxtellar XR and Trokendi XR that utilize our proprietary technologies, Solutrol and Microtrol, respectively, each of which has been proven and validated through use in products that are currently on the market. Among them is Carbatrol, an AED that has been shown to reduce side effects compared to immediate release carbamazepine products. We believe that our 20 years of history and portfolio of technologies have enabled us to develop highly-customized product candidates that overcome challenges of the molecules' pharmacokinetic profiles. Our differentiated approach to product development and the strength of our technologies have allowed us to develop a once-daily formulation of oxcarbazepine with Oxtellar XR

(14) Duh, M.S., *The risks and costs of multiple-generic substitution of topiramate*, published June 2009 in *Neurology*.

where others have failed, and to develop Trokendi XR with what we believe to be a unique pharmacokinetic profile.

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

The FDA approved our NDA for Oxtellar XR on October 19, 2012 as adjunctive therapy for partial seizures in adults and in children 6 years to 17 years of age and we launched the product on February 4, 2013. The FDA granted tentative approval of Trokendi XR on June 25, 2012, as 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 similar seizures or with seizures associated with Lennox-Gastaut syndrome. The final approval for Trokendi XR may not be made effective until the expiration of the marketing exclusivity protection that Topamax has regarding safety information of topiramate in a specific pediatric population, which expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. In early December, 2012, the Company submitted to the FDA a request for final approval as an amendment to the NDA including a safety data update, a new package insert and packaging configurations for Trokendi XR and was informed that should the FDA approve such amendment, it will most likely be in the form of a tentative approval because the review period of such amendment would be expected to conclude in the second quarter prior to the June 22, 2013 expiration of the pediatric exclusivity. The Company continues to expect getting the final approval and commercially launching Trokendi XR in the third quarter of 2013. If we are successful in obtaining final FDA approval, we believe that Trokendi XR will be the first once-daily topiramate product approved for the monotherapy and adjunct therapy of epilepsy. We believe that Trokendi XR could, over time, capture a significant share of the topiramate prescriptions, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market during the last 15 years.

Oxtellar XR (extended release oxcarbazepine)

Oxtellar XR is a novel oral once-daily extended release formulation of oxcarbazepine, which we launched on February 4, 2013. The product was approved by the FDA on October 19, 2012 as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age and will have three years of marketing exclusivity. In addition, two U.S. patents have been issued covering Oxtellar XR. Oxtellar XR delivers oxcarbazepine, another effective AED, which is marketed by Novartis under the brand name Trileptal and is available in a generic form. Trileptal was initially developed and approved in the United States in 2000. Trileptal is indicated for monotherapy and adjunctive therapy of epilepsy. It reached peak worldwide sales of $721 million in 2006, before generic products entered the U.S. market in October 2007.(15) With approximately 3.4 million total oxcarbazepine prescriptions in 2011 and 3.5 million prescriptions in 2012, oxcarbazepine represents approximately 2.8% of total AED prescriptions, according to data from IMS Health. Oxcarbazepine is an active voltage-dependent sodium channel blocker that, despite its effectiveness in treating epilepsy, is associated with many side effects that tend to limit its use. The side effects associated with taking oxcarbazepine include, among others, dizziness, double vision, somnolence, nausea, fatigue and vomiting. Oxtellar XR has been designed to reduce side effects, resulting in improved patient compliance and tolerability.

With its novel pharmacokinetic profile that delivers lower peak plasma concentrations, slower rate of input and smoother and more consistent blood levels compared to immediate release products such as Trileptal, we believe Oxtellar XR has the potential of improving the tolerability of oxcarbazepine by reducing the side effects experienced by patients. This could enable more patients to effectively tolerate higher doses of oxcarbazepine, which would permit them to benefit from the resulting efficacy and greater seizure control that have been previously reported in patients at higher doses. In addition, Oxtellar XR once-per-day dosing is designed to improve patient compliance compared to the current immediate release products that are taken multiple times per day.

Oxtellar XR Development Program

We submitted an NDA for Oxtellar XR that was accepted for filing by the FDA in February 2012 and approved on October 19, 2012. The various clinical trials conducted on Oxtellar XR and that supported the NDA were designed to select the best extended release once-per-day formulation that delivers equivalent levels of oxcarbazepine compared to immediate release twice-per-day Trileptal, as well as to test the robustness and consistency of our technology in delivering the once-per-day formulation across a full range of product strengths. We also have scaled up our production of Oxtellar XR through our contract manufacturing organization, or CMO, at its commercial manufacturing facility, and will scale up commercial production of Trokendi XR in preparation for final FDA approval, if received.

In our pilot clinical trial in 32 healthy subjects, which took place in Canada, Oxtellar XR demonstrated a superior adverse event profile when compared to the immediate release oxcarbazepine therapy Trileptal. In this trial, a single center, open-label, randomized, two-way crossover, two-sequence trial, we compared multiple dose administration of Oxtellar XR tablets and Trileptal tablets in 32 healthy adult volunteers under fasting conditions. While the steady-state crossover comparison trial was designed to evaluate the steady-state bioavailability of the different formulations of oral oxcarbazepine at 1200 mg doses, the trial also assessed the safety and tolerability of repeat oral dosing of Oxtellar XR tablets in healthy subjects at 1200 mg in comparison to Trileptal.

(15) Based on sales data as reported in Novartis AG's Annual Report on Form 20-F for the fiscal year ended December 31, 2006 and in a media release issued by Novartis International AG on January 21, 2008.

In this trial, the adverse events, or AEs, were observed in 30 healthy subjects using a total daily dose of 1200 mg of each of Trileptal and Oxtellar XR. There were 190 total AEs reported for Trileptal, while Oxtellar XR generated a total of only 120 AEs, a reduction of 37%. Of these, a total of 197 AEs were considered by the principal investigator to be possibly drug related: 131 for Trileptal and 66 for Oxtellar XR. More specifically, Trileptal demonstrated a 36.7% occurrence rate of dizziness as compared to Oxtellar XR which demonstrated a 0.0% occurrence rate in our trial. In other trials, Oxtellar XR demonstrated higher occurrence rates of dizziness. The results from these trials and the pilot clinical trial are preliminary and based on small populations.

In the pivotal Phase III trial for Trileptal, refractory patients had increasing reductions in seizures as dose levels increased, including 50% median reduction in seizures at the highest dose of 2400 mg. However, Trileptal is not without a host of side effects at the highest doses, which result in many subjects discontinuing treatment. Approximately 67% of subjects at the 2400 mg dose of Trileptal and 36% of subjects at the 1200 mg dose discontinued their participation in the trial because of the adverse events associated with the drug.

Epilepsy can be broadly characterized into partial and generalized seizures. Partial seizures occur in a specific location of the brain, affecting the physical or mental activity controlled by that particular area of the brain, whereas generalized seizures occur throughout both hemispheres of the brain at once. Partial seizures may be further subdivided into both simple and complex seizures. This refers to the effect of such a seizure on consciousness; simple seizures cause no interruption to consciousness (although they may cause sensory distortions or other sensations), whereas complex seizures interrupt consciousness to varying degrees.

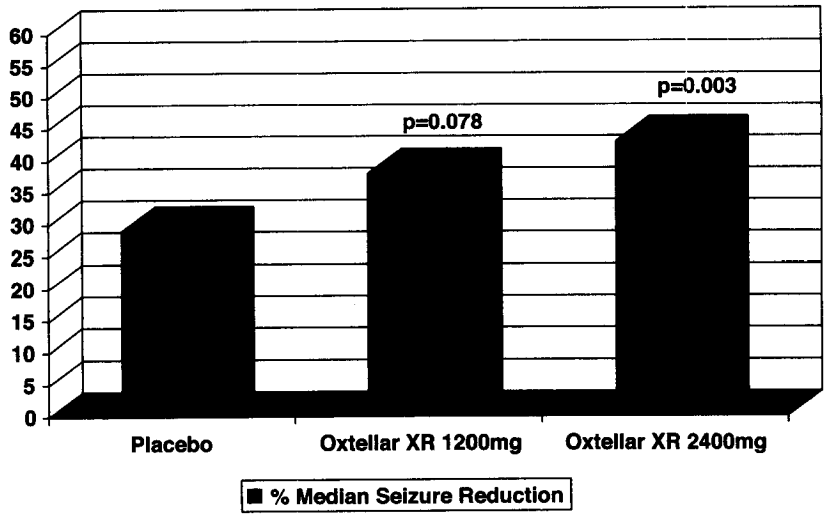
The Phase III trial of Oxtellar XR was a multi-center, multiple-dose, randomized (1:1:1 ratio), double-blind, placebo-controlled, three-arm, parallel group trial in male and female subjects (18 to 65 years of age, inclusive) with refractory partial epilepsy on at least one and up to three concomitant AEDs. The trial was completed with 366 patients comprising the intent-to-treat, or ITT, population and 248 completing the study across 8 different countries in North America and Europe. Patients were randomized to one of three treatment groups, and took either Oxtellar XR (1200 mg/day or 2400 mg/day) or placebo.

The primary objective of the trial was to evaluate the efficacy of Oxtellar XR as an adjunctive therapy in the treatment of seizures of partial origin in adults with refractory epilepsy on at least one and up to three other AEDs. The secondary objectives were to primarily assess the safety and tolerability of adjunctive Oxtellar XR in the treatment of seizures of partial origin in subjects with refractory epilepsy on at least one and up to three other AEDs.

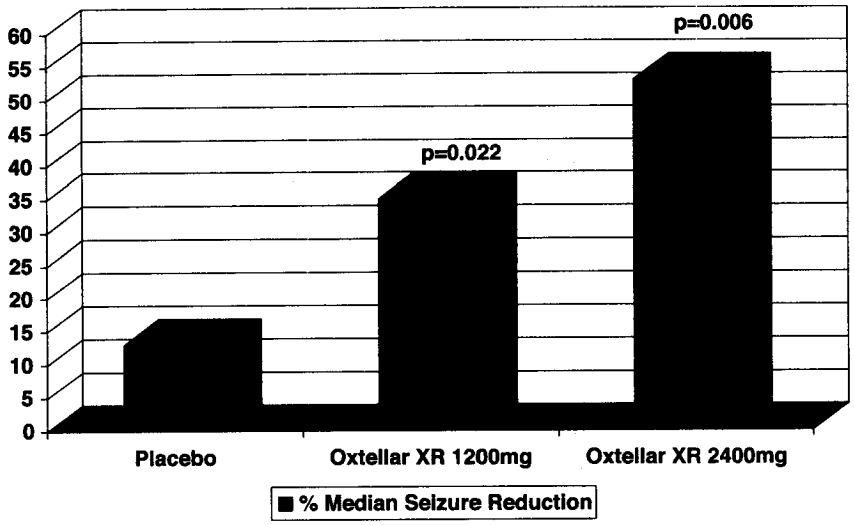
The primary endpoint was the median percentage change from baseline in partial seizure frequency per 28 days. Seizure frequency was assessed at baseline over 4-8 weeks. Patients had to have experienced a minimum of 3 seizures in a 28-day period to be included in the study. Drug titration to 1200 mg or 2400 mg occurred over 4 weeks using increments of 600 mg/week, and then was maintained between 12 and 13 weeks.

The median seizure reduction achieved in the study was 43% for Oxtellar XR 2400 mg/day with a p-value (p) of 0.003 versus placebo (123 patients), 38% for Oxtellar XR 1200 mg/day with p= 0.078 versus placebo (122 patients), and 29% for placebo (121 patients). In North America, the median reduction was 53% (35 patients) for Oxtellar XR 2400 mg/day with p=0.006 versus placebo, 35% (40 patients) for Oxtellar XR 1200 mg/day with p=0.022 versus placebo, and 13% for placebo (41 patients).

Percent Median Seizure Reduction per 28 Days: All Countries



Percent Median Seizure Reduction per 28 Days: North America



Secondary endpoints included treatment response (i.e., how many responders had ≥50% reduction in partial seizure frequency), and how many patients were seizure-free. At 2400 mg/day, Oxtellar XR provided significant treatment response (p=0.018) and seizure-free rates during treatment (p=0.013) and maintenance (p=0.008) periods versus placebo.

Treatment Response and Seizure-Free Rates (ITT Population)

	Oxtellar XR 1200 mg/day (n=122)	Oxtellar XR 2400 mg/day (n=123)	Placebo (n=121)
Treatment response			
n	109	111	117
Responder, n (%)	44 (36.1)	50 (40.7)	34 (28.1)
Non-responder, n (%)	65 (53.3)	61 (49.6)	83 (68.6)
Pvalue versus placebo	0.075	0.018	
Seizure-free rates (treatment phase)			
Subjects with valid diary entry	109	111	117
Seizure free, n (%)	6 (4.9)	14 (11.4)	4 (3.3)
Pvalue versus placebo	0.528	0.013	
Seizure-free rates (maintenance phase)			
Subjects with valid diary entry	97	88	109
Seizure free, n (%)	4 (3.3)	17 (13.8)	7 (5.8)
Pvalue versus placebo	0.546	0.008	

Safety assessments were conducted throughout the study. AE rates were similar for patients receiving placebo and Oxtellar XR 1200 mg/day (55.4% and 56.6%, respectively); AE rates were slightly higher in patients receiving Oxtellar XR 2400 mg/day (69.1%). The most frequently reported AEs with Oxtellar XR were dizziness, somnolence, headache, nausea, double vision, and vomiting. Treatment-related AEs occurred in 58.5%, 43.4% and 38.8% of those on Oxtellar XR 2400 mg/day, Oxtellar XR 1200 mg/day, and placebo, respectively. Severe AEs occurred in 7.3%, 9.0% and 8.3% of those on Oxtellar XR 2400 mg/day, 1200 mg/day, and placebo, respectively. Severe treatment-related AEs occurred in 6.5%, 6.6% and 4.1% of those on Oxtellar XR 2400 mg/day, Oxtellar XR 1200 mg/day, and placebo, respectively. Serious AEs occurred in 8.1%, 5.7%, and 5.8% of those on Oxtellar XR 2400 mg/day, Oxtellar XR 1200 mg/day, and placebo, respectively. Treatment-related serious AEs occurred in 4.9%, 0% and 2.5% of those on Oxtellar XR 2400 mg/day, Oxtellar XR 1200 mg/day, and placebo, respectively. One death (resulting from ovarian cancer) occurred on placebo and no deaths occurred on Oxtellar XR therapy. AEs led to study discontinuation in 12.4% (n=15) of patients receiving placebo, 16.4% (n=20) of patients receiving Oxtellar XR 1200 mg/day, and 30.1% (n=37) of patients receiving Oxtellar XR 2400 mg/day.

In summary, Oxtellar XR 2400 mg/day significantly reduced partial seizure frequency from baseline versus placebo. Seizure frequency reduction with Oxtellar XR 1200 mg/day was greater than but did not separate from placebo. This finding may be explained by the high placebo response rate noted in some of the sites outside the U.S. in this study and is consistent with a general trend of higher placebo response rates observed in pivotal studies of other new AEDs. Although the 1200 mg/day dose did not reach statistical significance when compared to placebo, concentration response analyses revealed that the 1200 mg/day dose is effective and, therefore, was included in the Oxtellar XR approved label by the FDA as a recommended daily dose. Both Oxtellar XR doses were generally well tolerated with no new safety signals observed. The improved tolerability of Oxtellar XR, especially at doses up to 2400 mg/day, may translate to improved adherence and better patient outcomes.

Commercialization Strategy

Oxtellar XR is the only once-daily oxcarbazepine product indicated for the treatment of epilepsy in the U.S. as an adjunctive therapy and competes against the existing immediate release oxcarbazepine products on the market. We believe that Oxtellar XR could, over time, capture a significant share of the oxcarbazepine prescription market, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market over the past 15 years. In early 2013, to

support the commercial launch of Oxtellar XR, which was granted three years of market exclusivity by the FDA, we built a small specialty sales force of approximately 75 representatives. These sales representatives are primarily targeting neurologists to promote the use of Oxtellar XR as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age in the United States. We expanded our agreement with the CMO to provide for the production of commercial quantities of Oxtellar XR to fulfill expected demand through the commercial launch of the product.

Trokendi XR (extended release topiramate)

Trokendi XR is a novel oral once-daily extended release topiramate product for the treatment of epilepsy. The FDA issued a tentative approval of Trokendi XR in June 2012, as 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 similar seizures or with seizures associated with Lennox-Gastaut syndrome. The final approval for Trokendi XR may not be made effective until the period of marketing exclusivity protection associated with safety information regarding a specific pediatric population, which expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. In early December, 2012, the Company submitted to the FDA a request for final approval as an amendment to the NDA including a safety data update, a new package insert and packaging configurations for Trokendi XR and was informed that should the FDA approve such amendment, it will most likely be in the form of a tentative approval because the review period of such amendment would be expected to conclude in the second quarter prior to the June 22, 2013 expiration of the pediatric exclusivity. The Company continues to expect getting the final approval and commercially launching Trokendi XR in the third quarter of 2013. Topiramate is marketed by Johnson & Johnson under the brand name Topamax and is also available in a generic form. Topiramate is currently available only in immediate release form and is indicated for monotherapy and adjunctive therapy of epilepsy and for the treatment of migraine. Topamax reached peak worldwide sales of $2.7 billion in 2008, before generic products entered the U.S. market in March 2009.(16) With approximately 10 million total topiramate prescriptions in the U.S. in 2011 and 10.6 million prescriptions in 2012, topiramate continues to represent a significant portion of prescriptions with approximately 8.4% of total prescriptions, according to data from IMS Health. Topiramate is believed to work in epilepsy through various mechanisms. It enhances the inhibitory effect of the GABA (gamma-aminobutyric acid) neurotransmitter that regulates neuronal excitability throughout the nervous system, blocks the excitatory effect of the glutamate neurotransmitter, blocks the sodium channel and inhibits the carbonic anhydrase enzyme. The side effects associated with taking topiramate, which have tended to limit its use, include, among others, dizziness, fatigue, somnolence and slowing of certain cognitive functions. We believe that this creates an opportunity for us to offer patients Trokendi XR as an alternative therapy to immediate release topiramate with an improved once-per-day profile.

Trokendi XR is designed to improve patient compliance and to have a better tolerability profile compared to the current immediate release products that are taken multiple times per day. Trokendi XR's pharmacokinetic profile delivers lower peak plasma concentrations and lower input rate over an extended time period resulting in smoother and more consistent blood levels of topiramate during the day compared to immediate release Topamax. We believe such a profile mitigates blood level fluctuations that are typically associated with many of the side effects or breakthrough seizures that patients can suffer when taking immediate release products. These side effects can lead patients to skipping doses, and such non-compliance could place them at higher risk for breakthrough seizures.

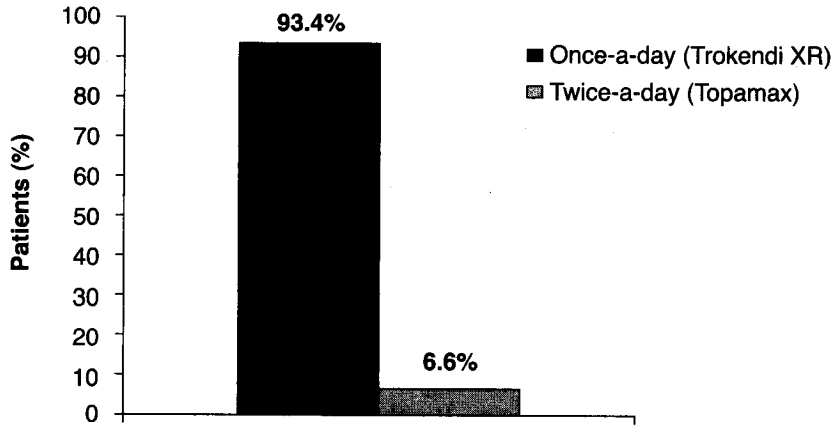
Trokendi XR was studied in a U.S. Phase II, multicenter, open-label, sequentially-designed conversion clinical trial among patients between the ages of 18 and 65 having partial-onset or primary generalized seizures. Prior to enrolling in the study, patients were taking topiramate twice-a-day immediate release

(16) Based on sales data as reported in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2010.

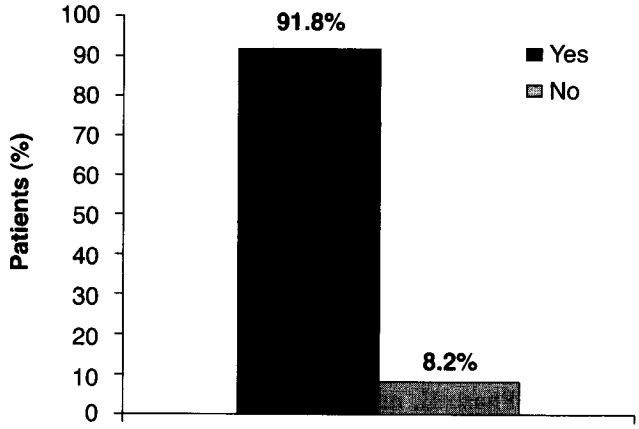
products with total daily regimen that ranged from 200 mg-400 mg. Patients were first converted to equivalent Topamax twice-a-day immediate release doses for two weeks and then converted to an equivalent once daily dose of Trokendi XR for two more weeks. The study successfully met its primary objective of showing that Trokendi XR is bioequivalent to Topamax immediate release in epilepsy patients. For example, the ratio of dose-normalized (200 mg) geometric least-square means Trokendi XR versus Topamax and the 90% intervals (CIs) were within the bioequivalence criteria of 80-125% for Area under the Curve (AUC) (101.69, 90% CI; 87.10, 118.72), maximum concentration $C_{max,}$ (97.30, 90% CI; 84.50, 112.04), and minimum concentration $C_{min,}$ (100.59, 90% CI; 83.24, 121.56). Trokendi XR was also well tolerated and the majority of the patients (85.5%) converted from Topamax immediate release to Trokendi XR with no treatment related AEs. There were no serious AEs or deaths and all reported AEs were mild to moderate. There were no notable differences in seizure frequency between the treatments.

