SUPERNUS PHARMACEUTICALS INC
Form S-1/A
November 26, 2012

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As filed with the Securities and Exchange Commission on November 26, 2012

Registration No. 333-184930

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 1
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**20-2590184**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1550 East Gude Drive
Rockville, MD 20850
(301) 838-2500

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Jack A. Khattar
President and Chief Executive Officer
1550 East Gude Drive
Rockville, MD 20850
(301) 838-2500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Mark I. Gruhin **Craig F. Zappetti** **Saul Ewing LLP** **1919 Pennsylvania Avenue, N.W.**	**Gregory S. Patrick** **Supernus Pharmaceuticals, Inc.** **Vice President, Chief Financial Officer** **1550 East Gude Drive**	**Edward A. King** **Mitchell S. Bloom** **Goodwin Procter LLP** **Exchange Place**

Suite 550
Washington, DC 20006-3434
Telephone: (202) 342-3444
Facsimile: (215) 972-2284

Rockville, MD 20850
Telephone: (301) 838-2500
Facsimile: (301) 424-1364

Boston, MA 02109
Telephone: (617) 570-1000
Facsimile: (617) 523-1231

Approximate date of commencement of proposed sale to public:
As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 26, 2012

PRELIMINARY PROSPECTUS

6,000,000 Shares

Supernus Pharmaceuticals, Inc.

Common Stock

We are offering 6,000,000 shares of our common stock. Our common stock is listed on The NASDAQ Global Market under the symbol "SUPN". On November 23, 2012, the last reported sale price of our common stock on The NASDAQ Global Market was $12.05 per share.

We are an "emerging growth company" as defined by the Jumpstart Our Business Act of 2012 and as such we are eligible for reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 10 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public Offering Price	$	$
Underwriting Discounts and Commissions	$	$
Proceeds to Supernus, before expenses	$	$

Delivery of the shares of common stock is expected to be made on or about , 2012. We have granted the underwriters an option for a period of 30 days to purchase an additional 900,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Joint Book-Running Managers

Jefferies **Piper Jaffray** **Cowen and Company**

Co-Managers

Stifel Nicolaus Weisel **Lazard Capital Markets**

Prospectus dated , 2012

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We are responsible for the information contained in this prospectus. We have not authorized anyone to provide you with different information and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

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SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus. While this summary highlights what we consider to be the most important information about us, you should carefully read this prospectus and the registration statement of which this prospectus is a part, each in their entirety, before investing in our common stock, especially the risks of investing in our common stock, which we discuss under "Risk Factors," the information set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes beginning on page F-1.

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

Supernus Pharmaceuticals, Inc.

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 stand alone 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, Inc. We are planning for the commercial launch of two neurology products for the treatment of epilepsy in 2013 and are developing multiple product candidates in psychiatry to address the large market opportunity in 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, including neurologists and psychiatrists, and to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

We use our proprietary technologies to enhance the therapeutic benefits of approved drugs through advanced extended release formulations. On October 19, 2012, the U.S. Food and Drug Administration, or the FDA, granted final approval of Oxtellar XR (extended release oxcarbazepine), formerly known as SPN-804, for the treatment of epilepsy. We anticipate the commercial launch of Oxtellar XR to occur during the first quarter of 2013. On November 15, 2012, the FDA granted a three year marketing exclusivity to Oxtellar XR. We believe that Oxtellar XR will be the first extended release formulation of oxcarbazepine for the treatment of epilepsy available in the U.S. On June 25, 2012, the FDA granted tentative approval of Trokendi XR (extended release topiramate), formerly known as SPN-538, for the treatment of epilepsy. The final approval for Trokendi XR may not be made effective until the expiration of the marketing exclusivity period that Topamax has regarding safety information of topiramate in a specific pediatric population. This marketing exclusivity expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. We anticipate the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA. We believe that Trokendi XR will be the first extended release formulation of topiramate for the treatment of epilepsy available in the U.S.

Our psychiatry product candidates include SPN-810 (molindone hydrochloride), which completed a Phase IIb trial as a novel treatment for impulsive aggression in patients with ADHD, and SPN-812, which completed a Phase IIa trial as a novel non-stimulant treatment for ADHD.

In addition to these products and product candidates, 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.