When asked two questions at the end of the study about their preference, the sixty-one (61) subjects who completed the study responded as follows:

Which treatment do you prefer? The once-a-day treatment or twice-a-day treatment?



Does the once-a-day treatment (Trokendi XR) help you to be more compliant in taking your medication?



Trokendi XR Development Program

The FDA issued tentative approval of Trokendi XR in June 2012. We pursued a Section 505(b)(2) regulatory strategy, which allowed us to rely in our NDA filing on the FDA's findings of safety and effectiveness of Topamax. The various clinical trials conducted on Trokendi XR were designed to select the best extended release once-per-day formulation that delivers equivalent levels of topiramate compared to the immediate release twice-per-day Topamax product, as well as to test the robustness and consistency of our technology in delivering the once-per-day formulation across a full range of product strengths. We believe that the data generated by our studies support our Section 505(b)(2) regulatory strategy of establishing Trokendi XR as bioequivalent to Topamax. We also have scaled up production of the product candidate at our commercial contract manufacturing facility and have conducted studies that confirm that the commercial scale product is bio-equivalent to the clinical product that was initially developed at our research laboratories.

Commercialization Strategy

If we are successful in obtaining final regulatory approval, we believe that Trokendi XR will be the first once-daily topiramate product approved in the U.S., as 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. We believe that Trokendi XR could, over time, capture a significant share of the topiramate prescriptions, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market over the past 15 years. As discussed above, we have built our sales and marketing capabilities in the United States to complete the launch of Oxtellar XR. Upon the commercial launch of Trokendi XR, assuming receipt of final approval from the FDA, we expect to further expand our sales and marketing capabilities later this year. We expanded our agreement with the CMO to provide for the production of commercial quantities of Trokendi XR to prepare for the commercial launch of Trokendi XR assuming receipt of final approval by the FDA. In 2012, two U.S patents were issued covering the product.

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.(17) An estimated 50% of children with ADHD continue to meet criteria for ADHD into adolescence.(18) In 2011, the U.S. market for ADHD prescription drugs was more than $4.4 billion, according to data from Datamonitor.(19)

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

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

(19) R & D Trends: *Attention Deficit Hyperactivity Disorder*, published June 2011, at www.datamonitor.com.

Diagnosis of ADHD requires a comprehensive clinical evaluation based on identifying patients who exhibit the core symptoms of inattention, hyperactivity, and impulsivity. Generally, behavior is sufficiently severe and persistent to cause functional impairment. 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. It is estimated that the annual societal cost of illness for ADHD is more than $36 billion.(20)

Current Treatment Options

Since Ritalin was introduced, stimulant therapies have grown to become the most common form of treatment for ADHD. Studies indicate that approximately 80% of ADHD patients respond to stimulants.(21) A key difference between older and newer oral stimulants is the duration of action. Most of the older stimulants, representing approximately 35% of total oral stimulant prescriptions based on IMS Health data, are immediate release products that last approximately four hours, requiring multiple administrations throughout the day. In contrast, most of the recently launched products, representing approximately 65% of total oral stimulant prescriptions based on IMS Health data, are extended release formulations that last up to twelve hours or more.

While stimulant treatments calm and improve the concentration of ADHD patients, these drugs have been shown to have various side effects including loss of appetite, insomnia and, to a lesser degree, cardiovascular effects. Stimulant treatments are controlled substances and can be associated with social stigma and the potential for abuse. Approximately 30% of patients with ADHD are non-responsive to or non-tolerant of treatment with stimulants.(22) Non-stimulants offer physicians an alternative ADHD therapy, including for patients who have coexisting conditions, such as conduct disorder, major depressive disorder, or bipolar disorder, that are contraindicated for stimulant use based on the risk for stimulant abuse.

(20) Pelham, W.E., *The Economic Impact of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents*, published July 2007 in *Journal of Pediatric Psychology*.

(21) Swanson, J.M., *Attention-deficit hyperactivity disorder and hyperkinetic disorder*, published February 1998 in *The Lancet* and Budur, K., *Non-Stimulant Treatment for Attention Deficit Hyperactivity Disorder*, published July 2005 in *Psychiatry*.

(22) Wigal, S.B., *Efficacy and Safety Limitations of Attention-Deficit Hyperactivity Disorder Pharmacotherapy in Children and Adults*, published August 2009 in *CNS Drugs* and Budur, K., *Non-Stimulant Treatment for Attention Deficit Hyperactivity Disorder*, published July 2005 in *Psychiatry*.

Coexisting Conditions

Studies show that as many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, conduct disorder, anxiety disorder and depression.(23) In addition, it has been estimated that approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.(24) Untreated, these serious conduct problems can place patients at risk of persistent aggressive and anti-social behavior, such as knowingly destroying property, physically attacking people and bullying. These patients also face an increased risk of suicidal behavior, and are at high risk of entering the juvenile justice system and developing substance abuse problems later in adulthood.

Aggression is usually divided into two subtypes: predatory (i.e., "cold") aggression, which can be described as goal-oriented, controlled and/or planned, and impulsive or affective (i.e., "hot") aggression, which can be described as reactive, unplanned and/or uncontrolled. Patients with ADHD who exhibit aggression commonly demonstrate the "hot," or impulsive, type of aggression. For these patients, this "hot" aggression is generally recurrent, occurs outside of a justifiable social context, has intensity, frequency, duration or severity that is disproportionate to its triggers and causes distress and impairment to the patient. Impulsive aggression represents a broad category of maladaptive, aggressive behaviors that can complicate the management of ADHD, autism, bipolar disorder, post-traumatic stress disorder and other psychiatric disorders.

Current Treatments for Impulsive Aggression in Patients with ADHD

Currently, there are no approved medications for treating impulsive aggression in patients with ADHD. The current treatment options for impulsive aggression in patients with ADHD include psychosocial interventions, such as school- or family-based behavioral therapies, which are usually not wholly effective. In the large, multisite Multimodal Treatment Study of Children with ADHD,(25) 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 address 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, lipid abnormalities, and diabetes, which is of particular concern when treating pediatric populations.

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

(24) Jensen, P.S., *Consensus Report on Impulsive Aggression as a Symptom Across Diagnostic Categories in Child Psychiatry: Implications for Medication Studies*, published March 2007 in *Journal of the American Academy of Child and Adolescent Psychiatry*.

(25) 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*.

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 one product candidate for depression, each of which is designed to bring important advancements in therapy.

SPN-810 (molindone hydrochloride)

We are developing SPN-810 (molindone hydrochloride extended release formulation) as a novel treatment for impulsive aggression in patients with ADHD. We initiated a Phase IIb trial of SPN-810 in the United States in June 2011, for which we received preliminary results in November 2012. The trial's primary objective was to study three different doses of SPN-810 ranging from 12 mg per day to 54 mg per day depending on patients' weight. The study accomplished its objectives of establishing a dose range at which the drug is effective and confirmed the efficacy of SPN-810 in the treatment of impulsive aggression in ADHD patients weighing 30 kg or more. Based on the efficacy demonstrated by the low and medium doses in this study across several measures in these patients, we have decided to advance the program into later stage development. We are continuing to analyze the full dataset in depth and plan to subsequently meet with the FDA to discuss next steps in the development program and the design and protocol for Phase III clinical trials of SPN-810. If approved by the FDA, SPN-810 could be the first product available to address this serious, unmet medical need. We submitted INDs for SPN-810 in 2008 and 2009.

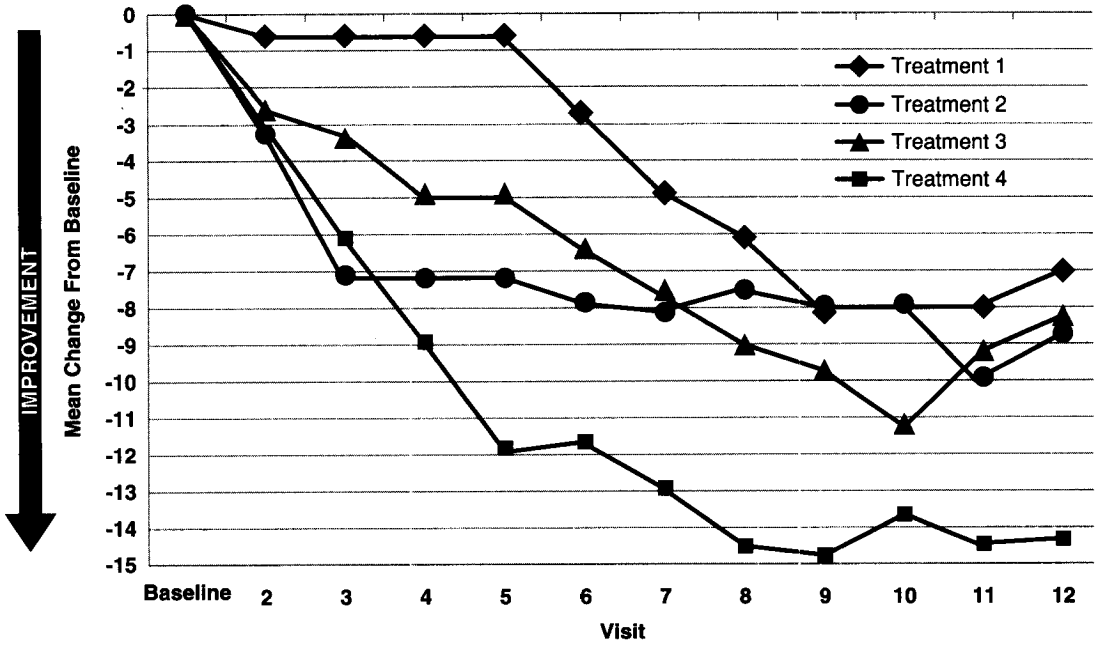
We are studying SPN-810, which contains molindone hydrochloride, as a treatment of impulsive aggression in patients with ADHD. Molindone hydrochloride was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. Molindone hydrochloride is unusual among anti-psychotics in that it is less likely to be associated with weight gain. In addition, we believe the lower doses tested for the proposed indication of impulsive aggression should be more easily tolerated than the higher doses approved to treat schizophrenia. SPN-810's low potential to cause weight gain leads us to believe that SPN-810 could be an attractive candidate among the anti-psychotic drugs for the effective treatment of impulsive aggression in patients with ADHD. Although initially we are developing SPN-810 as a treatment of impulsive aggression, if we are successful in demonstrating the effectiveness of SPN-810 for the treatment of impulsive aggression in patients with ADHD, we may then look to develop the product candidate for the treatment of other patient populations that have impulsive aggression, such as autism and bipolar disorder.

SPN-810 Development Program

We have completed five clinical trials for SPN-810, including a Phase IIa U.S. trial in which we tested the safety and tolerability of SPN-810, immediate release molindone hydrochloride, in patients with ADHD who suffer from serious persistent conduct problems. This open-label, dose-ranging trial randomized 78 children, 6 to 12 years of age, into one of four treatment groups, which were given four different doses of immediate release molindone hydrochloride, between 10 mg and 40 mg per day, depending on weight, three times a day over a six-week treatment period, after 2-5 weeks of titration. SPN-810 was well tolerated in the trial, with no clinically meaningful changes in standard hematology, clinical chemistry values, vital signs or electrocardiogram, or ECG, results. Besides safety and tolerability assessments, the primary outcome measure was the change in the Nisonger Child Behavior Rating Form-Typical Intelligence Quotient, or NCBRF-TIQ, conduct problem subscale scores from baseline to endpoint in the ITT population. NCBRF-TIQ is a well established instrument that has been used for assessing child and adolescent behavior. Scores improved after baseline in all treatment groups. By visit 12, after 6 weeks of treatment, the mean reduction from baseline values for each treatment group was 7.0, 8.7, 8.2 and 14.3, in groups 1, 2, 3 and 4, respectively, representing decreases of 34%, 34%, 32% and 55%, respectively. In addition, the difference between group 1 and group 4 was statistically significant ($p \leq 0.041$) at all time points except visit 2 and the greatest improvement in scores

on the NCBRF-TIQ conduct problem subscale was seen in group 4, which was the highest-dose group (14.8 mean reduction). The below chart summarizes the mean change in NCBRF-TIQ conduct problem subscale observed in our Phase IIa trial.

NCBRF-TIQ Conduct Problem Subscale:
Mean Change From Baseline (ITT Population)



NCBRF-TIQ Conduct Problem Subscale:
Mean Change from Baseline in ITT Population

Secondary outcomes included changes in other ADHD and conduct problem scales, as described in the table below. SPN-810 demonstrated improved scores over time in all treatment groups, with more marked improvements in higher-dose groups than in lower-dose groups as set out in greater detail in the table below.

% Improvement from Baseline to Last Visit,
Secondary Outcome Measures (ITT Population)

	Treatment Groups			
Outcome Measure	**Group 1 n=20**	**Group 2 n=19**	**Group 3 n=19**	**Group 4 n=20**
CGI-S				
% Improvement	23%	21%	27%	36%
SNAP-IV Subscales				
ADHD Inattention				
% Improvement	24%	31%	34%	39%
ADHD Hyperactivity/Impulsivity				
% Improvement	28%	27%	28%	41%
ADHD-Combined				
% Improvement	26%	29%	31%	40%
ODD				
% Improvement	34%	33%	28%	51%

CGI-S=Clinical Global Impression-Severity Scale, an assessment tool to rate the severity of the condition; ODD=Oppositional Defiant Disorder, a coexisting condition of ADHD; SNAP-IV=Swanson, Nolan and Pelham Questionnaire, a commonly used scale to measure ADHD.

In June 2011, we initiated 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 effectiveness of SPN-810, extended release, at three different doses in reducing impulsive aggression after at least three weeks of treatment. The primary endpoints were the effect in reducing impulsive aggression as measured by change in the score of the Retrospective—Modified Overt Aggression Scale, or R-MOAS, and the rate of remission. Secondary endpoints include measurement of the effectiveness of SPN-810 on Clinical Global Impression and ADHD scales as well as evaluation of the safety and tolerability of the drug. In addition, we are exploring the potential added advantages of an extended-release formulation, such as greater compliance and, therefore, effectiveness in school-age children and lower unwanted side effects or interpatient variability. Patients who completed the study were offered the opportunity to continue into an open-label phase of six months duration. We received preliminary results in November 2012.

For all patients, low and medium doses of SPN-810 met the efficacy endpoint of rate of remission of aggression and showed statistical significance versus placebo with p-values of 0.009 and 0.043 and percent of patients with R-MOAS remission of 51.9% and 40.0%, respectively. The low and medium doses showed a reduction in score for the R-MOAS of 62.6% and 57.9%, respectively, with p-values of 0.071 and 0.115.

For patients of 30 kg or more in weight, the low and medium doses of SPN-810 showed statistical significance versus placebo on the change in R-MOAS primary endpoint with p-values of 0.024 and 0.049, and high percent reduction in the R-MOAS scores of 80.9% and 75.2%, respectively. In addition, both doses resulted in remission of aggression with statistical significance versus placebo with p-values of 0.004 and 0.021 with percent of patients with R-MOAS remission of 66.7% and 53.3%, respectively. The low dose also met the secondary endpoints of Clinical Global Impression, or CGI, for Severity and Improvement, and of the Swanson, Nolan and Pelham Rating Scale, or SNAP-IV, rating for Oppositional Defiant Disorder with statistical significance versus placebo with p-values of 0.007, 0.017 and 0.039, respectively, and improvements of 41.3%, 34.5% and 49.3%. The high dose did not show statistically significant efficacy across any of these measures.

For patients under 30 kg in weight, while the low and medium doses showed improvements over placebo in the primary endpoints and the SNAP-IV rating for Oppositional Defiant Disorder, the studied doses did not show statistical significance versus placebo on efficacy measures. Coupled with the fact that the high dose did not show efficacy with statistical significance, this unexpected result leads us to believe that the most effective doses are those that achieve certain plasma concentrations (related to body weight) that do not exceed a level beyond which some sort of saturation threshold is reached.

Efficacy in Patients ≥ 30 kg on Low to Medium Doses

Primary Efficacy Endpoints (Treatment vs. placebo in ITT population)	Placebo	Low Dose	Medium Dose	High Dose
R-MOAS Change Overall (% improvement)	(38.5)	(62.6)	(57.9)	(39.7)
Patients (<30kg)	(35.3)	(42.3)	(44.4)	(33.7)
Patients (≥30kg)	(41.5)	(80.9)	(75.2)	(44.4)
R-MOAS Remission Overall (% of patients)	(20.0)	(51.9)	(40.0)	(32.3)
Patients (<30kg)	(25.0)	(33.3)	(26.7)	(21.4)
Patients (≥30kg)	(16.7)	(66.7)	(53.3)	(41.2)

R-MOAS=Retrospective-Modified Overt Aggression Scale; R-MOAS Change=from Baseline (Visit 5) to Endpoint (Visit 10); R-MOAS Remission=Score of ≤10 (LOCF=Last Observation Carried Forward) at Endpoint (Visit 10)

Efficacy in Patients ≥ 30 kg on Low to Medium Doses

Primary Efficacy Endpoints (Treatment vs. placebo in ITT population)	Placebo	Low Dose	Medium Dose	High Dose
R-MOAS Change Overall (% improvement)	(38.5)	(62.6)	(57.9)	(39.7)
Patients (<30kg)	(35.3)	(42.3)	(44.4)	(33.7)
Patients (≥30kg)	(41.5)	(80.9)	(75.2)	(44.4)
R-MOAS Remission Overall (% of patients)	(20.0)	(51.9)	(40.0)	(32.3)
Patients (<30kg)	(25.0)	(33.3)	(26.7)	(21.4)
Patients (≥30kg)	(16.7)	(66.7)	(53.3)	(41.2)

R-MOAS=Retrospective-Modified Overt Aggression Scale; R-MOAS Change=from Baseline (Visit 5) to Endpoint (Visit 10); R-MOAS Remission=Score of ≤10 (LOCF=Last Observation Carried Forward) at Endpoint (Visit 10)

Statistical Significance in Patients ≥ 30 kg on Low Dose

Secondary Efficacy Endpoints (Treatment vs. placebo in ITT population)	Low Dose P-value	Medium Dose P-value	High Dose P-value
CGI-Severity Overall	0.133	0.308	0.245
Patients (<30kg)	0.42	0.839	0.946
Patients (≥30kg)	0.007	0.117	0.125
CGI-Improvement Overall	0.175	0.061	0.888
Patients (<30kg)	0.494	0.664	0.756
Patients (≥30kg)	0.017	0.028	0.654
SNAP-IV—ODD Subscale Overall	0.061	0.122	0.661
Patients (<30kg)	0.639	0.173	0.607
Patients (≥30kg)	0.039	0.179	0.861

CGI=Clinical Global Impression; SNAP-IV=Swanson, Nolan and Pelham, ADHD Rating Scale; ODD=Oppositional Defiant Disorder

Efficacy in Patients ≥ 30 kg on Low Doses

Secondary Efficacy Endpoints (Treatment vs. placebo in ITT population)	Placebo	Low Dose	Medium Dose	High Dose
CGI-Severity Overall (% improvement)	19.6	28.2	25.5	26.7
Patients (<30kg)	22.9	17.0	22.4	23.9
Patients (≥30kg)	15.9	41.3	31.1	29.5
CGI-Improvement Overall (% improvement)	15.1	20.0	28.1	18.2
Patients (<30kg)	15.1	6.2	23.5	12.5
Patients (≥30kg)	15.1	34.5	35.5	21.2
SNAP-IV—ODD Subscale Overall (% improvement)	18.0	34.4	30.3	21.4
Patients (<30kg)	12.8	17.4	23.2	17.9
Patients (≥30kg)	21.5	49.3	39.3	24.2

CGI=Clinical Global Impression; SNAP-IV=Swanson, Nolan and Pelham, ADHD Rating Scale; ODD=Oppositional Defiant Disorder

We will be conducting further analyses of the full dataset including analyzing the pharmacokinetic and pharmacodynamic relationship from the pharmacokinetic data generated from the study at various doses for patients in different weight groups.

SPN-810 was well tolerated throughout the study across all doses. The two serious 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. Analysis of all safety and clinical lab data has not yet been completed, though SPN-810 seemed to have a good safety and tolerability profile.

Safe and Well Tolerated

Number (%) of Patients with:	Placebo	Low Dose	Medium Dose	High Dose
Any adverse event (AE)	18 (58.1)	11 (37.9)	18 (60.0)	21 (67.7)
Adverse reaction	7 (22.6)	6 (20.7)	11 (36.7)	13 (41.9)
Severe AEs	0 (0.0)	1 (3.4)	4 (13.3)	1 (3.2)
Severe Adverse Reaction	0 (0.0)	1 (3.4)	2 (6.7)	0 (0.0)
Any serious AE (SAE)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Serious Adverse Reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AEs leading to discontinuation	1 (3.2)	1 (3.4)	2 (6.7)	3 (9.7)

Adverse Reaction=those AEs considered possibly or definitely study drug related, according to investigator

Safe and Well Tolerated

Adverse Reaction (%) of Patients	Placebo	Low	Medium	High
Decreased appetite	0	0	3.3	6.5
Increased appetite	3.2	6.9	6.7	6.5
Sedation	6.5	6.9	6.7	6.5
Somnolence	3.2	0	0	6.5
Fatigue	0	0	0	9.7
Dystonia	0	0	6.7	0

Adverse Reactions in ≥5% of patients across Titration & Maintenance Periods

SPN-812

We are developing SPN-812, which is currently in Phase II development, as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. The active ingredient in SPN-812 has an extensive safety record in Europe, where it was previously marketed for many years as an anti-depressant. SPN-812 has not been developed and marketed in the United States and, therefore, it would be considered and reviewed by the FDA as an NCE. We submitted one IND for SPN-812 in 2010.

SPN-812 would provide an additional option to the few non-stimulant therapies currently available. We believe that SPN-812 could be more effective than other non-stimulant therapies due to its different pharmacological profile. 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.(26) 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.

(26) 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*.

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 which 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 in the active arm were administered SPN-812 at a single dose level three times a day over five weeks, after a one-week titration phase. The primary endpoint was safety, and SPN-812 was shown to be safe and well tolerated by patients. The secondary endpoints included: the efficacy of SPN-812 as measured by Total ADHD Symptom Score on the Conners' Adult ADHD Rating Scale, or CAARS, a commonly-used measurement for ADHD in adults, as rated by each of the investigators and the patients, and the effectiveness of SPN-812 when compared to placebo as determined by changes in the CGI—Improvement, or CGI-I, score. Patients in the active group achieved overall significant median reductions from baseline in investigator-rated CAARS total ADHD symptom scores by study end, of 11.5 points versus 6.0 points for placebo ($p=0.0414$) and in self-rated CAARS total symptom scores by study end, of 10.5 points versus 1.0 for placebo ($p=0.0349$). With respect to the other secondary endpoint of CGI-I scores, patients exhibited a trend, although not statistically significant, toward larger median reductions in scores from baseline versus placebo.

Given the positive results of this Phase IIa trial, we are focused on developing an extended release formulation that will be the subject of a future Phase IIb trial.

SPN-809

We are developing SPN-809 as 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 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. Depression is a serious and common disease affecting approximately 121 million people worldwide.(27) Based on IMS Health data, the worldwide market for anti-depressants is approximately $12 billion.

SPN-809 is a norepinepherine reuptake inhibitor that represents an opportunity to offer a differentiated treatment option for patients suffering from depression in the United States. Initial market research suggests that psychiatrists would like to have such a once-daily option at their disposal to treat various patients. 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.

Other Product Candidates

We have additional product candidates in various stages of early development that cover a range of CNS disorders.

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

(27) World Health Organization, *Epilepsy: aetiogy, epidemiology and prognosis*, Fact Sheet No. 165, revised February 2001.

dosing, enhanced patient compliance, and improved tolerability in certain specific applications. Our broad portfolio of technologies and extensive expertise in this area, built over the past 20 years, enable us to develop products that are technically difficult to formulate and by design are harder for others to copy. We have employed our technologies in the development of our legacy products, as well as in our current product portfolio.

Microtrol (multiparticulate delivery platform)

Microtrol is based on the use of coated and uncoated multi-particulates that can be filled into capsules, administered as a sprinkle, or compressed into tablets as varying ratios to achieve novel customized release profiles. The following approved and marketed products incorporate our Microtrol technology:

- Sanctura XR (trospium chloride), a treatment for overactive bladder;
- Oracea (doxycycline), a treatment for inflammatory lesions of rosacea;
- Carbatrol (carbamazepine), an anti-epilepsy treatment;
- Equetro (carbamazepine), a treatment for bipolar disorder; and
- Adderall XR (mixed amphetamine salts), a stimulant ADHD treatment.

We do not expect the above products to contribute to our future financial position. Carbatrol, Equetro and Adderall XR are legacy products that were developed by us when we were formerly Shire Laboratories. In addition, in April 2008, we monetized the revenues underlying the future royalty streams relating to Sanctura XR and Oracea by transferring certain of our royalty payment rights and other license rights for such products to TCD Royalty Sub LLC, or Royalty Sub, in exchange for $63 million. We primarily reinvested the proceeds from this transaction into our research and development activities. In December 2011, we sold 100% of our equity ownership interests in Royalty Sub. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—History of our Company" and Note 10 of the audited financial statements for additional details regarding the sale of Royalty Sub.

Solutrol (matrix delivery platform)

Solutrol is a matrix delivery system that can deliver poorly soluble, highly soluble, and pH dependent compounds in a reproducible and complete manner. Solutrol has been incorporated into Intuniv (guanfacine), a nonstimulant ADHD treatment, which is currently licensed to and marketed by Shire plc. In April 2009, this license became fully paid up when we sold to Shire the right to receive royalties and milestone payments owed to us for $36.9 million, which we primarily reinvested into our research and development activities.

EnSoTrol (osmotic delivery system)

EnSoTrol is comprised of a solubility enabled core and other agents surrounded by a semi-permeable membrane with a laser-drilled hole. When EnSoTrol is introduced to the contents of the gastrointestinal tract, it will induce solubilization of the core contents via fluid intake across the membrane coating. The solubilized core contents are then released through the laser-drilled hole along the osmotic gradient, thus yielding a surface-area controlled constant release profile. EnSoTrol has been tested in several clinical trials, including Phase III trials conducted by United Therapeutics for an oral formulation of treprostinil diethanolamine, or treprostinil that is the subject of an NDA.

In June 2006, we entered into a license agreement with United Therapeutics Corporation, or United Therapeutics, for the worldwide development and commercialization of an oral formulation of treprostinil, which utilizes EnSoTrol for the treatment of pulmonary arterial hypertension, or PAH, as well as for other indications. Under the terms of the license agreement, we have received

pre-commercial milestone payments of $1.5 million. Remaining milestone payments to us could total up to approximately $6.0 million, which includes milestone payments that could total $2.0 million based on the satisfaction of development milestones of oral treprostinil in PAH and up to approximately $4.0 million for the development of additional treprostinil products for a second indication. If United Therapeutics receives approval to market and sell an oral formulation of treprostinil, we will be entitled to receive royalties in the single digits based on net sales worldwide. On October 23, 2012, the FDA issued a complete response letter declining approval of the product. We do not expect to receive any royalties for this oral formulation unless and until final marketing approval from the FDA is received and United Therapeutics launches this product. Our license agreement with United Therapeutics will expire, on a country-by-country and product-by-product basis, 12.5 years from the first commercial sale of each product in such country. United Therapeutics may terminate, at its option, the agreement for a technical, strategic or market-related cause after giving us a reasonable opportunity to cure. We may terminate the agreement if, after having launched a product in a country, United Therapeutics or its sublicensee discontinues the sale of such product for a prolonged period of time for reasons unrelated to force majeure, regulatory or safety issues. In addition, either party may terminate the agreement for the material, uncured breach by the other party and in certain events of bankruptcy or insolvency of the other party.

Other Technologies

We also have proprietary techniques for identifying lead molecules and optimizing their oral delivery consisting of ProScreen, ProPhile and OptiScreen technologies. ProScreen is a predictive screen for lead candidates that warrant oral delivery. ProPhile is a suite of in silico modeling tools that enables multivariate analysis and pharmacokinetic prediction. OptiScreen is a technology for formulation optimization including solubility or permeability enhancement leading to oral bioavailability improvement. We believe that this suite of technologies enables us to optimize the delivery and the development of existing chemical entities and marketed products.

Sales and Marketing

We have built our sales and marketing capabilities in the United States to launch Oxtellar XR and, assuming receipt of final approval from the FDA, Trokendi XR. Additionally, there are plans to further expand our sales and marketing capabilities later this year. Having two epilepsy products that can be promoted to the same physician audience would allow us to leverage our commercial infrastructure with these prescribers. Once we have obtained approval for any of our product candidates in our psychiatry portfolio, we anticipate adding additional sales force members who will be dedicated to marketing our psychiatry products.

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently depend on third-party CMOs for all of our required raw materials and drug substance for our preclinical research and clinical trials. We do not have contractual relationships for the commercial manufacture of all our product candidates. 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 and as needed third-party consultants to manage our manufacturing contractors.

For both Oxtellar XR and Trokendi XR, we have entered into agreements with leading CMOs headquartered in North America for the manufacture of the final commercial products. They offer a comprehensive range of contract manufacturing and packaging services and have successfully handled

the scale up of Oxtellar XR to a commercial production scale and will scale up commercial production of Trokendi XR in preparation for commercialization of this product, assuming final FDA approval.

Competition

The biotechnology and pharmaceutical industries are highly competitive. A number of multinational pharmaceutical companies as well as large biotechnology companies are pursuing the development of or are currently marketing pharmaceutical products in the anti-epilepsy and ADHD markets on which we are focusing.

Epilepsy

There are currently over 15 branded products, as well as their generic counterparts, on the U.S. market indicated to treat some form of epilepsy. Several NCEs have entered the epilepsy market including Potiga, Vimpat and Banzel. Another NCE, Stedesa, could be approved later in 2013 and enter the market thereafter. Based on IMS Health prescription data from 1994 to 2005 for NCE launches for seizure disorders, such NCEs, on average, experienced slow market penetration characterized by a 0.58% to 1.1% market share point gain on an annual basis. We believe this is because physicians are often reluctant to change a stable patient's existing therapy and risk a breakthrough seizure in their patients.

Oxtellar XR competes with all immediate release oxcarbazepine products including Trileptal and related generic products. We are not aware of any other company that is currently developing an extended release oxcarbazepine anti-epileptic product in the United States. In addition, we believe that Oxtellar XR's once-daily formulation solves a drug delivery challenge specific to oxcarbazepine that must be overcome by all potential competitors. We are aware of companies who have modified-release oxcarbazepine products that are marketed outside of the United States but, to our knowledge, such products are not being pursued for the U.S. market. These modified-release oxcarbazepine products include Apydan, which is developed by Desitin Arzneimittel GmbH, and requires twice-daily administration.

If final approval is received, Trokendi XR will compete with all immediate release topiramate products including Topamax and related generic products. We are aware that Upsher-Smith Laboratories, Inc., or Upsher-Smith, conducted a Phase III clinical trial for an extended release topiramate product, which it has described as an internally developed program for the management of epilepsy in adults using its proprietary formulation technology. If this product candidate is approved by the FDA before Trokendi XR, then Upsher-Smith could obtain three years of marketing exclusivity, which would significantly delay our entry into the U.S. market.

ADHD

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: Adderall XR, an extended release stimulant treatment designed to provide once-daily dosing; Vyvanse, a stimulant prodrug product launched in 2007; and Intuniv, a non-stimulant treatment launched in November 2009. 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 large pharmaceutical companies including Eli Lilly, Otsuka America, Inc., BMS, AstraZeneca plc and Abbott Laboratories to develop additional treatment options for ADHD.

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 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. 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.

Patent Portfolio

Our extended release oxcarbazepine patent portfolio currently includes four U.S. patents, two of which cover Oxtellar XR. We have also obtained two patents for extended release oxcarbazepine in Europe, one patent in Canada and one patent in Mexico. In addition, we have certain pending U.S. and foreign patent applications that are directed to various extended release formulations containing oxcarbazepine. The issued U.S. patents covering Oxtellar XR will expire in 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 two U.S. patents that cover Trokendi XR. We have one patent issued in Europe for extended release topiramate and have certain pending U.S. and foreign patent applications in Canada and other countries that relate to the U.S. patents directed to various extended release formulations containing topiramate. The two issued U.S. patents will expire in 2027 and 2029, respectively. 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 two families of pending U.S. non-provisional and foreign counterpart patent applications relating to our SPN-810 product candidate. Patents, if issued, from the applications could have terms expiring from 2029 to 2031. 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.

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, or 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, or 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 where the USPTO erred in calculating the PTA for the patents in question 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.

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

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, or 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-812 product candidate and issuance of a U.S. patent covering SPN-812 based on a U.S. patent application in our portfolio, 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®," "ProScreen®," "OptiScreen®," "ProPhile®," "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. Litigation to enforce our own patent rights is subject to uncertainties that cannot be quantified in advance. In the case of 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 will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business."

In-Licensing Arrangements

Afecta Pharmaceuticals, Inc.

We have entered into two license agreements with Afecta Pharmaceuticals, Inc., or 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, or 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 based on the Rune product concept, 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 based on the Rune product concept, 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 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 tentatively approved products and product candidates, including Trokendi XR, must receive final approval from the FDA before they may be marketed legally in the United States.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or 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, or 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 manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practices, or cGMP; and
- FDA review and approval of the NDA.

The testing and approval process require 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.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. 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, or 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 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.

Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

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.

During the development of a new drug, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase III clinical

trial protocol design and analysis that will form the primary basis of an efficacy claim. An SPA is intended to provide assurance that if the agreed upon clinical trial protocol is followed, the clinical trial endpoints are achieved, and there is a favorable risk-benefit profile, the data may serve as the primary basis for an efficacy claim in support of an NDA. However, SPA agreements are not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. In particular, SPAs are not binding on the FDA if previously unrecognized public health concerns arise during the performance of the clinical trial, other new scientific concerns regarding the product candidate's safety or efficacy arise, or if the sponsoring company fails to comply with the agreed upon clinical trial protocol.

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.

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments, and 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. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, which was reauthorized under the Food and Drug Administration Safety and Innovation Act of 2012, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. 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 1 month to 6 years of age.

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.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also 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. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five year exclusivity period and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, 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.

We pursued a regulatory strategy pursuant to Section 505(b)(2) in connection with our NDA submissions for Oxtellar XR and Trokendi XR. In the NDA submissions for our other product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize their commercial opportunities.

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 is 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 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 restoration term 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 USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

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, or API, or active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or 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. However, the FDCA will not prevent the submission or approval of another 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, 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 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 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, 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 will be 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.

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, or 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, beginning in 2011, the new 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 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 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 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 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 February 28, 2013, we employed 193 full-time employees, up from 110 full-time employees as of December 31, 2012. Approximately 54 employees are engaged in research development activities and 139 are in administrative, business development and sales and marketing positions. We consider relations with our employees to be good. None of our employees are represented by a labor union.

ITEM 1A. RISK FACTORS

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 which may never be successfully commercialized.

To date, we have expended significant time, resources, and effort on the development of Oxtellar XR and Trokendi XR, and a substantial majority of our resources are now focused on the commercial launch in the United States of our approved product, Oxtellar XR, which commenced on February 4, 2013, and preparing for the commercial launch of our tentatively approved product, Trokendi XR, which we anticipate to occur in the third quarter of 2013. All of our other product candidates are in earlier stages of 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 commercialize Oxtellar XR and our ability to successfully obtain final marketing approval for and commercialize Trokendi XR. We may not sell Trokendi XR in the United States until the FDA grants final marketing approval and, therefore, our planned commercial launch of Trokendi XR in the United States could experience unanticipated delays or problems and may be prohibited altogether, notwithstanding its tentative approval by the FDA.

Our ability to successfully commercialize Oxtellar XR and Trokendi XR will depend on, among other things, our ability to:

- maintain commercial manufacturing arrangements with third-party manufacturers for Oxtellar XR and Trokendi XR;
- produce, through a validated process, sufficiently large quantities and inventory of our products to permit successful commercialization;
- build and maintain a wide variety of internal sales, distribution and marketing capabilities sufficient to build commercial sales of our products;
- establish collaborations with third parties for the commercialization of our products in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- secure widespread acceptance of our products from physicians, health care payors, patients and the medical community;
- properly price and obtain adequate coverage and reimbursement of the product by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements; and
- manage our growth and spending as costs and expenses increase due to commercialization.

There are no guarantees that we will be successful in completing these tasks. Successful commercialization will also depend on whether we can adequately protect against and effectively

respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective. If we are unable to successfully complete these tasks, we may not be able to commercialize Trokendi XR in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

In addition, we have begun, and will need to continue, investing substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in support of our commercial launch of Oxtellar XR and preparation for the commercial launch of Trokendi XR. We have committed and will commit these additional resources prior to obtaining final approval of Trokendi XR from the FDA. If we are unable to successfully obtain final FDA approval of Trokendi XR or complete these activities, or experience unanticipated delays or problems, our costs could substantially increase and our business, financial condition and results of operations will be adversely affected. In addition, we have certain revenue expectations with respect to the sale of Oxtellar XR and Trokendi XR. If we cannot successfully commercialize and achieve those revenue expectations with respect to Oxtellar XR and Trokendi XR, this would result in a material adverse impact on our anticipated revenues and liquidity.

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

Adoption of Oxtellar XR or Trokendi XR may be slow or limited for a variety of reasons including competing branded and generic therapies or safety issues. If either Oxtellar XR or Trokendi XR is not successful in gaining broad commercial acceptance, our business would be harmed.

The rate of adoption of Oxtellar XR and, if approved by the FDA, Trokendi XR will be dependent on several factors including our ability to educate and increase physician awareness of the benefits and cost-effectiveness of our products relative to competing therapies. The degree of market acceptance of any of our 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, if approved by the FDA, Trokendi XR will be subject to continual review by the FDA, and we cannot assure you that newly discovered or developed 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 have rapidly expanded our operations to support the commercial launch of Oxtellar XR and will continue to do so to support increased commercialization of Oxtellar XR and, if approved by the FDA, Trokendi XR, which has significantly increased our costs, and until we achieve economies of scale, we will incur negative margins on sales of Oxtellar XR and Trokendi XR.

We have and expect to continue to significantly increase our investment in commercial infrastructure. We will need to effectively manage the expansion of our operations and facilities and continue to grow our infrastructure to commercialize Oxtellar XR and, if approved by the FDA, Trokendi XR. We must effectively manage our supply chain and distribution network, all of which requires strict planning in order to meet production timelines. In addition to the 75 salespeople we hired to launch Oxtellar XR, we continue to add marketing and sales personnel, and personnel in all other areas of our operations, which strains our existing managerial, operational, financial and other resources. As a result of the scaling of our commercial operations, we expect to incur negative margins on any sales of Oxtellar XR and, if approved by the FDA, Trokendi XR until we are able to generate significant sales volume. We will also need to maintain our commercial manufacturing arrangements with third parties for any approved product to avoid the loss of revenue from potential sales of such product, and adversely impact its market acceptance. If we fail to manage the growth in our systems and personnel appropriately and successfully in order to achieve our commercialization plans for Oxtellar XR and Trokendi XR, our revenues could suffer and our business could be harmed.

We are dependent on the success of our product candidates, which may never receive regulatory approval or be successfully commercialized.

To date, we have expended significant time, resources, and effort on the development of our product candidates, and a substantial majority of our resources are now focused on the commercialization of Oxtellar XR, and planning for the commercialization of our tentatively approved product, Trokendi XR, in the United States. All of our other product candidates are in earlier stages of 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 commercialize Oxtellar XR and our ability to successfully obtain final marketing approval for and commercialize Trokendi XR. Trokendi XR has received tentative approval from the FDA and may never be commercialized until we receive final marketing approval from the FDA.

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

- 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 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;
- successfully complete our clinical trials; and
- manage our spending as costs and expenses increase due to commercialization and clinical trials.

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 Oxtellar XR, Trokendi XR or any of our other product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business. In addition, 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 have limited sales and marketing experience and resources, and 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 launch Oxtellar XR and, assuming receipt of final approval from the FDA, Trokendi XR. Additionally, there are plans to further expand our sales and marketing capabilities later this year. We have limited sales and marketing experience and have been building such capabilities by investing significant amounts of financial and management resources. We have committed and will commit additional resources to develop internal sales and marketing capabilities prior to any confirmation that Trokendi XR has received final approval from the FDA or any other of our product candidates have been approved by the FDA. We believe that net proceeds from the November 2012 stock offering, together with cash on hand, will be sufficient to fund the commercialization of Oxtellar XR, and complete development and fund the expected commercialization of Trokendi XR if approved by the FDA. We commenced the commercial launch of Oxtellar XR in February 2013 and anticipate the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA. If final FDA approval or the commercial launch of Trokendi XR is delayed for any reason, we could incur significant additional expenses prior to being able to realize any revenues. Further, we could face a number of additional risks in establishing internal sales and marketing capabilities, including:

- we may not be able to attract talented and qualified personnel to build an effective marketing or sales force capability;
- the cost of establishing a marketing and sales force capability may not be justifiable in light of the revenues generated by Oxtellar XR, Trokendi XR if it receives final approval, or any of our product candidates if approved by the FDA; and
- our direct sales and marketing efforts may not be successful.

If we are unable to establish adequate sales and marketing capabilities or are unable to do so in a timely manner, we may not be able to generate product revenues and may never become profitable.

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

Physicians may not prescribe Oxtellar XR, Trokendi XR, if approved by the FDA, or any of our product candidates if approved by the FDA, 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 generic products;
- the extent to which each product or product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- 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 stable patient's existing therapy (even for an NCE) and risk a breakthrough seizure or tolerability issues in their patients. Although Oxtellar XR and, if commercially launched, Trokendi XR, are not NCEs, they would be subject to the risk that they will not be able to gain significant market share against existing AEDs. 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 become or remain profitable on a timely basis, if at all.

Final marketing approval of Trokendi XR, or 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.