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

Product	Indication	Status
Oxtellar XR	Adjunctive therapy for epilepsy	Final approval by FDA
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

Our Neurology Portfolio

Epilepsy is a chronic neurological disorder characterized by recurrent convulsive seizures resulting from hyperactivity in the brain cells. It is estimated to affect 50 million people worldwide[(1)] and 2 million people in the United States.[(2)] Achieving reliable seizure control for patients, and avoiding the serious health and life dangers that can be associated with sudden unexpected, or breakthrough, seizures depends on patients being compliant and diligent in taking their medications. We believe there are a number of benefits associated with extended release products in epilepsy that create a significant market opportunity for us, including:

- Extended release products have been shown to improve compliance and reduce breakthrough seizures.[(3)]
- Extended release products have been shown to reduce side effects and improve tolerability.[(4)]
- Managed care plans have not limited the success of extended release products.[(5)]
- Extended release products generally have performed well in the market.[(6)]

Oxtellar XR (extended release oxcarbazepine)

Oxtellar XR is a novel oral once-daily extended release formulation of oxcarbazepine for which we received final FDA approval in October 2012, as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age. Oxcarbazepine is marketed by Novartis under the brand name Trileptal and is available in a generic form. Trileptal is indicated for monotherapy and adjunctive therapy of epilepsy. 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 and vomiting.

With a novel pharmacokinetic profile that delivers lower peak plasma concentrations, a slower rate of input and smoother, 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. We were granted three year market exclusivity for Oxtellar XR, and anticipate the commercial launch of Oxtellar XR during the first quarter of 2013.

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

(2) 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*).

(3)

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

(4)

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

(5)

IMS Health data and Epilepsy Foundation, *Private Health Insurance and Medication Switching*.

(6)

IMS Health data.

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Trokendi XR (extended release topiramate)

Trokendi XR is a novel oral once-daily extended release topiramate product for the treatment of epilepsy for which we received tentative FDA approval 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. Topiramate is marketed by Johnson & Johnson under the brand name Topamax and is available in a generic form. Topiramate is currently available only in immediate release form for monotherapy and adjunctive therapy of epilepsy and for the treatment of migraine. It works by enhancing the inhibitory effect of the GABA (Gamma-Aminobutyric Acid), neurotransmitter that regulates neuronal excitability throughout the nervous system, blocking the excitatory effect of the glutamate neurotransmitter, attenuating the sodium channels and inhibiting the carbonic anhydrase enzyme. The side effects associated with taking topiramate, which have tended to limit its use, include, among others, dizziness, fatigue, kidney stones, somnolence and slowing of certain cognitive functions.

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 entire day compared to immediate release Topamax. Trokendi XR was tentatively approved by the FDA in June 2012. 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. We anticipate the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA.

Our Psychiatry Portfolio

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.[7] An estimated 60% to 80% of children with ADHD continue to meet the criteria for ADHD into adolescence, and as many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, conduct disorder, anxiety disorder and depression.[8] In addition, approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.[9] There are currently no approved products for the treatment of impulsive aggression in individuals with ADHD.

SPN-810 (molindone hydrochloride)

We are developing SPN-810 as a novel treatment for impulsive aggression in patients with ADHD. On November 6, 2012, we received preliminary results of our recently completed Phase IIb trial of SPN-810 in the United States. The trial's primary objective was to study three different doses of SPN-810 ranging from 12mg per day to 54mg per day depending on patients' weight. The study accomplished its objective of establishing a dose range at which the drug is effective and supported the efficacy of SPN-810 (molindone hydrochloride extended release formulation) in the treatment of impulsive aggression in ADHD patients weighing 30kg 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

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

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

(9) 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*.

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development. We will be analyzing the full dataset in depth, and subsequently planning on meeting with the FDA to discuss next steps in the development program and the design and protocol for Phase III clinical trials. 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. Molindone hydrochloride is unusual among anti-psychotics in that it is less likely to be associated with weight gain.

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. We completed a proof-of-concept Phase IIa trial of SPN-812 in the first quarter of 2011, in which SPN-812 was well tolerated and demonstrated a statistically significant improvement over placebo as a treatment for ADHD. The trial was a randomized, double-blind, placebo-controlled trial in 52 adults with a current diagnosis of ADHD, with 26 subjects per treatment group. Given the positive results of this Phase IIa trial, we are focused on developing an extended release formulation for testing in a future Phase IIb trial. SPN-812 has not been developed and marketed in the United States and, therefore, it would be considered and reviewed by the FDA as a new chemical entity, or NCE.

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 to enable the treatment of new indications. Our key proprietary technology platforms include: Microtrol (multiparticulate delivery platform), Solutrol (matrix delivery platform) and EnSoTrol (osmotic delivery system). These technologies create customized product profiles designed to meet efficacy needs, permit more convenient and less frequent dosing, enhance patient compliance and improve tolerability in certain specific applications. Our proprietary technologies have been used in the following FDA approved and marketed products: Carbatrol (carbamazepine), Equetro (carbamazepine), Adderall XR (mixed amphetamine salts), Sanctura XR (trospium chloride), Oracea (doxycycline) and Intuniv (guanfacine). We do not expect these products to contribute to our future cash position as we have either monetized the future revenues associated with them or we developed them when we were formerly Shire Laboratories.

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 are currently focused on building our own targeted specialty sales force and marketing capabilities in the United States to commercially launch Oxtellar XR and, once approved, Trokendi XR.