With respect to Trokendi XR, we submitted an NDA under Section 505(b)(2) of the FDCA, which allows us to rely in our submissions on the existing data from the NDA of Topamax. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments, and 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 or clinical trials demonstrating safety and effectiveness. The FDA could refuse to approve our current NDA submission, or require additional information to sufficiently demonstrate safety and effectiveness. For example, we initially submitted an NDA for Trokendi XR in January 2011, but the FDA refused to file the NDA and raised questions relating to chemistry and manufacturing control issues. Although, the FDA accepted the NDA for filing in November 2011, it granted only tentative approval for Trokendi XR in June 2012 citing the need for inclusion on the product's label of certain pediatric safety information of the reference listed drug Topamax, which is the subject of marketing exclusivity until June 2013. There can be no assurance that the FDA will grant final approval of our NDA when this marketing exclusivity expires or at any time thereafter.

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

- could determine that we cannot rely on 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 for Trokendi XR, or any of our other product candidates, 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 the API used in our product candidates;
- 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)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from

approving any Section 505(b)(2) application that we submit. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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 and, ultimately, 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 potential products liability claims. Any undesirable side effects that are caused by any of our product candidates could have a material adverse effect upon that product candidate's development program and 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 dizziness, paresthesia, headaches, cognitive deficiencies such as memory loss and speech impediment, digestive problems, somnolence, double vision, gingival enlargement, nausea, weight gain, 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 the product candidate, 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 risks of such side effects for distribution to patients;
- 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, especially if an extended or controlled release topiramate anti-epileptic drug is approved before Trokendi XR receives final approval, our business would be materially harmed.

Other third parties may seek approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate anti-epileptic drugs in the United States. If any of these parties obtain FDA approval of an extended release topiramate product before we do, they may be entitled to three years of marketing exclusivity. Such exclusivity would, for example, delay the commercialization of Trokendi XR and, as a result, we may never achieve significant market share for this tentatively approved product. Consequently, revenues from product sales of these products would be similarly delayed and our business, including our development programs, and growth prospects would suffer. For example, we are aware that Upsher-Smith's USL255 (extended release topiramate) is in Phase III clinical development for the treatment of epilepsy in adults and its NDA may have been filed or is being prepared for filing. If Upsher-Smith's USL255 product is approved by the FDA before Trokendi XR, then Upsher-Smith may obtain three years of marketing exclusivity based on its Phase III clinical trial, which would significantly delay our entry into the U.S. market. Even if Trokendi XR is approved before USL255, we may not be entitled to any marketing exclusivity and, other than under circumstances in which third parties may infringe or are infringing our patents, we may not be able to prevent the submission or approval of another full NDA for any competitor's extended or controlled release topiramate product candidate, including USL255. 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 active API, or active moiety, which is the molecule responsible for the action of the drug substance. Although protection under the Hatch-Waxman Amendments will not prevent the submission or approval of another full Section 505(b)(1) NDA, such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. While the FDA granted a three year marketing exclusivity period for Oxtellar XR, the FDA has not yet determined whether it will grant marketing exclusivity for Trokendi XR and we cannot assure you that we will receive any such marketing exclusivity from the FDA for Trokendi XR or any of our product candidates. If we are unable to obtain marketing exclusivity for our products or 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 testing 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, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- 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 imposed by the FDA.

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, an IRB 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. For instance, the efficacy demonstrated by SPN-810 in its most recent Phase IIb study was not statistically significant for all efficacy measures for the study. Additionally, 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 institutional review boards or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If we experience delays in completion of, or if we terminate any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues will be diminished.

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 competing products will limit the demand 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. We anticipate that we will face intense competition when our product candidates are approved by regulatory authorities and we begin the commercialization process for our products. For instance, there are over 15 branded products, as well as their generic counterparts, on the U.S. market indicated to treat epilepsy. In addition, several NCEs have entered the epilepsy market including Potiga, Vimpat and Banzel. Another NCE, Stedesa, could be approved later in 2013 and enter the market thereafter. In addition, competition in the ADHD market in the United States 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. As a result, we may not be able to recover expenses incurred in connection with the development of our product candidates or realize revenues from any commercialized product.

In addition to already marketed competing products, we believe certain companies are developing other products which could compete with our product candidates should they be approved by regulatory authorities. For example, according to Datamonitor, as of April 2010, there were 47 compounds in preclinical and clinical development for epilepsy across the United States, Japan, France, Germany, Italy, Spain and the United Kingdom. Datamonitor reported that approximately 13 were in late-stage (Phase II or later) clinical trials as of June 2011. We are also aware that Upsher-Smith's USL255 (extended release topiramate) is in Phase III clinical development for the treatment of epilepsy in adults and its NDA may have been filed or is being prepared for filing. If successful, such competing product could limit the potential success of Trokendi XR, and our growth prospects would be materially impaired. In addition, we are aware of companies who are marketing outside of the United States modified-release oxcarbazepine products, such as Apydan, which is developed by Desitin Arzneimittel GmbH and requires twice-daily administration. We are also aware that Qsymia, an oral drug containing ER topiramate and another API, is available in extended release for treatment of weight management. If companies with modified-release oxcarbazepine products outside of the United States obtain approval for their products within the United States, then such competing products may limit the potential success of Oxtellar XR. 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 if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially 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 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; or
- seize or detain products or require us to initiate a product recall.

In addition, our product labeling, advertising and promotion of our approved product, and our tentatively approved product 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 improperly 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.

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 obtain FDA approval and market our products and product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our bioequivalence and/or clinical trials, increase the costs associated with conducting our bioequivalence

and/or clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial.

Manufacturers of pharmaceutical products need to comply with cGMP requirements enforced by the FDA through their facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. 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 candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our product candidates.

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

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

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 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 will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell their approved products and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we 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, Trokendi XR or any of our product

candidates, which could prevent us from being able to commercialize 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
- 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 the following matters related to Paragraph IV Certification Notice Letters that we have received in connection with 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.

- *Sanctura XR Litigation.* We are involved in a patent infringement matter filed in response to three Paragraph IV Certification Notice Letters that we received in June 2009, November 2009 and April 2010 regarding an ANDA submitted to the FDA by each of Watson Laboratories, Inc., Sandoz Inc. and Paddock Laboratories, Inc., respectively, requesting approval to market and sell generic versions of Sanctura XR trospium chloride extended release capsules, a product that is manufactured and sold by Allergan, Inc., which is the marketing partner of Endo

Pharmaceuticals Solutions Inc. The ANDA filers alleged in their respective original notice letters that U.S. Patent Number 7,410,978 issued to us is invalid, unenforceable and/or will not be infringed by the respective company's manufacture, use or sale of the product described in its ANDA submission. Our patent covers extended-release formulations containing trospium chloride and expires on February 1, 2025, and is licensed to Endo Pharmaceuticals Solutions Inc. Each of the ANDA filers subsequently amended their respective notice letters to include other U.S. patents related to Sanctura XR trospium chloride (specifically, U.S. Patent Nos. 7,759,359; 7,763,635; 7,781,448; and 7,781,449). In March 2012, the court ruled that the defendants' proposed products infringe the patents-in-suit and that the patents-in-suit are invalid. Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. filed an appeal, and the Federal Circuit heard argument on June 14, 2012. The Federal Circuit issued a Rule 36 summary affirmance of the District Court's decision that the patents were invalid on June 18, 2012. Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. filed a petition for writ of certiorari on September 17, 2012, which was denied by the U.S. Supreme Court on October 15, 2012, thereby declining to disturb the earlier judicial finding that the patents are invalid. We do not expect the resulting entry of competitive generic products to have a material adverse effect on our current business.

- *Oracea Litigation.* We are involved in a patent infringement case filed in the District of Delaware in response to Paragraph IV Certification Notice Letters that we received in September 2011 and September 2012 regarding an ANDA submitted to the FDA by Amneal Pharmaceuticals LLC, requesting approval to market and sell generic versions of Oracea (30 mg immediate release, 10 mg delayed release doxycycline), a product that is manufactured and sold by Galderma Laboratories, L.P. Amneal alleged its notice letters that U.S. Patent Nos. 7,749,532, or the '532 patent, and 8,206,740, or the '740 patent, which are both assigned to us, are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product described in its ANDA. In addition, in October 2010, we received a complaint for declaratory judgment from Mylan Pharmaceuticals Inc., or Mylan, alleging invalidity of the '532 patent. This case was tried in July 2011 in the District of Delaware. The district court held that Mylan infringed certain claims of the patent, and that the patent claims are valid. This district court decision is currently being appealed by Mylan; Lupin Limited and Lupin Pharmaceuticals, Inc.; and Impax Laboratories, Inc. to the U.S. Court of Appeals for the Federal Circuit. The '532 patent and the '740 patent cover once-daily formulations of doxycycline, including their methods use in treating rosacea and processes regarding their preparation. Both patents expire on December 19, 2027 and are licensed to Galderma Laboratories, L.P. We intend to support Galderma Laboratories, L.P. in these matters. We do not expect an adverse decision in the foregoing matters will have a material adverse effect on our current business.

- *Intuniv Litigation.* We are involved in several patent infringement actions in district courts throughout the United States, which were filed in response to Paragraph IV Certification Notice Letters that we received in March, April and October 2010, and February, March and October 2011, regarding ANDAs submitted to the FDA requesting approval to market and sell generic versions of Intuniv, a product that is manufactured and sold by Shire LLC. The defendants in these cases are Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd; Actavis Elizabeth LLC and Actavis, Inc.; Watson Pharmaceuticals, Inc., Watson Laboratories, Inc.—Florida Watson Pharma, Inc. and ANDA, Inc.; Impax Laboratories, Inc.; Sandoz Inc. and Mylan Pharmaceuticals Inc. and Mylan Inc. The ANDA filers allege that our U.S. Patent Nos. 6,287,599 and 6,811,794 are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product described in its ANDA submissions. A bench trial was held on September 17-20, 2012 in the District of Delaware in the case against defendants Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd.; Actavis Elizabeth LLC; and Actavis, Inc. No decision has yet been issued by the district court in that case. Prior to the trial in the District of Delaware, Shire LLC settled all claims against defendants Anchen

Pharmaceutical, Inc., Anchen Inc. and TWi Pharmaceuticals, Inc. in connection with TWi's ANDA for a generic version of Intuniv. Our patents cover extended-release formulations containing guanfacine hydrochloride, with the latest patent expiration in July 2022. Both of these patents are licensed to Shire LLC. We intend to support Shire LLC in its efforts to contest this matter. We do not expect an adverse decision in the foregoing matter will have a material adverse effect on our current business.

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. 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, 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 to use one of our proprietary technologies for an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of PAH, as well as for other indications. This oral formulation was the subject of an NDA for PAH submitted by United Therapeutics and accepted for filing by the FDA in February 2012. On October 23, 2012, United Therapeutics received a complete response letter from the FDA declining to approve the product. Accordingly, we do not expect to receive any royalties for this formulation in this indication unless and until final marketing approval from the FDA is received and until United Therapeutics launches this product. We are entitled to receive milestones and royalties for use of this formulation in other indications. If we materially breach any of our obligations under the license agreement, however, we could lose the potential to receive any future royalty payments thereunder, which could be financially significant to us.

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;
- may 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;
- may 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;
- may not have sufficient resources necessary to carry the product candidate through clinical development, marketing approval and commercialization;
- may fail to comply with applicable regulatory requirements;
- may not be able to obtain the necessary marketing approvals; or
- may 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 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 expect to rely on third-party suppliers and manufacturers for the final commercial products. If any of these vendors is unable to perform its 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 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. Our current arrangements impose various development, royalty and other obligations on us. If we materially breach these obligations or if Afecta or Rune fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which would result in our inability to develop, manufacture and sell products that are covered by such intellectual property.

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

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 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. 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. 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 12 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.

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.

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

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

- decreased demand for any product 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;
- 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 any of our 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. We have expanded our insurance coverage to include the sale of commercial products prior to the commercialization of our products. 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 and adversely affect our business.

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 are pursuing various therapeutic opportunities through our pipeline. 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 amortization expenses;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

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

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant 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 candidate 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.

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.

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.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We will need to manage our anticipated growth and increased operational activity. Our personnel, systems and facilities currently in place may not be adequate to support this future growth. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth. Our need to effectively execute our growth strategy requires that we:

- manage our regulatory approvals and clinical trials effectively;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities;
- commercialize our product candidates;
- improve our operational, financial and management controls, reporting systems and procedures; and
- attract and motivate sufficient numbers of talented employees.

This future 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. 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.

We may not be able to manage our business effectively if we are unable to attract, motivate and retain key members of our current 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. We do not have any employment agreements with any member of our senior management team except Mr. Khattar. 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.

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 fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which 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 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.

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.

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.

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

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

was to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

We 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 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.

Risks Related to Our Finances and Capital Requirements

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

In recent years, we have focused primarily on developing our current products and product candidates, with the goal of commercializing these products and supporting regulatory approval for these product candidates. We have financed our operations primarily through private placements of convertible preferred stock, our collaboration and license arrangements, the monetization of certain future royalty streams under our existing licenses for 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 and the completion of our initial public offering in May 2012 and a follow-on offering in November 2012. We have incurred significant operating losses since our inception in 2005. We incurred net losses of approximately $33.5 million, $38.5 million and $46.3 million in the years ended December 31, 2008, 2010 and 2012, respectively. We realized net income of approximately $0.5 million and $53.8 million in the years ended December 31, 2009 and 2011, respectively, due to one-time items. As of December 31, 2012, we had an accumulated deficit of approximately $86.3 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs and from selling, general and administrative costs associated with our operations. For example, the expenses that we have incurred relating to the research and development of Oxtellar XR and Trokendi XR from inception to December 31, 2012 are approximately $53.3 million and $32.5 million, respectively. 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 to incur significant and increasing marketing and selling costs prior to and during the commercial launch of our current products. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when, or if, we will become profitable.

Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect 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 and increasing operating losses for the foreseeable future. In this regard, the report of our independent registered public accounting firm with respect to our consolidated financial statements as of and for the period ended December 31, 2012 contains an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. While we believe that the proceeds of the follow-on offering, together with our cash, cash equivalents and marketable securities and anticipated future product revenues will be sufficient to fund the commercialization of Oxtellar XR and, if we receive final approval by the FDA, Trokendi XR, there can be no assurance that we will be able to obtain the additional capital that we anticipate needing in order to become cash flow positive. In addition, we may need to obtain additional funds to develop and commercialize our other product candidates. The inclusion of a going concern statement by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

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. Although we believe the proceeds of the November 2012 public offering, together with our cash, cash equivalents and marketable securities and anticipated future product revenues, will be sufficient to allow us to fund the commercialization of Oxtellar XR, and, assuming receipt of FDA approval, Trokendi XR, we will need to obtain additional capital through equity offerings, debt financing, payments under new or existing licensing and research and development collaboration agreements, or any combination thereof, in order to become cash flow positive and to develop and commercialize additional product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

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

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

- the rate of progress 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;

- our ability to successfully launch our products and to continue to increase the level of sales in the marketplace;
- the actions of our competitors and their success in selling competitive product offerings;
- the costs of establishing sales, marketing, manufacturing and distribution capabilities for our products; 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 have never recognized any revenues from our own sales of our products, and we may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate revenues from sales of our products and our product candidates. To date, we have not recognized any significant revenues from our own sales of our products or product candidates and have incurred significant operating losses. 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 Oracea, Sanctura XR and Intuniv licensed products. In May 2009, in exchange for a one-time, lump-sum payment, we licensed all of our rights for Intuniv to an affiliate of Shire plc on a royalty-free, fully paid-up basis. In addition, in connection with our sale of all of our equity interests in Royalty Sub in December 2011, the purchaser acquired all of our license rights to Sanctura XR and Oracea. Accordingly, we no longer generate any revenues from those products.

Our ability to generate product revenues is dependent on our ability to successfully commercialize Oxtellar XR, and, if approved, Trokendi XR. Our ability to successfully commercialize our products depends on, among other things:

- generating revenue from the sale of Oxtellar XR;
- our obtaining final regulatory approval of Trokendi XR; and
- our manufacturing of commercial quantities of our approved products, including Oxtellar XR, at acceptable cost levels.

After our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercialization. It is possible that we will never have sufficient product sales revenues to achieve profitability.

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 the timing, market acceptance of our products, and amount of development milestones and royalty revenues received under our collaboration license agreements.

Once we commercialize one or more of our products, our net loss and other operating results will be affected by numerous factors, including:

- 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 future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- any intellectual property infringement lawsuit in which we may become involved;
- our ability to establish 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;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- the achievement and timing of milestone payments under our existing collaboration and license agreements; and
- the level of market acceptance for any approved product candidates and underlying demand for that product and wholesalers' buying patterns.

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.

Prior to May 1, 2012 we operated as a private company and therefore, have limited experience operating as a public company and complying with public company obligations. Complying with these requirements has increased our costs and requires additional management resources, and we still 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 costs, particularly after we are no longer an "emerging growth company." The Securities Exchange Act of 1934, as amended, or 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 other personnel 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 will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify 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 you that our internal controls over financial reporting will prove to be effective.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports 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 that 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 recently enacted 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. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls 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 net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the transactions contemplated by the recent follow-on offering in November 2012.

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

In addition, it is possible that the follow-on offering that occurred in November 2012, either on a standalone basis or when combined with future transactions, including issuances of new shares of our common stock, will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses

prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 and those attributes already subject to limitations as a result of our prior ownership changes may be subject to more stringent limitations. As of December 31, 2012, we had approximately $80.8 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of approximately $4.6 million available to offset future taxable income. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2025, if not utilized. In 2011, we completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception. Due to the significant costs and complexities associated with such study, we have not updated this study in 2012. Accordingly, our ability to utilize the aforementioned carryforwards and tax credits may be limited. As a result, we may not be able to take full advantage of these carryforwards or tax credits for federal and state tax purposes.

Risks Related to Our Indebtedness

Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.

In January 2011, we entered into a secured credit facility pursuant to a loan and security agreement among Oxford Finance Corporation, as collateral agent and lender, and Compass Horizon Funding Company LLC, as lender, which was subsequently amended in December 2011, and promissory notes issued in favor of each lender, providing for term loans of up to an aggregate of $30.0 million. On January 26, 2011, we drew down our initial $15.0 million of term loans under our secured credit facility and on December 30, 2011 we drew down the second $15.0 million. All obligations under our secured credit facility are secured by substantially all of our existing property and assets (excluding our intellectual property) and by a pledge of the capital stock of, subject to certain exceptions, our U.K. subsidiary and any future subsidiary. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- we will need to repay our debt by making payments of interest and principal, including a final payment of $750,000 representing 2.5% of the aggregate principal amount of the term loans borrowed under our secured credit facility, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities;
- we may have difficulty obtaining financing in the future for working capital, capital expenditures, acquisitions or other purposes;
- our failure to comply with the restrictive covenants in our loan and security agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the lenders could seek to enforce their security interests in the assets securing such indebtedness; and
- we will be charged a prepayment premium of 2.0% if we prepay the debt within 15 months after the respective amortization dates of the term loans, and a prepayment premium of 1.0% if such prepayment is made thereafter.

To the extent additional debt is added to our current debt levels, the risks described above would increase.

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

Since our inception in 2005, we have generated no revenue from product sales and have incurred significant operating losses. As of December 31, 2012, we had an accumulated deficit of $86.3 million. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to develop and seek marketing approval for our product candidates. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our secured credit facility. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations would be significantly limited, and we may be required to delay, significantly curtail or eliminate one or more of our programs.

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

We are subject to a number of restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.

Our secured credit facility imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit our ability and the ability of our U.K. subsidiary and any future subsidiary to, among other things:

- dispose of certain assets;
- change our lines of business;
- engage in mergers or consolidations;
- incur additional indebtedness;
- create liens on assets, including our intellectual property;
- pay dividends and make distributions on or repurchase our capital stock; and
- engage in certain transactions with affiliates.

Our secured credit facility also includes certain customary representations and warranties and affirmative covenants. Our failure to comply with the restrictions contained in our secured credit facility, if not cured by us or waived by our lenders, could result in an event of default. All obligations under our secured credit facility are secured by substantially all of our existing property and assets (excluding our intellectual property) and by a pledge of the capital stock of, subject to certain exceptions, our U.K. subsidiary and any future subsidiary. In the event of a default under our secured credit facility, our lenders could take various actions, including the acceleration of all amounts due under our secured credit facility and all actions permitted to be taken by a secured creditor, which could have a material adverse effect on our business or prospects.

In certain circumstances we could be required to pay damages if we fail to perform our obligations under the license agreements related to Sanctura XR and Oracea.

In December 2011, we sold 100% of our equity ownership interests in Royalty Sub. In accordance with the terms of the sale, we retained certain duties and obligations under two licensing agreements related to Sanctura XR and Oracea. If we fail to perform the continuing duties and obligations under these licensing agreements, we may be required to indemnify the purchaser of Royalty Sub for damages arising due to such failure. For example, pursuant to these agreements, we have an obligation to use commercially reasonable efforts to preserve, maintain, and maximize the commercial value of our licensed patents covering Sanctura XR and Oracea, which includes the obligation to pay patent office maintenance fees in order to keep these patents in force. If we fail to pay such patent office maintenance fees, these patents may expire and Royalty Sub's royalty stream from such patents may terminate. In such a scenario, we may be called upon to pay damages to the purchaser of Royalty Sub due to the loss of patent licensing revenue that Royalty Sub would have received from the sale of Sanctura XR and Oracea.

Risks Related to Securities Markets and Investment in Our Stock

Future sales of our common stock may depress our stock price.

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 have outstanding 30,621,869 shares of common stock as of December 31, 2012, of which approximately 15,916,256 shares are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act of 1933, as amended. In addition, as of December 31, 2012, we had outstanding options to purchase 569,911 shares of common stock and warrants to purchase 42,083 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. A large portion of these shares and options are held by a small number of persons and investment funds. Moreover, certain holders of shares of common stock will have rights, subject to some conditions, that require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

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 2,341,875 and 213,273 shares of our common stock are reserved for future issuance under the 2012 Equity Incentive Plan and the 2012 Employee Stock Purchase Plan, respectively. These shares may now be freely sold in the public market upon issuance. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock.

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 would 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.

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 78.8% of our outstanding common stock. As a result, these stockholders are collectively able to significantly influence or control 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 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 Company will allow us to maintain an active trading market on The NASDAQ Global Market or otherwise or how liquid that market might become. If an active public market is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you, 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, 2012, we had options to purchase 569,911 shares of common stock outstanding, with exercise prices ranging from $0.40 to $12.92 per share and a weighted average exercise price of $5.72 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. You will also experience dilution if we issue additional shares of common stock under the warrants that we issued to our lenders. As of December 31, 2012, 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 previously traded publicly for only a short time. 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;
- 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;
- variations in our quarterly operating results;
- changes in accounting principles;
- litigation or public concern about the safety of our potential products;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- additions or departures of key personnel;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- any third-party coverage and reimbursement policies for our 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.

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, 2018 with an option for a five-year extension. In January 2013, we signed a lease for approximately 11,900 square feet of office space in an adjacent building located at 1500 East Gude Drive, Rockville, MD 20850 with a co-terminus lease term date of April 30, 2018. We believe that these facilities are sufficient for our present operations.

ITEM 3. LEGAL PROCEEDINGS

We were involved in a patent infringement matter filed in response to three Paragraph IV Certification Notice Letters that we received in June 2009, November 2009 and April 2010 regarding an ANDA submitted to the FDA by each of Watson Laboratories, Inc., Sandoz Inc. and Paddock Laboratories, Inc., respectively, requesting approval to market and sell generic versions of Sanctura XR trospium chloride extended release capsules, a product that is manufactured and sold by Allergan, Inc., which is the marketing partner of Endo Pharmaceuticals Solutions Inc. In March 2012, the court ruled that the defendants' proposed products infringe the patents-in-suit and that the patents-in-suit are invalid. Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. filed an appeal, and the Federal Circuit heard argument on June 14, 2012. The Federal Circuit issued a Rule 36 summary affirmance of the District Court's decision that the patents were invalid on June 18, 2012. Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. filed a petition for writ of certiorari on September 17, 2012, which was denied by the U.S. Supreme Court on October 15, 2012, thereby declining to disturb the earlier judicial finding that the patents are invalid.

From time to time and in the ordinary course of business, we are subject to various claims, charges and litigation. For example, we may be required to file infringement claims against third parties for the infringement of our patents. For additional information regarding the patent litigation matters in which

we are involved, please see "Risk Factors-We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful."

Although the outcome of litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us, we do not believe the outcome of any such litigation, individually or in the aggregate, will have a material adverse effect on our financial condition, results of operations or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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
Second Quarter 2012 (from May 1, 2012)	$15.20	$4.30
Third Quarter	$16.68	$8.70
Fourth Quarter	$14.98	$6.75

On December 31, 2012, the closing price of our common stock on The NASDAQ Global Market was $7.17 per share. As of December 31, 2012, we had 41 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. Additionally, our ability to pay dividends on our common stock is limited by restrictions on the ability of our subsidiary and us to pay dividends or make distributions, including restrictions under the terms of the agreements governing our indebtedness. For additional information, see "Management's Discussion and Analysis of Financial Condition and Results of 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.

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 Form 10-K. The consolidated financial data as of December 31, 2011 and 2012 and for the fiscal years ended December 31, 2010, 2011 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 this selected consolidated financial data in conjunction with the sections entitled "Capitalization" and "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.

	Year Ended December 31,		
	2010	2011	2012
	(in thousands, except share and per share date)		
Consolidated Statement of Operations Data:			
Revenues	$ 106	$ 803	$ 1,480
Operating Expenses:			
Research and development	35,149	30,627	23,517
Selling, general and administrative	5,080	7,928	20,132
Total operating expenses	40,229	38,555	43,649
Operating loss from continuing operations	(40,123)	(37,752)	(42,169)
Other income (expense):			
Interest income	107	31	120
Interest expense	—	(1,866)	(3,575)
Other	542	117	(660)
Loss from continuing operations before income taxes	(39,474)	(39,470)	(46,284)
Income tax benefit	399	16,245	—
Loss from continuing operations	(39,075)	(23,225)	(46,284)
Discontinued operations:			
Income from discontinued operations, net of tax	612	2,188	—
Gain on disposal of discontinued operations, net of tax	—	74,852	—
Income from discontinued operations	612	77,040	—
Net (loss) income	(38,463)	53,815	(46,284)
Cumulative dividends on Series A convertible preferred stock	(3,430)	(3,430)	(1,143)
Net (loss) income attributable to common stockholders	$ (41,893)	$ 50,385	$ (47,427)
(Loss) Income per common share:			
Basic and diluted			
Continuing operations	$ (26.77)	$ (16.60)	$ (2.72)
Discontinued operations	0.39	47.99	—
Net (loss) income	$ (26.38)	$ 31.39	$ (2.72)
Weighted average number of common shares:			
Basic and diluted	1,587,968	1,605,324	17,440,910

	Year Ended December 31,		
	2010	2011	2012
		(in thousands)	
Consolidated Balance Sheet Data:			
Unrestricted cash and cash equivalents and marketable securities	$ 32,704	$ 48,544	$ 88,508
Restricted cash and cash equivalents and marketable securities	1,714	245	279
Working capital	24,607	30,629	68,758
Total assets	47,009	53,730	93,989
Notes payable, including current portion	—	29,486	22,897
Non-current liabilities of discontinued operations	75,000	—	—
Accumulated deficit	(93,786)	(39,971)	(86,255)
Total stockholders' equity (deficit)	(44,320)	9,443	57,570

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, or CNS diseases. Our two lead products are Oxtellar XR and Trokendi XR both of which are neurology products for the treatment of epilepsy. The Food & Drug Administration, or FDA, granted final approval for Oxtellar XR (extended-release oxcarbazepine) on October 19, 2012 and we launched this product commercially on February 4, 2013. Additionally, on November 15, 2012, the FDA granted Oxtellar XR a three-year marketing exclusivity period. We may be able to report revenue from prescriptions which are sold in the first quarter in the Quarterly Report on Form 10-Q that we will file for the quarter ended June 30, 2013.

Trokendi XR (extended-release topiramate) received tentative approval from the FDA on June 25, 2012 and may not receive final approval until after the expiry of marketing exclusivity associated with safety information of Topamax's NDA in a specific pediatric population. In early December, 2012, the Company submitted to the FDA a request for final approval as an amendment to the NDA including a safety data update, a new package insert and packaging configurations for Trokendi XR and was informed that should the FDA approve such amendment, it will most likely be in the form of a tentative approval because the review period of such amendment would be expected to conclude in the second quarter prior to the June 22, 2013 expiration of the pediatric exclusivity. The Company continues to expect getting the final approval and commercially launching Trokendi XR in the third quarter of 2013.

We intend to market both products through our in-house sales force. We hired approximately 75 sales representatives for the commercial launch of Oxtellar XR and we may expand this sales force to over 100 sales representatives over the next six months to support the launch of Trokendi XR later this year.

In addition to our two lead products, we have a product pipeline with several lead product candidates. SPN-810 (molindone hydrochloride) is being developed as a treatment for impulsive aggression in patients with ADHD and completed a Phase IIb trial that showed positive topline results. We expect to advance this program into later stage clinical development after we meet with the FDA. Our plans for SPN-810 involve a continued, in-depth analysis of the full dataset from the Phase IIb trial along with plans to meet with the FDA to discuss the next steps in the development program and the design and protocol for Phase III clinical trials.

SPN-812 is being developed as a non-stimulant treatment for ADHD. SPN-812 completed a Phase IIa proof on concept trial in 2011 and we are currently focused on developing an extended release formulation that will be the subject of a future Phase IIb trial.

Critical Accounting Policies and Use of Estimates

The significant accounting policies and basis of presentation for our consolidated financial statements are described in Note 3 "Summary of Significant Accounting Policies". The preparation of our financial statements in accordance with U.S. generally accepted accounting principles requires (GAAP) us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, 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. We carry inventories at the lower of cost or market using the first-in, first-out method. Although at December 31, 2012 inventory is 100% raw materials, in the future inventory values will include materials, labor, overhead and other direct and indirect costs. Inventory is evaluated for impairment through consideration of factors such as lower of cost or market, net realizable value, expiry and obsolescence. Our inventories have values that do 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 the market research we used to project future demand and based on anticipated product dating.

We capitalize inventories produced in preparation for commercial launches when it becomes probable the related product candidates will receive regulatory approval and the related costs will be recoverable through the commercial sale of the product. Accordingly, we began to capitalize inventories for Trokendi following the June 25, 2012 tentative approval from the FDA and for Oxtellar XR following the October 19, 2012 final approval from the FDA. Prior to capitalization, the costs of manufacturing drug product is recognized in research and development expense in the period the cost is incurred. Therefore, manufacturing costs incurred prior to capitalization are included in research and development; such costs incurred after capitalization are included in cost of sales.

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

Revenue Recognition—Product Sales. We anticipate recognizing revenue from product sales during 2013. Revenue from product sales will be 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 and all performance obligations have been met and returns can be reasonably estimated. Product sales are recorded net of accruals for estimated rebates, chargebacks, discounts, co-pay assistance and other accruals (collectively, "sales deductions") as well as estimated product returns.

Our products will be 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 the pharmacies. Though these distributors will be invoiced concurrent with the product shipment, we will be unable to recognize revenue upon shipment until such time as we can reasonably estimate and record accruals for sales deductions and product returns

utilizing historical information and market research projections. Specific consideration for sales of both Oxtellar XR and Trokendi XR are:

- *Rebates.* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program as well as negotiated discounts with commercial health-care providers. Rebates are amounts owed after the final dispensing of the products to a benefit plan participant and are based upon contractual agreements or legal requirements with the public sector (e.g. Medicaid) and private sector benefit providers. The allowance for rebates is based on statutory and contractual discount rates and expected utilization. Our estimates for expected utilization of rebates are based in part on third party market research. Rebates are generally invoiced and paid quarterly in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.
- *Chargebacks.* Chargebacks are discounts that occur when contracted customers purchase directly from an intermediary distributor or wholesaler. Contracted customers, which currently consist primarily of Public Health Service institutions and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The distributor or wholesaler, in turn, charges back the difference between the price initially paid by the distributor or wholesaler and the discounted price paid to the distributor or wholesaler by the customer. The allowance for distributor/wholesaler chargebacks is based on known sales to contracted customers.
- *Distributor/Wholesaler deductions.* U.S. specialty distributor and wholesalers are offered various forms of consideration including allowances, service fees and prompt payment discounts. Distributor allowances and service fees arise from contractual agreements with distributors and are generally a percentage of the purchase price paid by the distributors and wholesalers. Wholesale customers are offered a prompt pay discount for payment within a specified period.
- *Co-pay assistance.* Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance from the Company. Liabilities for co-pay assistance will be based on actual program participation and estimates of program redemption using data provided by third-party administrators.
- *Returns.* Sales of our products are not subject to a general right of return; however, the Company will accept product that is damaged or defective when shipped directly from our warehouse or for expired product up to 12 months subsequent to its expiry date. Product that has been used to fill patient prescriptions is no longer subject to any right of return.

Although we have not recognized any revenue to date for sales of our own products, we anticipate doing so in 2013 and each of these rebates, chargebacks and other discounts will have an effect on the timing and amount of revenue recognized in any period.

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; 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;

stock-based compensation expense; and costs associated with non-clinical activities and regulatory approvals.

Stock-Based Compensation

Employee stock-based compensation is measured based on the estimated fair value 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. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures. The Company has awarded non-vested stock. Prior to the Company's IPO the estimated fair value of these awards was determined at the date of grant based upon the estimated fair value of the Company's common stock. Subsequent to the Company's IPO, the fair value of the common stock is based on observable market prices.

For stock option grants and non-vested stock subject to performance-based milestone vesting, the Company records the expense over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the applicable reporting date.

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.

Results of Operations

Comparison of the Year Ended December 31, 2011 and December 31, 2012

	Year Ended December 31,		Increase/ (decrease)
	2011	2012	
	(in thousands)		
Revenues:			
Development and milestone revenues	$ 803	$ 1,480	667
Total revenues	803	1,480	
Operating Expenses:			
Research and development	30,627	23,517	(7,110)
Selling, general and administrative	7,928	20,132	12,204
Total operating expenses	38,555	43,649	
Operating loss from continuing operations	(37,752)	(42,169)	
Interest income and other income (expense), net	148	(540)	(688)
Interest expense	(1,866)	(3,575)	1,709
Total other expense	(1,718)	(4,115)	
Loss from continuing operations before income taxes	(39,470)	(46,284)	
Income tax benefit	16,245	—	(16,245)
Loss from continuing operations	(23,225)	(46,284)	
Discontinued operations:			
Income from discontinued operations, net of tax	2,188	—	2,188
Gain on disposal of discontinued operations, net of tax	74,852	—	74,852
Income from discontinued operations	77,040	—	
Net income (loss)	$ 53,815	$(46,284)	

Revenues

Our revenues were approximately $1.5 million for the year ended December 31, 2012 compared to $0.8 million for the same period in 2011, representing an increase of $0.7 million. This increase is primarily attributable to one-time milestone payments of $1.1 million as well as the recognition of previously deferred up-front license payments of $0.4 million received under our license agreements with Stendhal in 2012.

Research and Development Expense

Our research and development expenses were $23.5 million for the year ended December 31, 2012, compared to $30.6 million for the same period in 2011, a decrease of $7.1 million or 23%. This decrease was primarily attributable to a decrease in clinical trial costs for Oxtellar XR of approximately $6.5 million and approximately $2.2 million for Trokendi XR, offset by increases in manufacturing and validation costs and general expenses.

Selling, General and Administrative Expense

Our selling, general and administrative expenses were $20.1 million for the year ended December 31, 2012 compared to $7.9 million for the same period in 2011, representing an increase of approximately $12.2 million or approximately 154%. This increase is mainly due to an increase in sales and marketing costs, associated with preparing for commercial launches of Oxtellar XR, which occurred in February

2013, and Trokendi XR, which is anticipated to occur, subject to obtaining final marketing approval, expected to occur during the third quarter of 2013, respectively.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net was an expense of approximately $0.5 million for the year ended December 31, 2012 compared to income of approximately $0.1 million for the same period in 2011, representing a change of $0.7 million. The change is primarily the result of the change in fair value of the derivative warrant liability during the year ended December 31, 2012 as compared to the year ended December 31, 2011.

Interest Expense

Interest expense was approximately $3.6 million for the year ended December 31, 2012, compared to $1.9 million for the same period in 2011. This increase is primarily due to the drawdown of the second $15.0 million under our secured credit facility in December 2011, resulting in this additional amount of indebtedness being outstanding and accruing interest throughout 2012.

Loss from continuing operations

Loss from continuing operations was $46.3 million for the year ended December 31, 2012, compared to a loss of $39.5 million for the same period in 2011. This increase is primarily due to the increase in interest expense and sales and marketing costs offset by the decrease in clinical trial costs.

Income from discontinued operations

Income from discontinued operations was $77.0 million for the year ended December 31, 2011. There were no activities related to discontinued operations in 2012 from the sale of TCD Royalty Sub, LLC in December 2011.

Comparison of the Year Ended December 31, 2011 and the Year Ended December 31, 2010

	Year Ended December 31,		Increase/ (decrease)
	2010	2011	
		(in thousands)	
Revenues:			
Development and milestone revenues	$ 106	$ 803	$ 697
Total revenues	106	803	
Operating Expenses:			
Research and development	35,149	30,627	(4,522)
Selling, general and administrative	5,080	7,928	2,848
Total operating expenses	40,229	38,555	
Operating loss from continuing operations	(40,123)	(37,752)	
Interest income and other income (expense), net	649	148	(501)
Interest expense	—	(1,866)	(1,866)
Loss from continuing operations before income taxes	(39,474)	(39,470)	
Income tax benefit	399	16,245	15,846
Loss from continuing operations	(39,075)	(23,225)	
Discontinued operations:			
Income from discontinued operations, net of tax	612	2,188	1,576
Gain on disposal of discontinued operations, net of tax	—	74,852	74,852
Income from discontinued operations	612	77,040	
Net income (loss)	$(38,463)	$ 53,815	

Revenues

Our revenues were approximately $0.8 million for the year ended December 31, 2011 compared to approximately $0.1 million for the same period in 2010, representing an increase of $0.7 million. This increase was principally attributable to a one-time milestone payment of $0.8 in 2011 under our license agreement with United Therapeutics.

Research and Development

Our research and development expenses were $30.6 million for the year ended December 31, 2011 compared to $35.1 million for the same period in 2010, representing a decrease of approximately $4.5 million or approximately 13%. This decrease was attributable to a decrease in clinical trial costs of approximately $4.8 million as the Phase III trial for Oxtellar XR was substantially completed by the first quarter of 2011.

Selling, General and Administrative

Our selling, general and administrative expenses were $7.9 million for the year ended December 31, 2011 compared to $5.1 million for the same period in 2010, representing an increase of approximately $2.8 million or approximately 56%. This increase was mainly due to an increase in marketing costs during the year ended December 31, 2011 associated with preparing for commercial launches of Oxtellar XR and Trokendi XR in 2013.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net was $0.1 million for the year ended December 31, 2011 compared to $0.6 million for the same period in 2010, representing a decrease of $0.5 million. The decrease was primarily the result of a federal grant credit received in 2010 under the federal Qualifying Therapeutic Discovery Project Program, which was created in March 2010 as part of the Patient Protection and Affordability Care Act of 2010.

Interest Expense

Interest expense was $1.9 million for the year ended December 31, 2011 which primarily consisted of interest expense associated with our secured credit facility, together with the amortization of the associated deferred financing costs and the debt discount arising from the allocation of fair value to the preferred stock warrants issued in connection with our term loans. There was no interest expense from continuing operations for the year ended December 31, 2010.

Loss from continuing operations

Loss from continuing operations was $23.2 million for the year ended December 31, 2011 compared to a loss of $39.1 million for the same period in 2010. This decrease was primarily due to the income tax benefit to continuing operations of $16.2 million in 2011 generated from the sale of TCD.

Income from discontinued operations

Income from discontinued operations was $77.0 million for the year ended December 31, 2011 compared to $0.6 million for the same period in 2010, representing an increase of approximately $76.4 million. This increase was due to a gain on sale of TCD Royalty Sub of approximately $74.9 million, net of taxes, calculated as the aggregate of the fair value of consideration of $27.0 million and the carrying value of Royalty Sub's assets and liabilities, less its fees and expenses. Additionally, in 2011, we realized increased royalty revenues of approximately $1.0 million from Oracea and Sanctura XR for the year ended December 31, 2011. For additional details on our discontinued operations, refer to Note 10 to our consolidated financial statements.

Liquidity and Capital Resources

Our working capital at December 31, 2012 was $68.8 million, an increase of $38.2 million compared to our working capital of $30.6 million at December 31, 2011. Our working capital increased in 2012 as a result of the net proceeds of $47.6 million from our May 2012 Initial Public Offering and net proceeds of $46.6 million from the sale of common stock in our follow-on offering in November 2012. These increases were offset by the use of cash reserves to fund our operating expenses as we continued our clinical development programs and increased our sales, marketing and manufacturing activities in preparation for the commercial launches of Oxtellar XR and Trokendi XR in 2013.

We expect to continue to incur significant sales and marketing expenses in 2013 related to the launches of Oxtellar XR and of Trokendi XR, assuming receipt of final marketing approval. In addition, we expect to incur substantial expenses related to our research and development efforts, primarily related to preclinical activities and our development efforts for SPN-810 and SPN-812.

The Company's current operating assumptions, which reflect management's best estimate of future revenue and operating expenses, indicate that current cash on hand, including the cash proceeds received from the common stock offerings in 2012, should be sufficient to fund operations as currently planned into the fourth quarter of 2013. The Company will need to raise additional capital through either a public offering of its common stock, a private placement offering of equity securities, issuance of a debt instrument, or any combination thereof, to fund deficits in operating cash flows and continue

its business operations as currently planned. However, there can be no assurance that such financing will be available to the Company at any given time or available on favorable terms. The type, timing, and terms of financing selected by the Company will be dependent upon the Company's cash needs, the availability of financing sources, and the prevailing conditions in the financial markets.

In the event the Company does not gain access to additional funding, the Company will likely revise its commercial plans for Oxtellar XR and Trokendi XR, its planned clinical trials, other development activities, capital expenditure plans, and the scale of its operations, until it is able to obtain sufficient financing to do so, or pursue other alternatives. If the Company is required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs, these events could have a material adverse effect on the Company's business, results of operations and financial condition.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2012 (except as noted below):

Contractual Obligations	Less than 1 Year	1 - 3 Years	3 - 5 Years	Greater than 5 Years	Total
			($ in thousands)		
Secured Credit Facility(1)	$11,809	$11,416	$ —	$ —	$23,225
Interest on Secured Credit Facility(1)	1,971	1,392	—	—	3,363
Operating leases(2)	966	1,989	2,070	354	5,379
Purchase obligations(3)	3,410	—	—	—	3,410
Total(4)	$18,156	$14,797	$2,070	$354	$35,377

(1) Annual interest expense is currently $2.0 million on $23.2 million of principal outstanding currently.

(2) Our commitments for operating leases relate to our lease of copiers and office and laboratory space as of December 31, 2012.

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

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

We have obtained exclusive licenses from third parties for proprietary rights to support the product candidates in our psychiatry portfolio. Under license agreements with Afecta, we have an exclusive option to evaluate Afecta's CNS pipeline and to obtain exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. We do not owe any future milestone payments for SPN-810. We will also 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. 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

There were no off-balance sheet arrangements during the year ended December 31, 2012 that have or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to our interest.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-04, *Fair Value Measurement (Topic 820)* (ASU 2011-04), which contains amendments to achieve common fair value measurement and disclosures in U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 explains how to measure fair value for financial reporting. The guidance does not require fair value measurements in addition to those already required or permitted by other Topics. The provisions of ASU 2011-04 became effective January 1, 2012. The adoption of ASU 2011-04 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity.

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 and, 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.

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 and cash equivalents. As of December 31, 2012, we had unrestricted cash, cash equivalents, and marketable securities of $88.5 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, 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 foreign currency or other derivative financial instruments.

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 currencies. 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 increased our net loss by approximately $559,000 for year ended December 31, 2012. Conversely, a hypothetical 10% depreciation in Euro exchange rates against the U.S. dollar from prevailing market rates would have decreased our net loss by approximately $559,000 for the year ended December 31, 2012. We do not believe that inflation and changing prices over the years ended December 31, 2010 2011 and 2012 had a significant impact on our consolidated results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Supernus Pharmaceuticals, Inc.
Consolidated Financial Statements
Years ended December 31, 2010, 2011 and 2012

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, 2011 and 2012, and the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012. 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, 2011 and 2012, and the consolidated results of its operations and its cash flows for the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that Supernus Pharmaceuticals, Inc. will continue as a going concern. As more fully described in Note 2, the Company has incurred recurring operating losses and negative cash flows from operations and will require additional capital to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The 2012 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

McLean, Virginia
March 15, 2013

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	December 31, 2011	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 48,544	$ 40,302
Marketable securities	—	48,206
Marketable securities—restricted	245	279
Accounts receivable	—	11
Interest receivable	—	664
Inventory	—	1,152
Prepaid expenses and other	466	983
Deferred financing costs, current	144	144
Total current assets	49,399	91,741
Property and equipment, net	1,310	1,421
Purchased patents, net	912	683
Other assets	55	55
Deferred financing costs, long-term	2,054	89
Total assets	$ 53,730	$ 93,989
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 11,763	$ 10,666
Deferred revenue	232	508
Secured notes payable, net of discount	6,775	11,809
Total current liabilities	18,770	22,983
Deferred revenue, net of current portion	465	309
Secured notes payable, net of current portion and discount	22,711	11,088
Other non-current liabilities	1,399	1,509
Supplemental executive retirement plan	245	279
Warrant liability	697	251
Total liabilities	44,287	36,419
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value—49,625,000 and 65,000,000 shares authorized at December 31, 2011 and 2012, respectively; 49,000,000 and zero shares issued and outstanding at December 31, 2011 and 2012 and respectively; aggregate liquidation preference of $69,520 and zero at December 31, 2011 and 2012, respectively	49	—
Common stock, $0.001 par value—62,625,000 and 130,000,000 shares authorized at December 31, 2011 and 2012, respectively; 1,662,321 and 30,621,869 shares issued and outstanding at December 31, 2011 and 2012, respectively	2	31
Additional paid-in capital	49,362	143,851
Accumulated other comprehensive income (loss)	1	(57)
Accumulated deficit	(39,971)	(86,255)
Total stockholders' equity	9,443	57,570
Total liabilities and stockholders' equity	$ 53,730	$ 93,989

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,		
	2010	2011	2012
Revenues	$ 106	$ 803	$ 1,480
Costs and expenses			
Research and development	35,149	30,627	23,517
Selling, general and administrative	5,080	7,928	20,132
Total costs and expenses	40,229	38,555	43,649
Operating loss from continuing operations	(40,123)	(37,752)	(42,169)
Other income (expense):			
Interest income	107	31	120
Interest expense	—	(1,866)	(3,575)
Other income (expense)	542	117	(660)
Total other income (expense)	649	(1,718)	(4,115)
Loss from continuing operations before income tax benefit	(39,474)	(39,470)	(46,284)
Income tax benefit	399	16,245	—
Loss from continuing operations	(39,075)	(23,225)	(46,284)
Discontinued Operations:			
Income from discontinued operations, net of tax	612	2,188	—
Gain on disposal of discontinued operations, net of tax	—	74,852	—
Income from discontinued operations	612	77,040	—
Net (loss) income	(38,463)	53,815	(46,284)
Cumulative dividends on Series A convertible preferred stock	(3,430)	(3,430)	(1,143)
Net (loss) income attributable to common stockholders	$ (41,893)	$ 50,385	$ (47,427)
Net (loss) income per common share:			
Basic and diluted			
Continuing operations	$ (26.77)	$ (16.60)	$ (2.72)
Discontinued operations	0.39	47.99	—
Net (loss) income	$ (26.38)	$ 31.39	$ (2.72)
Weighted-average number of common shares:			
Basic and diluted	1,587,968	1,605,324	17,440,910

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Income (Loss)

(in thousands)

	Year Ended December 31,		
	2010	2011	2012
Net (loss) income	$(38,463)	$53,815	$(46,284)
Other comprehensive (loss) income:			
Unrealized net (loss) gain on marketable securities	(2)	1	(58)
Other comprehensive (loss) income	(2)	1	(58)
Comprehensive (loss) income	$(38,465)	$53,816	$(46,342)

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(in thousands, except share data)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
					(in thousands)			
Balance, December 31, 2009	49,000,000	$ 49	1,584,012	$ 2	$ 49,114	$ 2	$(55,323)	$ (6,156)
Exercise of stock options	—	—	8,750	—	4	—	—	4
Stock-based compensation	—	—	—	—	297	—	—	297
Net loss	—	—	—	—	—	—	(38,463)	(38,463)
Other comprehensive income (loss)	—	—	—	—	—	(2)	—	(2)
Balance, December 31, 2010	49,000,000	49	1,592,762	2	49,415	—	(93,786)	(44,320)
Exercise of stock options	—	—	69,559	—	29	—	—	29
Stockbased compensation	—	—	—	—	(82)	—	—	(82)
Net income	—	—	—	—	—	—	53,815	53,815
Other comprehensive income (loss)	—	—	—	—	—	1	—	1
Balance, December 31, 2011	49,000,000	49	1,662,321	2	49,362	1	(39,971)	9,443
Stock-based compensation	—	—	—	—	443	—	—	443
Issuance of Employee Stock Purchase Plan shares	—	—	36,727	—	223	—	—	223
Exercise of stock options	—	—	159,264	—	265	—	—	265
Warrant Exercise	—	—	64,309	—	1,156	—	—	1,156
Issuance of common stock, net of underwriters' discount and offering costs	—	—	16,449,250	17	92,365	—	—	92,382
Conversion of preferred stock to common stock	(49,000,000)	(49)	12,249,998	12	37	—	—	—
Net loss	—	—	—	—	—	—	(46,284)	(46,284)
Other comprehensive income (loss)	—	—	—	—	—	(58)	—	(58)
Balance, December, 31, 2012	—	$ —	30,621,869	$31	$143,851	$(57)	$(86,255)	$ 57,570

See accompanying notes.

Supernus Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2010	2011	2012
Operating activities			
Net (loss) income	$(38,463)	$ 53,815	$(46,284)
Income from discontinued operations	(612)	(77,040)	—
Loss from continuing operations	(39,075)	(23,225)	(46,284)
Adjustments to reconcile (loss) income from continuing operations to net cash used in operating activities:			
Gain on sale of property and equipment	(54)	(25)	—
Change in fair value of warrant liability	—	85	710
Unrealized loss (gain) on marketable securities	(2)	1	(57)
Depreciation and amortization	1,188	879	871
Income tax benefit	(399)	(16,245)	—
Amortization of deferred financing costs and debt discount	—	218	330
Stock-based compensation expense	297	(82)	443
Changes in operating assets and liabilities:			
Accounts receivable	284	44	(11)
Interest receivable	220	114	(664)
Inventory	—	—	(1,152)
Prepaid expenses and other assets	74	(247)	(516)
Accounts payable, accrued expenses, and supplemental executive retirement plan	5,211	(959)	(1,098)
Deferred revenue	—	697	120
Other non-current liabilities	64	539	109
Net cash used in operating activities from continuing operations	(32,192)	(38,206)	(47,199)
Net cash (used in) provided by operating activities from discontinued operations	(352)	2,021	—
Net cash used in operating activities	(32,544)	(36,185)	(47,199)
Cash flows from investing activities			
Purchases of marketable securities	(32,781)	(17,890)	(97,674)
Sales and maturities of marketable securities	58,898	26,870	49,468
Purchases of property and equipment, net	(294)	(685)	(753)
Net cash provided by (used in) investing activities from continuing operations	25,823	8,295	(48,959)
Net cash provided by disposal/sale of discontinued operations	—	25,607	—
Net cash provided by (used in) investing activities	25,823	33,902	(48,959)
Cash flows from financing activities			
Proceeds from issuance of common stock	4	29	100,735
Proceeds from issuance of secured notes payable	—	30,000	—
Repayments of secured notes payable	—	—	(6,775)
Financing costs and underwriters discounts	(1,345)	(975)	(6,044)
Net cash (used in) provided by financing activities from continuing operations	(1,341)	29,054	87,916
Net cash provided by (used in) financing activities from discontinued operations	397	(1,967)	—
Net cash (used in) provided by financing activities	(944)	27,087	87,916
Net change in cash and cash equivalents	(7,665)	24,804	(8,242)
Cash and cash equivalents at beginning of year	31,405	23,740	48,544
Cash and cash equivalents at end of year	$ 23,740	$ 48,544	$ 40,302
Supplemental cash flow information:			
Cash paid for interest-Continuing operations	$ —	$ 1,412	$ 2,938
Noncash financial activity:			
Conversion of preferred stock	$ —	$ —	$ 49
Issuance of warrants	$ —	$ 612	$ —
Exercise of warrants	$ —	$ —	$ 1,156

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

Years ended December 31, 2010, 2011 and 2012

1. Organization and Nature of Operations

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

The Company is currently focused on the commercialization of Oxtellar XR (formerly known as SPN-804) and the anticipated commercialization of Trokendi XR (formerly known as SPN-538). Oxtellar XR received final approval from the Food and Drug Administration (FDA) on October 19, 2012 and the Company began the commercial launch of this product on February 4, 2013. Accordingly, the Company had not yet generated any revenues from product sales through December 31, 2012. In addition, Trokendi XR received tentative approval from the FDA on June 25, 2012. Except for profits earned in 2009 and 2011 due to non-recurring transactions, the Company has incurred net losses from operations since its inception. The Company had net (loss) income of approximately $(38.5) million, $53.8 million, and $(46.3) million during the years ended December 31, 2010, 2011 and 2012, respectively. The net income in 2011 was primarily due to a gain on the sale of TCD Royalty Sub LLC (TCD) of approximately $74.9 million, net of taxes, being reported as discontinued operations (see Note 10). The Company has financed its operations primarily through the sale of equity securities, issuance of debt instruments, and amounts received under its royalty and development agreements. Management expects operating losses to continue for the foreseeable future until one or more of its products are established in the marketplace. The Company will need to obtain additional capital through equity offerings, debt financings and/or payments under new or existing licensing and research and development collaboration agreements (see Note 2).

The Company's operations are subject to certain risks and uncertainties. The risks include the success of our product launches, receipt of final FDA approval for Trokendi XR, negative outcome of clinical trials, inability or delay in completing clinical trials or obtaining regulatory approvals, changing market conditions for products being developed by the Company, more stringent regulatory environment, the need to retain key personnel and protect intellectual property, product liability, and the availability of additional capital financing on terms acceptable to the Company.

2. Management's Plans as to Continuing as a Going Concern

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company needs to raise additional capital to continue its business operations as currently planned and to fund deficits in operating cash flows.

As described more fully in Note 9, the Company drew down $30.0 million under a secured credit facility (the Facility) during 2011. There is no remaining borrowing capacity under the Facility. As described in Note 10, during 2011, the Company sold all of its equity interest in its wholly-owned subsidiary, TCD, for consideration consisting of a cash receipt of $27.0 million and contingent consideration of $3.0 million to be received in the future if certain criteria are met. As described in Note 11, during 2012 the Company completed an initial public offering, raising approximately

2. Management's Plans as to Continuing as a Going Concern (Continued)

$47.6 million, net of expenses and a follow-on common stock offering raising approximately $46.6 million, net of expenses. The Company funded operations during 2012 principally through the use of proceeds from the 2011 draws under the Facility, cash received from the sale of TCD, and proceeds received from the public offerings of its common stock.

The Company's current operating assumptions, which reflect management's best estimate of future revenue and operating expenses, indicate that current cash on hand, including the cash proceeds received from the common stock offerings in 2012, should be sufficient to fund operations as currently planned into the fourth quarter of 2013. The Company will need to raise additional capital through either a public offering of its common stock, a private placement offering of equity securities, issuance of a debt instrument, or any combination thereof, to fund deficits in operating cash flows and continue its business operations as currently planned. However, there can be no assurance that such financing will be available to the Company at any given time or available on favorable terms. The type, timing, and terms of financing selected by the Company will be dependent upon the Company's cash needs, the availability of financing sources, and the prevailing conditions in the financial markets.

In the event the Company does not gain access to additional funding, the Company will likely revise its commercial plans for Oxtellar XR and Trokendi XR, planned clinical trials, other development activities, capital expenditure plans, and the scale of its operations, until it is able to obtain sufficient financing to resume planned operations or pursue other alternatives. If the Company is required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs, these events could have a material adverse effect on the Company's business, results of operations and financial condition. There can be no assurance that the Company will be able to adjust the scale of its operations and reduce its operating cash needs to allow operations to continue until additional financing can be secured.

These factors could significantly limit the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

3. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements include the accounts of Supernus Pharmaceuticals, Inc. and Supernus Europe Ltd., and included the accounts of TCD, its wholly-owned subsidiary, through December 14, 2011, the date that the Company sold 100% of its equity interests in TCD. These are collectively referred to herein as "Supernus" or "the Company." All significant intercompany transactions and balances have been eliminated in consolidation. The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP). The Company currently operates in one business segment.

The assets and liabilities related to TCD have identifiable cash flows that are largely independent of the cash flows of other groups of assets and liabilities, and the Company does not have significant continuing involvement with the related products. Accordingly, the remaining assets and liabilities, and

3. Summary of Significant Accounting Policies (Continued)

the results of operations, related to TCD are presented as discontinued operations for all periods in the accompanying consolidated financial statements. Accrued compensation and interest payable of approximately $1.5 million and $0.1 million, respectively, as of December 31, 2011 previously classified in our consolidated balance sheet as separate line items have been reclassified and included within "accounts payable and accrued expenses" to conform to current period presentation.

Reverse Stock Split

All share and per share amounts have been retroactively adjusted to give effect to a one-for-four reverse stock split of the Company's common stock effected on April 9, 2012.

Use of Estimates

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

Cash and Cash Equivalents

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

Marketable Securities

Marketable securities may consist of investments in U.S. Treasuries, various U.S. governmental agency debt securities, corporate bonds and other fixed income securities. Management classifies the Company's investments as available-for-sale. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive income, which is a separate component of stockholders' equity. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income is recognized as interest income when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with highly rated government or private sector financial institutions whose debt is rated as investment grade.

3. Summary of Significant Accounting Policies (Continued)

Marketable Securities—Restricted

The Company has established the Supernus Supplemental Executive Retirement Plan (SERP) for the sole purpose of receiving funds for two executives from a previous SERP and providing a continuing deferral program under the Supernus SERP. As of December 31, 2011 and December 31, 2012, the estimated fair value of the mutual fund investment securities within the SERP of approximately $245,000 and $279,000 respectively, has been recorded as restricted marketable securities. A corresponding noncurrent liability is also included in the consolidated balance sheets to reflect the Company's obligation for the SERP. The Company has not made, and has no plans to make, contributions to the SERP. The securities can only be used for purposes of paying benefits under the SERP.

Accounts Receivable

Accounts receivable are reported in the consolidated balance sheets at outstanding amounts, less an allowance for doubtful accounts if necessary. The Company extends credit without requiring collateral. The Company writes off uncollectible receivables when the likelihood of collection is remote. The Company evaluates the collectability of accounts receivable on a regular basis. An allowance, when needed, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts, and economic factors or events expected to affect future collections experience. No allowance was recorded as of December 31, 2011 or 2012.

Concentration of Credit Risk

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

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

Fair Value of Financial Instruments

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

The Company reports assets and liabilities that are measured at fair value using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of

3. Summary of Significant Accounting Policies (Continued)

observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2—Inputs are quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).
- Level 3—Unobservable inputs that reflect the Company's own assumptions, based on the best information available, including the Company's own data.

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

		Fair Value Measurements at December 31, 2011		
	Total Carrying Value at December 31, 2011	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$48,544	$48,544	$ —	$ —
Marketable securities-restricted	245	—	245	—
Total assets at fair value	$48,789	$48,544	$245	$ —
Liabilities:				
Warrant liability	$ 697	$ —	$ —	$697

3. Summary of Significant Accounting Policies (Continued)

	Total Carrying Value at December 31, 2012	Fair Value Measurements at December 31, 2012		
		Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$40,302	$31,561	$ 8,741	$ —
Marketable securities	48,206	—	48,206	—
Marketable securities—restricted	279	—	279	—
Total assets at fair value	$88,787	$31,561	$57,226	$ —
Liabilities:				
Warrant liability	$ 251	$ —	$ —	$251

The Company's Level 1 assets include money market funds and U.S. Treasuries and government agency debt securities with quoted prices in active markets. At December 31, 2012, Level 2 assets include mutual funds in which the SERP assets are invested, commercial paper, and corporate bonds and other fixed income securities. Level 2 securities are valued using third-party pricing sources that apply applicable inputs and other relevant data into their models to estimate fair value.

Level 3 liabilities include the fair market value of outstanding warrants to purchase Common Stock recorded as a derivative liability. Prior to the IPO on May 1, 2012, these warrants provided the right to purchase the Company's Series A convertible preferred stock (Series A Preferred Stock) that were converted to the right to purchase Common Stock upon the completion of the IPO. Prior to completion of the IPO, the fair value of the preferred stock warrant liability was calculated using a probability-weighted expected return model (PWERM). Subsequent to completion of the IPO, the fair value of the common stock warrant liability was calculated using a Monte-Carlo simulation on a Black-Scholes model with the following assumptions:

Exercise Price	$4 - $5 per share
Volatility	80%
Stock Price as of December 31, 2012	$7.17 per share
Term	8.1 - 9.0 years
Dividend Yield	0.0%
Risk-Free Rate	1.6% - 1.8%

Significant changes to these assumptions would result in increases/decreases to the fair value of the outstanding warrants.

3. Summary of Significant Accounting Policies (Continued)

Changes in the fair value of the warrants are recognized as Other income (expense) in the Consolidated Statements of Operations. The following table presents information about the Company's common stock warrant liability as of December 31, 2010, 2011 and 2012, in thousands:

	Year Ended December 31, 2011 and 2012
Balance at December 31, 2010	$ —
Issuance of Series A Preferred Stock warrants(1)	612
Changes in fair value of warrants included in earnings	85
Balance at December 31, 2011	697
Exercise of warrants (credited to paid in capital)	(1,156)
Changes in fair value of warrants included in earnings	710
Balance at December 31, 2012	$ 251

(1) Upon consummation of the Company's Initial Public Offering, the warrants to purchase Series A Preferred Stock were converted to warrants to purchase common stock.

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

Inventory

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

Inventory is evaluated for impairment through consideration of factors such as the net realizable value, lower of cost or market, obsolescence, and expiry. Inventories do not have carrying values that exceed either cost or net realizable value.

Property and Equipment

Property and equipment are stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

3. Summary of Significant Accounting Policies (Continued)

Depreciation and amortization are computed using the straight-line method over the following average useful lives:

Computer equipment	3 years
Software	3 years
Lab and office equipment	5 - 10 years
Furniture	7 years
Leasehold improvements	Shorter of lease term or useful life

Intangible Assets

Intangible assets consist primarily of purchased patents. Patents are carried at cost less accumulated amortization, which is calculated on a straight-line basis over the estimated useful lives of the patents, generally estimated to be ten years. The carrying value of the patents is assessed for impairment annually during the fourth quarter of each year, or more frequently if impairment indicators exist. There were no indicators of impairment identified at December 31, 2011 or 2012.

Deferred Financing Costs

Deferred financing costs consist of financing syndication costs incurred by the Company in connection with the sale of non-recourse notes issued by TCD (see Note 9), financing costs incurred by the Company in connection with the closing of the Company's term loans (see Note 9) and legal, accounting and other costs incurred in connection with preparing for the Company's stock offerings. The Company amortized deferred financing costs associated with the non-recourse notes until December 14, 2011, at which time the non-recourse notes were assumed by the purchaser of TCD (see Note 10). The Company amortizes deferred financing costs associated with term loans over the term of the related debt using the effective interest method. Upon completion of its IPO and upon completion of the follow-on offering, the Company reclassified all previously deferred financing costs related to the offerings as a charge against proceeds received.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of purchased patents and property and equipment. The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. Evaluating for impairment requires judgment, including the estimation of future cash flows, future growth rates and profitability and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of the long-lived assets over its estimated fair value. For the years ended December 31, 2011 and 2012, the Company determined that there was no impairment of the Company's long-lived assets.

3. Summary of Significant Accounting Policies (Continued)

Preclinical Study and Clinical Trial Accruals and Deferred Advance Payments

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

Income Taxes

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

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

Revenue Recognition

The Company's revenues have been generated through collaboration and research and development agreements. These agreements include fees for development services provided to customers, payments for achievement of specified development, regulatory and sales milestones, and to a lesser extent, upfront license payments, which comprise the Company's development and milestone revenue, as well as royalties on product sales of licensed products, Oracea, Sanctura XR, and Intuniv, which comprise the Company's royalty revenue. Royalty revenue related to these products are included as a component of discontinued operations in the consolidated statement of operations in the years ended December 31, 2010 and 2011. There were no royalties received from continuing operations in any of years ended December 31, 2010, 2011, or 2012. The Company records any amounts received in advance of services performed as deferred revenue and recognizes the amount as revenue ratably over the period it is earned.

3. Summary of Significant Accounting Policies (Continued)

Multiple Element Arrangements

For arrangements entered into with multiple elements, the Company evaluates whether the components of each arrangement are separate elements based on certain criteria. Accordingly, revenues from collaboration agreements are recognized based on the performance requirements of the agreements. The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed and determinable, and collection is reasonably assured.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and the Company has no further significant performance obligations in exchange for the license.

As of January 1, 2011, the Company adopted Accounting Standard Update (ASU) No. 2009-13, *Revenue Recognition (Topic 605)—Multiple-Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force* (ASU No. 2009-13) which was codified in ASC 605-25. ASU No. 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available; third-party evidence, if VSOE is unavailable; and estimated selling prices if neither VSOE or third-party evidence is available. In addition, ASU No. 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. The adoption of ASU No. 2009-13 did not impact the Company's consolidated financial statements, as the Company did not enter into or modify any multiple element arrangements during 2011. The Company evaluates new or materially modified multiple element arrangements pursuant to the guidance in ASC 605-25.

Product Sales

The Company will record revenue from product sales 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 can be reasonably estimated. Product sales are recorded net of accruals for estimated rebates, chargebacks, discounts, co-pay assistance and other accruals (collectively, "sales deductions") and returns.

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

3. Summary of Significant Accounting Policies (Continued)

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

- *Chargebacks.* Chargebacks are discounts that occur when contracted customers purchase directly from an intermediary distributor or wholesaler. Contracted customers, which currently consist primarily of Public Health Service institutions and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The distributor or wholesaler, in turn, charges back the difference between the price initially paid by the distributor or wholesaler and the discounted price paid to the distributor or wholesaler by the customer. The allowance for distributor/wholesaler chargebacks is based on known sales to contracted customers.
- *Distributor/Wholesaler deductions and discounts.* U.S. specialty distributors and wholesalers are offered various forms of consideration including allowances, service fees and prompt payment discounts. Distributor allowances and service fees arise from contractual agreements with distributors and are generally a percentage of the purchase price paid by the distributors and wholesalers. Wholesale customers are offered a prompt pay discount for payment within a specified period.
- *Co-pay assistance.* Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. Liabilities for co-pay assistance will be based on actual program participation and estimates of program redemption using data provided by third-party administrators.
- *Returns.* Sales of our products are not subject to a general right of return; however, the Company will accept product that is damaged or defective when shipped directly from our warehouse or for expired product up to 12 months subsequent to its expiry date. Product that has been used to fill patient prescriptions is no longer subject to any right of return.

Our products will be distributed through wholesalers and specialty distributors. Each of these distributors will take title to and ownership of the product upon physical receipt of the product and distribute these products to pharmacies. Until there is sufficient history of product sales, the Company cannot make a reasonable estimate of either future product returns, expected rebates and chargebacks, or expected sales deductions from the eventual sale of these products to healthcare providers. Therefore, the Company will not record revenue based upon the shipment of product to the distributors, even though the distributors are invoiced upon product shipment. Instead, the Company will recognize revenue at the time the prescription of our product is filled and delivered to the patient end-user until such time as it can reasonably estimate expected sales deductions and returns, at which time the Company will begin to recognize revenue at the time of shipment of product to the distributors.

On February 4, 2013, the Company launched Oxtellar XR, its first commercial product. We anticipate the launch of Trokendi XR to occur during the third quarter of 2013, pending receipt of final approval from the FDA.

3. Summary of Significant Accounting Policies (Continued)

Milestone Payments

Milestone payments have been recognized as revenue when the collaborative partner acknowledges completion of the milestone and substantive effort was necessary to achieve the milestone. On January 1, 2011, the Company adopted ASU No. 2010-17, Revenue Recognition-Milestone Method (ASU No. 2010-17) which was codified in ASC 605-28. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive effort on the Company's part is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and,
- a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and amortized over the appropriate period. The adoption of ASU No. 2010-17 did not have a material impact on the Company's consolidated results of operations, financial position, or liquidity.

The Company's recorded milestone revenues were approximately, $0.0, $0.8 million, and $1.1 million during the years ended December 31, 2010, 2011 and 2012, respectively. During the years ended December 31, 2011 and 2012, after the adoption of ASU No. 2010-17, the Company recorded revenues upon achievement of the milestone, as the Company concluded that the milestone was substantive in accordance with its accounting policy.

Research and Development Costs

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

3. Summary of Significant Accounting Policies (Continued)

stock-based compensation expense; and costs associated with non-clinical activities and regulatory approvals.

Stock-Based Compensation

Employee stock-based compensation is measured based on the estimated fair value 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. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures. The Company has awarded non-vested stock. Prior to the Company's IPO the estimated fair value of these awards was determined at the date of grant based upon the estimated fair value of the Company's common stock. Subsequent to the Company's IPO, the fair value of the common stock is based on observable market prices.

For stock option grants and non-vested stock subject to performance-based milestone vesting, the Company records the expense over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the applicable reporting date.

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 changes in the fair value of the Company's common stock.

Warrant Liability

In January 2011, the Company entered into a secured credit facility pursuant to a loan and security agreement with certain lenders, which was subsequently amended in December 2011, providing for term loans of up to an aggregate of $30.0 million. In connection with the drawdown of $15.0 million under the secured credit facility on January 26, 2011, the Company issued to its lenders warrants to purchase an aggregate of 375,000 shares of the Company's Series A Preferred Stock at an exercise price of $1.00 per share. The warrants became exercisable immediately and expire on January 26, 2021. Upon completion of the Company's IPO on May 1, 2012, the lender warrants converted into warrants to purchase 93,750 shares of Common Stock at an exercise price of $4.00 per share. These warrants are recorded as a derivative liability and, as such, the Company reflects the warrant liability at fair value in the consolidated balance sheets. The fair value of this derivative liability is re-measured at the end of every reporting period and the change in fair value is reported in the consolidated statements of operations as other income (expense). On October 5, 2012, a holder exercised warrants to purchase an aggregate of 75,000 shares of common stock via a cashless net share settlement election in accordance with the terms of the agreement, pursuant to which we issued the warrant holder 49,137 shares of common stock. As of December 31, 2011 and December 31, 2012, the fair value of the outstanding warrants was estimated to be approximately $460,000 and $114,000, respectively. The change in fair value of approximately $85,000 and $506,000 has been recorded in other income (expense) in the

3. Summary of Significant Accounting Policies (Continued)

Company's consolidated statements of operations for the year ended December 31, 2011 and 2012, respectively.

In connection with the drawdown of the second $15.0 million under the secured credit facility on December 30, 2011, the Company issued to its lenders warrants to purchase an aggregate of 200,000 shares of the Company's Series A Preferred Stock at an exercise price of $1.50 per share. The warrants became exercisable immediately and expire on December 30, 2021. Upon completion of the Company's IPO on May 1, 2012, the warrants converted into warrants to purchase 49,999 shares of Common Stock at an exercise price of $5.00 per share. These warrants are recorded as a derivative liability and, as such, the Company reflects the warrant liability at fair value in the consolidated balance sheets. The fair value of this derivative liability is re-measured at the end of every reporting period and the change in fair value is reported in the consolidated statements of operations as other income (expense). On October 5, 2012, a holder exercised warrants to purchase an aggregate of 26,667 shares of common stock via a cashless net share settlement election in accordance with the terms of the agreement, pursuant to which we issued the warrant holder 15,172 shares of common stock. As of December 31, 2011 and 2012, the fair value of the outstanding warrants was estimated to be approximately $237,000 and $137,000, respectively. The change in fair value of approximately $204,000 has been recorded in other income (expense) in the Company's consolidated statements of operations for the year ended December 31, 2012.

The terms of the warrant agreements provide for "down-round" anti-dilution adjustment for the warrants in certain situations whereby the Company sells or issues (a) shares at a price per share less than the exercise price of the warrants, or (b) equity-linked financial instruments with strike prices less than the exercise price of the warrants. As a result of this "down round" provision, the warrants continue to be classified as derivative liabilities.

Subsequent to the completion of its IPO, which occurred on May 1, 2012, the fair value of the Common Stock warrants is determined using a Black-Scholes model within a Monte-Carlo framework. The Monte-Carlo simulation is a generally accepted statistical method used to estimate fair value based on the application of subjective assumptions, consistently applied for each period, including the probability, timing and magnitude of the Company's issuance of additional common stock in future financings or raising capital via debt issuance. This valuation is computed at the end of each fiscal quarter to reflect conditions at each valuation date until the warrants are exercised or they expire. In addition to assumptions regarding future equity financings, consideration is also given to the current stock price, anticipated stock volatility going forward, and the anti-dilution provisions embedded in the warrant agreements.

Earnings (Loss) Per Share

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

3. Summary of Significant Accounting Policies (Continued)

of the Company's Series A Preferred Stock. The following common stock equivalents were excluded in the calculation of diluted earnings (loss) per share because their effect would be anti-dilutive as applied to the loss from continuing operations as of December 31, 2010, 2011 and 2012:

	Year Ended December 31,		
	2010	2011	2012
Series A Preferred Stock	12,249,998	12,249,998	4,049,863
Warrants to purchase Series A Preferred Stock/ Common Stock	—	143,749	21,090
Stock options, Non-Vested Stock Options and ESPP Awards	767,428	598,109	256,939

Recently Issued Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820) (ASU 2011-04), which contains amendments to achieve common fair value measurement and disclosures in U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 explains how to measure fair value for financial reporting. The guidance does not require fair value measurements in addition to those already required or permitted by other Topics. The provisions of ASU 2011-04 became effective January 1, 2012. The adoption of ASU 2011-04 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity.

4. Unrestricted Marketable Securities

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

At December 31, 2012:

Available for Sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	$48,259	$1	$(54)	$48,206

The Company has not experienced any other-than-temporary losses on its marketable securities and restricted marketable securities.

5. Inventory

Inventories consist of the following, in thousands:

	December 31, 2011	December 31, 2012
Raw materials	$—	$1,152
Work-in-process	—	—
Finished goods	—	—
	$—	$1,152

There were no inventory reserves at December 31, 2011 and 2012. As of December 31, 2012 the Company had recorded approximately $0.9 million of inventory related to raw materials for Trokendi XR, which has received tentative approval from the FDA. We anticipate recovering these amounts through future product sales of Trokendi XR upon receipt of final approval.

6. Property and Equipment

Property and equipment consist of the following, in thousands:

	December 31, 2011	December 31, 2012
Computer equipment	$ 586	$ 615
Software	209	209
Lab equipment and furniture	3,465	3,896
Leasehold improvements	1,486	1,779
	5,746	6,499
Less accumulated depreciation and amortization	(4,436)	(5,078)
	$ 1,310	$ 1,421

Depreciation expense on property and equipment for the years ended December 31, 2010, 2011 and 2012 was approximately $959,000, $650,000, and $642,000, respectively.

7. Purchased Patents

In connection with a purchase agreement with Shire Laboratories, Inc., the Company acquired certain patents in 2005. The following sets forth the gross carrying amount and related accumulated amortization of the patents, in thousands:

		December 31, 2011		December 31, 2012	
	Weighted-Average Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Purchased patents	10.0	$2,292	$1,380	$2,292	$1,609

Amortization expense for the years ended December 31, 2010, 2011 and 2012 was approximately $229,000 each year. The estimated annual aggregate amortization expense through December 31, 2015

7. Purchased Patents (Continued)

is $229,000. The net book value of intangible assets as of December 31, 2011 and 2012 was approximately $0.9 million, and $0.7 million, respectively.

8. Accrued Liabilities

Accrued Liabilities are comprised of the following (and is included within the accounts payable and accrued expenses line item on the consolidated balance sheets), in thousands:

	December 31,	
	2011	2012
Accrued Clinical Trial Costs	$6,501	$3,335
Accrued Compensation	1,547	2,492
Interest Payable	138	213
Other Accrued Liabilities	1,089	1,820
	$9,275	$7,860

Accrued clinical trial costs consist primarily of investigator fees, contract research organization services and laboratory costs. Other accrued expenses consist primarily of marketing, sales and miscellaneous accrued expenses.

9. Notes Payable

Secured Notes Payable

In January 2011, the Company entered into a secured credit facility pursuant to a loan and security agreement with certain lenders, which was subsequently amended in December 2011, providing for term loans of up to an aggregate of $30.0 million. On January 26, 2011 and December 30, 2011, the Company drew down $15.0 million and $15.0 million, respectively, of term loans under this secured credit facility. The term loans bear interest at a fixed rate per annum of 11.0% and will mature on August 1, 2014 and January 1, 2015, respectively. Principal and interest payments are due over the remaining term of the loans. As of December 31, 2012, the Company is required to make the following principal payments, in thousands:

	As of December 31, 2012
Year ending December 31:	
2013	$11,809
2014	10,847
2015	569
	$23,225

The Company may voluntarily prepay all, but not less than all, outstanding term loans under its secured credit facility at any time, subject to the payment of a premium. With respect to any prepayment, the premium is 5.0%, if such prepayment is made before the amortization date (*i.e.*, to reduce a debt by making payments against the principal balance in installments or regular transfers), 2.0% if such

9. Notes Payable (Continued)

prepayment is made during the 15-month period after the amortization date, and 1.0% if such prepayment is made thereafter. Upon the maturity of any outstanding term loans or the acceleration or prepayment thereof, the Company will also be required to make a final payment equal to 2.5% of the aggregate principal amount, or $750,000, of the term loans borrowed under the secured credit facility. This final payment is being recorded as additional interest expense over the term of the loans. As of December 31, 2011 and 2012, the Company had accrued $0.1 million and $0.3 million, respectively, related to this final payment, included within notes payable on the consolidated balance sheet.

The Company capitalized financing costs of approximately $498,000 in issuing the secured notes payable, which are being amortized to interest expense over the term of the debt. The balance of deferred financing costs was approximately $378,000 and $233,000 at December 31, 2011 and 2012, respectively. The carrying value of the secured notes payable at December 31, 2011 and 2012 includes a debt discount of $514,000 and $328,000, respectively, related to the estimated fair value of the warrants issued in connection with the issuance of the notes. The Company recorded interest expense related to the secured notes payable of approximately $1.5 million and $2.9 million for the year ended December 31, 2011 and 2012, respectively. In addition, amortization of debt discount related to notes payable was $0.3 million and $0.6 million at December 31, 2011 and 2012, respectively.

All obligations under the secured credit facility are secured by substantially all of the Company's existing property and assets (excluding its intellectual property) and subject to certain exceptions, by a pledge of the capital stock of the Company's U.K. subsidiary and any future subsidiary. The fair value of the secured notes payable approximates its carrying value as of December 31, 2011 and 2012.

10. Sale of TCD Royalty Sub Reported as Discontinued Operations

Pursuant to a Unit Purchase Agreement executed on December 14, 2011, the Company sold 100% of its equity ownership interests in TCD to an entity affiliated with Orbimed Advisors LLC, one of its stockholders, hereafter referred to as the "Purchase Transaction." The purchase price consisted of $27.0 million cash payment, assumption of all assets and liabilities and a milestone payment of $3.0 million payable within 10 days of the occurrence of the earlier of the following conditions:

- The purchaser receives royalty payments equal to at least $35.1 million, the purchaser has not entered into a transaction to sell, refinance or monetize its equity interests in TCD, and no generic formulations of the products underlying the royalty payments and related license agreements have entered the market, or
- The purchaser receives proceeds in excess of the aggregate of (a) $27.0 million, plus (b) the purchase price paid by the purchaser, if any, to acquire a beneficial interest in one or more of the Notes, plus (c) the aggregate redemption price paid by the purchaser, if any, to redeem any of the Notes, from any transaction that refinances or liquidates the equity interests in TCD or the Notes.

The purchase price was determined through a competitive bidding process, involving more than one bidder and multiple rounds of negotiations between each potential buyer and the Company. The Company entered into the purchase transaction with an entity affiliated with OrbiMed Advisors LLC, which offered the highest purchase price.

10. Sale of TCD Royalty Sub Reported as Discontinued Operations (Continued)

Pursuant to the Purchase Transaction, the Company retained duties and obligations under certain notes and related agreements, including the Purchase and Sale Agreement, the Residual License Agreements and the Servicing Agreement, for so long as the notes remain outstanding. The purchaser assumed all rights and obligations of the notes.

The Company also retained certain duties and obligations under the ongoing Servicing Agreement. The Company will continue to perform these services in exchange for a quarterly fee of $10,000, or $40,000 annually. These retained duties consist of taking commercially reasonable steps to collect the royalty amounts due and enforcing the related provisions under the license agreements. In particular, the Company is required to monitor receipt of the royalty payments due under the license agreements and to confirm that the payments are received on a timely basis, calculated properly and made available to the trustee.

At the time the aforementioned Notes cease to be outstanding, the purchaser must make an election to either (1) terminate the Servicing Agreement and execute the New Servicing Agreement, which was contemplated and drafted at the time of the Purchase Transaction, or (2) obtain from the Company the assignment and transfer of all the licensed intellectual property and all of the Company's rights and obligations under the license agreements subject to certain conditions described in the Unit Purchase Agreement.

The Company determined it had not retained any interest nor any of the risks and rewards of TCD ownership nor had it guaranteed any payment of principal and interest on the Notes. The Company is serving as an agent for the debt holders in discharging its retained duties. Therefore, pursuant to ASC 810-10, "Consolidation", the Company accounted for the Purchase Transaction as a sale of a subsidiary and is calculating the resulting gain as the aggregate of the fair value of consideration and the carrying value of TCD's assets and liabilities, less its fees and expenses. Since the assets and liabilities of TCD had identifiable operations and cash flows that are independent from the Company and the Company does not have a significant continuing involvement with TCD operations, the sale of TCD is reported as discontinued operations in the Company's consolidated statements of operations. Accordingly, the gain on the sale of the subsidiary, as well as any results of operations related to TCD, are presented as discontinued operations in all periods presented in the accompanying financial statements. Should the Company receive the milestone payment or additional consideration, the fair value of amounts received, less any related fees and expenses, will be recorded as "gain on the sale of the subsidiary," a component of discontinued operations.

11. Stockholders' Equity (Deficit)

Upon consummation of the IPO in May 2012, the 49,000,000 outstanding shares of Series A Preferred Stock automatically converted to 12,249,998 shares of Common Stock.

Until the Series A Preferred Stock was converted into shares of common stock, dividends on the Series A Preferred Stock were cumulative and accrued at a rate per annum of $0.07 per share, subject to adjustment for certain dilutive events. The Company was not obligated to pay the dividends unless it declared or paid dividends on any other shares of capital stock or in the event of a liquidation, dissolution or winding up of the Company. As of December 31, 2011 and 2012 dividends of approximately $20.5 million and $0, respectively, had been accumulated.

11. Stockholders' Equity (Deficit) (Continued)

Common Stock

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

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

12. Share-Based Payments

Stock Option Plans

The Supernus Pharmaceuticals, Inc. 2005 Stock Plan (the 2005 Plan), which is stockholder-approved, permits the grant of options, purchase rights, and awards to its employees, officers, directors, consultants, or advisors for up to 2,000,000 shares of Common Stock. Option awards are granted with an exercise price equal to the estimated fair value of the Company's Common Stock at the grant date; those option awards generally vest in four annual installments, starting on the first anniversary of the date of grant and have ten-year contractual terms. The 2005 Plan provides for the issuance of Common Stock of the Company upon the exercise of stock options. A portion of the grants to certain employees vests upon the achievement of specified Company milestones.

Under the 2005 Plan, if an optionee is terminated for cause, the Company has the right and option to purchase, for a period of 180 days from the termination date, the shares of Common Stock the optionee obtained through the exercise of a stock option. The purchase price will equal the estimated fair market value of the Common Stock determined by mutual agreement between the Company and the optionee. There were no shares subject to repurchase at December 31, 2010, 2011 and 2012. The 2005 Plan was closed in 2012 with the approval of the 2012 Plan and no further options will be granted under the 2005 Plan.

During 2012, the Company adopted the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan (the 2012 Plan), which is stockholder-approved, and provides for the grant of stock options and certain other awards, including stock appreciation rights, restricted and unrestricted stock, stock units, performance awards, cash awards and other awards that are convertible into or otherwise based on the Company's common stock, to the Company's key employees, directors, and consultants and advisors. The 2012 Plan is administered by the Company's Board of Directors and provides for the issuance of up to 2,500,000 shares of the Company's Common Stock. Option awards are granted with an exercise price equal to the estimated fair value of the Company's Common Stock at the grant date; those option

12. Share-Based Payments (Continued)

awards generally vest in four annual installments, starting on the first anniversary of the date of grant and have ten-year contractual terms. The 2012 Plan provides for the issuance of Common Stock of the Company upon the exercise of stock options. Stock-based compensation recognized related to the grant of employee and non-employee stock options, and non-vested stock was as follows:

	Year Ended December 31,		
	2010	2011	2012
	(in thousands)		
Research and development	$ 53	$ 63	$208
Selling, general and administrative	244	(145)	131
Total	$297	$ (82)	$339

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

	Year Ended December 31,		
	2010	2011	2012
Fair value of common stock	$1.60 - $7.04	$2.56 - $3.36	$5.07 - $12.92
Expected volatility	60.3% - 61.5%	59.1% - 74.7%	68.3% - 71.6%
Dividend Yield	0%	0%	0%
Expected term	6.25 years	0.41 - 6.25 years	6.25 years
Risk-free rate	1.65% - 2.72%	0.15% - 2.93%	0.89% - 1.14%
Expected forfeiture rate	5%	0% - 5%	0% - 5%

Fair Value of Common Stock—For all option grants prior to the completion of the Company's IPO on May 1, 2012, the fair value of the Common Stock underlying the option grants was determined by the Board, with the assistance of management, which intended all options granted to be exercisable at a price per share not less than the per share fair value of the Company's Common Stock underlying those options on the date of grant. The Company utilized methodologies, approaches and assumptions as set forth in the Technical Practice Aid, when estimating the fair value of Common Stock at each grant date.

Given the lack of an active public market for the Common Stock, the Board employed a third-party valuation firm to assist in the determination of fair value by completing contemporaneous valuations. In the absence of a public market, and as a clinical stage company with no significant revenues from product sales, the Company considered a range of factors to determine the fair market value of the Common Stock at each grant date. The factors include: (1) the achievement of clinical and operational milestones by the Company, (2) the status of strategic relationships with collaborators, (3) the significant risks associated with the Company's stage of development, (4) capital market conditions for life science companies, particularly similarly situated privately held, early-stage life science companies, (5) the Company's available cash, financial condition, and results of operations, (6) the most recent sales of the Company's preferred stock, and (7) the preferential rights of the outstanding preferred stock.

12. Share-Based Payments (Continued)

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

Expected Volatility—Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company does not maintain an internal market for its shares and its shares are not traded privately. The Company has identified several public entities of similar size, complexity, and stage of development and, accordingly, historical volatility has been calculated using the volatility of these companies. The Company will continue to use the guideline peer group volatility information until the historical volatility of its own Common Stock is relevant to measure expected volatility for future option grants.

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

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

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

Expected Forfeiture Rate—The forfeiture rate is the estimated percentage of options granted that are expected to be forfeited or canceled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on turnover data with further consideration given to the class of employees to whom the options were granted.

12. Share-Based Payments (Continued)

The following table summarizes stock option activity under the 2005 Plan and the 2012 Plan:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Outstanding, December 31, 2010	664,479	$ 1.72	7.83
Granted	144,750	$ 5.80	
Exercised	(69,559)	$ 0.40	
Forfeited or expired	(141,561)	$ 2.17	
Outstanding, December 31, 2011	598,109	$ 2.75	7.71
Granted	188,136	$10.73	
Exercised	(159,264)	$ 1.67	
Forfeited or expired	(57,070)	$ 2.45	
Outstanding, December 31, 2012	569,911	$ 5.72	7.88
As of December 31, 2012:			
Vested and expected to vest	564,083	$ 5.72	7.87
Exercisable	200,312	$ 2.11	5.73

The aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable as of December 31, 2010 is approximately $589,000, $585,000 and $463,000, respectively. The aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable as of December 31, 2011 is approximately $1.9 million, $1.8 million and $1.2 million, respectively. The aggregate intrinsic value of options outstanding, vested and expected to vest, and exercisable as of December 31, 2012 is approximately $1.6 million, $1.5 million and $1.0 million, respectively.

The weighted-average, grant-date fair value of options granted for the years ended December 31, 2010, 2011 and 2012 was $1.68, $3.64, and $6.85 per share, respectively. The total fair value of the underlying Common Stock related to shares that vested during the years ended December 31, 2010, 2011 and 2012 was approximately $104,000, $113,000, and $218,000, respectively. The total intrinsic value of options exercised amounted to approximately $26,000, $262,000, and $748,000, respectively, during the years ended December 31, 2010, 2011 and 2012. As of December 31, 2011 and 2012, the total unrecognized compensation expense, net of related forfeiture estimates, was approximately $768,000 and $1,651,000, respectively, which the Company expects to recognize over a weighted-average period of 3.09 and 3.06 years, respectively.

12. Share-Based Payments (Continued)

Stock Purchase Plan

During 2012, the Company adopted the Supernus Pharmaceuticals, Inc. 2012 Employee Stock Purchase Plan (the ESPP), which is stockholder-approved, and permits eligible employees to purchase shares of the Company's Common Stock using their after tax payroll deductions, subject to certain conditions. The ESPP is administered by the Company's Board of Directors and provides for the issuance of up to 250,000 shares of the Company's Common Stock. Eligible employees can purchase shares, using their payroll deductions, at an amount equal to 85% of the lesser of the fair market value of the stock on (a) the first day of the option period or (b) the last day of the option period. During the year ended December 31, 2012, 36,727 shares of the Company's Common Stock were purchased by participating eligible employees. The Company incurred $104,000 of expense for this plan for the year ending December 31, 2012, which is included within research and development and selling, general and administrative expense on the consolidated statement of operations in the amount of $55,000 and $49,000, respectively. Common Stock reserved for future employee purchase under the ESPP totaled 213,273 shares as of December 31, 2012.

13. Income Taxes

The components of the income tax benefit were as follow, in thousands:

	Year Ended December 31,		
	2010	2011	2012
Current			
Federal	$ —	$14,090	$—
State	—	2,155	—
Deferred			
Federal	399	—	—
State	—	—	—
Total	$399	$16,245	—

For the years ended December 31, 2010, 2011 and 2012, there was a $0.4 million, $16.2 million and $0 benefit for federal or state income taxes based on continuing operations, respectively. A reconciliation

13. Income Taxes (Continued)

of the expected income tax benefit computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows, in thousands:

	Year Ended December 31,		
	2010	2011	2012
Income tax (benefit) computed at federal statutory tax rate	$(13,421)	$(13,419)	$(16,270)
Permanent items	61	57	396
State taxes	(2,142)	(2,155)	(2,487)
Change in valuation allowance	16,144	—	18,754
Uncertain tax position	190	129	(64)
Research and development credits	(1,267)	(857)	—
Other	36	—	(329)
Income tax benefit	$ (399)	$(16,245)	$ —

In 2011, the Company recorded pre-tax income from discontinued operations of approximately $93.3 million, which resulted in income tax expense from discontinued operations of approximately $36.8 million. This income tax expense from discontinued operations was completely offset by a $16.2 million income tax benefit generated from the 2011 loss from continuing operations and the utilization of net operating loss carryforwards.

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

As of December 31, 2012, the NOL carryforwards amounted to approximately $80.8 million and will begin to expire in various years beginning in 2025. As of December 31, 2012, the Company has available research and development credit carryforwards of approximately $3.9 million, which expire, if unused, starting 2025. The use of the Company's NOL carryforwards and research and development credits may be restricted due to changes in Company ownership. Additionally, despite the NOL carryforwards, the Company may have a future tax liability due to an alternative minimum tax or state tax requirements. The Company paid no income taxes in the years ended December 31, 2010, 2011 or 2012.

13. Income Taxes (Continued)

The deferred tax benefit has been entirely offset by valuation allowances. The significant components of the Company's deferred tax assets (liabilities) were as follow, in thousands:

	As of December 31,	
	2011	2012
Deferred tax assets:		
Net operating loss carryforward	$ 14,809	$ 32,714
Deferred rent credit	514	477
Accrued compensation and non-qualified stock options	48	60
Deferred financing costs	35	—
Depreciation and amortization	98	282
Research and development credits	5,018	3,901
Other	9	788
Net deferred tax asset before valuation allowance	20,531	38,222
Valuation allowance	(20,531)	(38,222)
Net deferred tax asset	$ —	$ —

The Company accounts for uncertain tax positions pursuant to the guidance in FASB ASC Topic 740, *Income Taxes*. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2011 and 2012, the Company did not accrue any interest related to uncertain tax positions. The Company's income taxes have not been subject to examination by any tax jurisdictions since its inception. Due to NOL and research and development credit carryforwards, all income tax returns filed by the Company are subject to examination by the taxing jurisdictions. The net change during the year ended December 31, 2012 in total valuation allowance of approximately $17.7 million is primarily due to an increase in the NOL carryforward related to the 2012 net loss from continuing operations.

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

	Year Ended December 31,		
	2010	2011	2012
Balance as of January 1	$ —	$642	$752
Gross increases related to prior-year tax positions	452	—	—
Gross increases (decrease) related to current-year tax positions	190	110	(64)
Balance as of December 31	$642	$752	$688

The Company believes that any of its uncertain tax positions would not result in adjustments to its effective income tax rate because likely corresponding adjustments to deferred tax assets would be offset by adjustments to recorded valuation allowances.

14. Commitments and Contingencies

The Company's lease for office and lab space extends through April 2018. Commencing in November 2013, the current base annual rent will be increased 2% per annum for the remaining term. The Company may elect to extend the term of the lease for an additional five-year term. The lease provides for a tenant improvement allowance of approximately $2.4 million in aggregate. As of December 31, 2010, 2011 and 2012, approximately $0.9 million, $1.4 million, and $1.7 million, respectively, of the allowance has been utilized and included in fixed assets and deferred rent.

Rent expense for the years ended December 31, 2010, 2011 and 2012 was approximately, $918,000, $906,000, and $906,000, respectively. Future minimum lease payments under non-cancelable operating leases as of December 31, 2012 are as follows, in thousands:

	As of December 31, 2012
Year ending December 31:	
2013	$ 966
2014	985
2015	1,004
2016	1,025
Thereafter	1,399
	$5,379

The Company has obtained exclusive licenses from third parties for proprietary rights to support the product candidates in the Company's psychiatry portfolio. Under license agreements with Afecta Pharmaceuticals, Inc. (Afecta), the Company has an exclusive option to evaluate Afecta's CNS pipeline and to obtain exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. The Company does not owe any future milestone payments for SPN-810. The Company will also be obligated to pay royalties to Afecta based on worldwide net sales of each of these products in the low-single digits. The Company has also entered into a purchase and sale agreement with Rune Healthcare Limited (Rune), where the Company obtained the exclusive worldwide rights to a product concept from Rune. There are no future milestone payments owing to Rune under this agreement. If the Company receives approval to market and sell any products based on the Rune product concept for SPN-809, the Company will be obligated to pay royalties to Rune based on net sales worldwide in the low single digits.

15. Employee Benefit Plan

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

15. Employee Benefit Plan (Continued)

Employees are 100% vested in their contributions to the 401(k) Plan. The Company matches 100% of a participant's contribution for the first 3% of their salary deferral and matches 50% of the next 2% of their salary deferral. As determined by the Board, the Company may elect to make a discretionary contribution not exceeding 60% of the annual compensation paid to all participating employees. The Company's contributions to the 401(k) Plan approximated $254,000, $267,000, and $323,000 for the years ended December 31, 2010, 2011 and 2012, respectively.

16. Related-Party Transactions

In December 2011, the Company entered into a Unit Purchase Agreement with Royalty Opportunities S.àr.l ("ROS") (see Note 10). Pursuant to the Unit Purchase Agreement, the Company sold 100% of its equity interests in TCD to ROS for a cash payment of $27.0 million upon closing, assumption of assets and liabilities, and a potential milestone payment of $3.0 million payable upon the occurrence of certain conditions. ROS is an affiliate of Orbimed Advisors LLC, one of the Company's Common Stock holders.

17. Collaboration Agreements

United Therapeutics

The Company has a license agreement with United Therapeutics to use one of its proprietary technologies for an oral formulation of Remodulin for the treatment of pulmonary arterial hypertension and potentially for additional indications. Through December 31, 2012, the Company has received $1.5 million in pre-commercial milestone payments under the agreement. Remaining milestone payments to the Company could total $2.0 million, based on satisfaction of development milestones of oral treprostinil in PAH and up to approximately $4.0 million for the development of additional treprostinil products for a second indication. If United Therapeutics receives approval to market and sell oral treprostinil for additional indications and/or any additional combination products that utilize the Company's technologies, the Company will receive royalties in the single digits based on net sales worldwide. The Company's license agreement with United Therapeutics will expire, on a country-by-country and product-by-product basis, 12.5 years from the first commercial sale of each product in such country. United Therapeutics may terminate, at its option, the agreement for a technical, strategic or market-related cause after giving the Company a reasonable opportunity to cure. The Company may terminate the agreement if, after having launched a product in a country, United Therapeutics or its sub-licensee discontinues the sale of such product for a prolonged period of time for reasons unrelated to force majeure, regulatory or safety issues. In addition, either party may terminate the agreement for the material, uncured breach by the other party and in certain events of bankruptcy or insolvency of the other party.

Stendhal License

In August 2011, we executed a Development and Licensing Agreement with Especificos Stendhal, S.A., DE C.V. (Stendhal) that provided Stendhal an exclusive license to our licensed intellectual property underlying our Oxtellar XR product, in Mexico, Venezuela, Colombia and other select markets in Central and South America. The agreement included the right to our patents, proprietary information, and know-how of our drug-delivery technology and pharmaceutical product underlying our Oxtellar XR

17. Collaboration Agreements (Continued)

product. Stendhal is responsible for all costs associated with clinical development, approval, commercialization and distribution of the product in the defined territory, which may be expanded upon certain events. We have received $750,000 from Stendhal, which is being recognized as revenue on a straight-line basis over the substantive obligation period until approval, which is estimated to be December 2013. We monitor this estimate on a quarterly basis to determine if facts and circumstances may have changed that would require a prospective adjustment of the recognition period. We may receive up to $3.0 million in additional milestone payments, based on certain regulatory and commercial milestones defined in the agreement. As of December 31, 2012, $0.4 million of up-front license payments received remained recorded as deferred revenue.

In September 2012, the Company executed a Development and Licensing Agreement (Stendhal License Agreement) with Stendhal that provided Stendhal with an exclusive license of the Company's licensed intellectual property underlying the Trokendi XR product in the defined territory. The license included the right to the Company's patents, proprietary information, and know-how of the Company's drug-delivery technology and pharmaceutical product underlying its Trokendi XR product. Stendhal is responsible for all costs associated with clinical development, approval, commercialization and distribution of the product in the defined territory. The Company will receive $1.8 million cash that will be recognized as revenue in a straight-line basis over its substantive obligation period of twelve years. As of December 31, 2012, approximately $0.5 million of this amount was recorded as deferred revenue. The Company monitors this estimate on a quarterly basis to determine if facts and circumstances may have changed that would require a prospective adjustment to the recognition period. The Company may receive up to an additional $1.8 million in future milestone payments, based on certain milestones defined in the Stendhal License Agreement.

18. Quarterly Financial Information (unaudited)

Quarterly financial information for fiscal 2012 and 2011 are presented in the following table, in thousands, except per share data:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2012				
Revenue	$ 208	$ 91	$ 91	$ 1,090
Total costs and expenses	8,086	9,348	12,381	13,834
Loss from operations	(9,277)	(10,013)	(13,482)	(13,512)
Net loss	(9,277)	(10,013)	(13,482)	(13,512)
Net loss per share, basic and diluted	(6.05)	(0.61)	(0.55)	(0.51)
2011				
Revenue	$ —	$ 750	$ 11	$ 42
Total costs and expenses	9,198	9,146	9,926	10,285
(Loss) income from continuing operations	(9,715)	(8,940)	(10,151)	5,581
(Loss) income from discontinued operations	(1,334)	1,563	417	76,394
Net (loss) income	(11,049)	(7,377)	(9,734)	81,975
Net (loss) income per share, basic, continuing operations	(6.64)	(6.15)	(6.90)	2.88
Net (loss) income per share, basic, discontinued operations	(0.84)	0.98	0.26	46.64
Net (loss) income per share, diluted, continuing operations	(6.64)	(6.15)	(6.90)	2.34
Net (loss) income per share, diluted, discontinued operations	(0.84)	0.98	0.26	37.80

For the quarter ended December 31, 2011 reported a net income from continuing operations of $5.6 million. This resulted from a net loss from continuing operations of $10.6 million offset by a tax benefit of $16.2 million from the sale of TCD Royalty sub (see Note 10).

19. Subsequent Events

In January 2013, the underwriters of the Company's follow-on offering (see Note 11) exercised their over-allotment options resulting in the sale of an additional 239,432 shares of the Company's Common Stock at a price of $8 per share.

In January 2013, we signed a lease for approximately 11,900 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, 2018.

On February 4, 2013, the Company commercially launched Oxtellar XR.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

CEO/CFO Certifications

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

Evaluation of Disclosure Controls and Procedures

Our management, including our CEO and CFO, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this Annual Report on Form 10-K has been appropriately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, to allow timely decisions regarding required disclosure. Based on that evaluation, our CEO and CFO have concluded that our disclosure controls and procedures are effective at the reasonable assurance level to ensure that material information relating to the company and our consolidated subsidiaries is made known to management, including the CEO and CFO, on a timely basis and during the period in which this Annual Report on Form 10-K was being prepared.

Changes in Internal Control

Our management, including our CEO and CFO, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2012, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

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

- pertain to the management of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2012. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework.

Based on our assessment, management believes that, as of December 31, 2012, the Company's internal control over financial reporting is effective based on those criteria.

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

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2013 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2012.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2013 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2012.

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

The information required by Item 201(d) of Regulation S-K is set forth below. The remainder of the information required by this Item 12 is incorporated by reference from our definitive proxy statement for our 2013 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2012.

The following table shows the number of securities that may be issued pursuant to our equity compensation plans (including individual compensation arrangements) as of December 31, 2012:

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)	Weighted average exercise price of outstanding options, warrants and rights(1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column(2)
Equity compensation plans approved by security holders	611,994	$5.64	2,341,875
Equity compensation plans not approved by security holders	—	—	—
Total	611,994	$5.64	2,341,875

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

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

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

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2013 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2012.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2013 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2012.

EXHIBIT 31.1

CERTIFICATION

I, Jack A. Khattar, certify that:

1. I have reviewed this Annual Report on Form 10-K of Supernus Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2013

By: /s/ JACK A. KHATTAR

Jack A. Khattar
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Gregory S. Patrick, certify that:

1. I have reviewed this Annual Report on Form 10-K of Supernus Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2013

By: /s/ GREGORY S. PATRICK

Gregory S. Patrick
Vice President and Chief Financial Officer

EXHIBIT 32.1

SUPERNUS PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. sec. 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Supernus Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jack A. Khattar, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2013

By: /s/ JACK A. KHATTAR
Jack A. Khattar
President and Chief Executive Officer

EXHIBIT 32.2

SUPERNUS PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. sec. 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with Annual Report of Supernus Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregory S. Patrick, Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2013

By: /s/ GREGORY S. PATRICK
Gregory S. Patrick
Vice President and Chief Financial Officer

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BOARD OF DIRECTORS

M. James Barrett, Ph.D.
Chairman of the Board
General Partner of New Enterprise Associates, Inc.

Michael Bigham
General Partner of Abingworth

Frederick M. Hudson
Partner KPMG, LLP (retired)

Jack A. Khattar
President, Chief Executive Officer and Secretary of Supernus Pharmaceuticals, Inc.

Charles W. Newhall, III
Co-founded New Enterprise Associates, Inc. (retired)

William A. Nuerge
Managing Partner of Fortress Pharms Advisors, LLC

John M. Siebert, Ph.D.
Chief Operating Officer of New Rhein Healthcare Investors, LLC.

CORPORATE HEADQUARTERS

Supernus Pharmaceuticals, Inc.
1550 East Gude Drive
Rockville, MD 20850

EXECUTIVE OFFICERS

Jack A. Khattar
President, Chief Executive Officer and Secretary

Gregory S. Patrick
Vice President, Chief Financial Officer

Padmanabh P. Bhatt, Ph.D.
Senior Vice President, Intellectual Property, Chief Scientific Officer

Jones W. Bryan, Ph.D.
Vice President of Business Development

Stefan K.F. Schwabe, M.D., Ph.D.
Executive Vice President of Research and Development, Chief Medical Officer

Victor Vaughn
Senior Vice President, Sales

TRANSFER AGENT / REGISTRAR

Computershare
350 Indiana Street
Suite 750
Golden, CO 80401
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STOCK LISTING
NASDAQ: SUPN

OUTSIDE COUNSEL

Saul Ewing LLP
1919 Pennsylvania Ave., N.W.
Suite 550
Washington, D.C. 20006

AUDITORS

Ernst & Young, LLP
8484 Westpark Dr.
McLean, VA 22102

ANNUAL MEETING

The annual meeting of shareholders will be held on April 24, 2013 at 10:00 am at Supernus Pharmaceuticals, Inc. (Corporate Headquarters) 1550 East Gude Drive Rockville, MD 20850

ANNUAL REPORT ON FORM 10-K

The Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission and other information may be obtained without charge by writing, phoning or visiting our website:

Supernus Pharmaceuticals, Inc.
1550 East Gude Drive
Rockville, MD 20850
(301) 838-2500
www.supernus.com