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. For example, we completed a Phase IIb trial of SPN-810 for impulsive aggression in patients with ADHD for which we received positive topline results in November 2012.

Develop differentiated products by applying our technologies to known drug compounds. We intend to continue to focus our development activities on known drug compounds and compounds with established mechanisms of action and thereby reduce the risks, costs and time typically associated with pharmaceutical product development. We intend to leverage our proprietary and in-licensed

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technologies and expand our patent portfolio to 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 product candidates 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 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, if appropriate, external collaborations.

Risks Associated With Our Business

Our ability to implement our business strategy is subject to numerous risks and uncertainties. As an early stage pharmaceutical company, we face many risks inherent in our business and our industry, as more fully described in the section entitled "Risk Factors" immediately following this summary, including the following:

Final marketing approval of Trokendi XR or any of our other 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.

We are dependent on the successful commercialization of Oxtellar XR and Trokendi XR, after it receives final approval.

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

We have never generated any revenues from our own sales of our products, and we may never achieve or maintain profitability.

If other extended or controlled release oxcarbazepine or topiramate anti-epileptic drugs are approved and successfully commercialized, our business could be materially harmed.

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

You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," prior to making an investment in our common stock.

Implications of being an Emerging Growth Company

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

Only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure.

Reduced disclosure about our executive compensation arrangements.

No non-binding advisory votes on executive compensation or golden parachute arrangements.

Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

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We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenues, we have more than $700 million in market value of our stock held by non-affiliates, or we issue more than $1 billion of non-convertible debt over a three-year period. In addition, the requirements for financial and other disclosure provided by Regulation S-K promulgated by the Securities and Exchange Commission also provide certain of these exemptions for smaller reporting companies. We are a smaller reporting company. We may choose to take advantage of some but not all of these reduced burdens. We have not taken advantage of all of these reduced reporting burdens in this prospectus, although we may choose to do so in future filings. If we do, the information that we provide stockholders may be different than you might get from other public companies in which you hold stock.

Corporate Information

We were incorporated in Delaware in 2005. Our principal executive office is located at 1550 East Gude Drive, Rockville, Maryland 20850. Our telephone number is (301) 838-2500.

On May 1, 2012, we completed an initial public offering of 10,000,000 shares of our common stock pursuant to which we also sold 449,250 additional shares of our common stock upon the subsequent exercise in full by the underwriters of their over-allotment option, resulting in net cash proceeds to us of $47.6 million after paying offering expenses of approximately $4.7 million.

We are the owner of various U.S. federal trademark registrations (®) and registration applications (TM), including the following marks referred to in this prospectus pursuant to applicable U.S. intellectual property laws: "Supernus®," "Microtrol®," "Solutrol®," "ProScreen®," "OptiScreen®," "ProPhile®," "Trokendi XR ," "Oxtellar XR ," and the registered Supernus Pharmaceuticals logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and *TM* symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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THE OFFERING

Common stock we are offering	6,000,000 Shares
Common stock to be outstanding after this offering	30,466,049 Shares
Over-allotment option	We have granted the underwriters an option for a period of up to 30 days to purchase up to 900,000 additional shares of common stock at the offering price.
Use of proceeds after expenses	We estimate that the net proceeds from this offering will be approximately $67.7 million, or approximately $77.8 million if the underwriters exercise their over-allotment option in full. We expect to use the net proceeds from this offering to fund the expected commercial launches of Oxtellar XR and Trokendi XR, the continued clinical development of SPN-810 and SPN-812, the repayment of a portion of the principal of the term loans under our secured credit facility and for other general corporate purposes. See "Use of Proceeds."
Risk factors	You should read the "Risk Factors" section of this prospectus beginning on page 10 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Global Market symbol	SUPN

The number of shares of our common stock to be outstanding after this offering is based on 24,466,049 shares of common stock outstanding as of September 30, 2012.

The number of shares of our common stock outstanding immediately after this offering excludes:

- 574,820 shares of common stock issuable upon the exercise of vested and nonvested options outstanding as of September 30, 2012, with exercise prices ranging from $0.40 to $12.92 per share and a weighted average exercise price of $4.89 per share (of which options to acquire 187,657 shares of common stock were vested as of September 30, 2012);

- 2,391,750 shares of common stock reserved for future issuance under our 2012 Equity Incentive Plan;

- 250,000 shares of common stock reserved for future issuance under our 2012 Employee Stock Purchase Plan;

- 49,137 shares of common stock issued in October 2012 upon the cashless net exercise of lender warrants with an exercise price of $4.00 per share;

- 15,172 shares of common stock issued in October 2012 upon the cashless net exercise of lender warrants with an exercise price of $5.00 per share;

- 18,750 shares of common stock issuable upon the exercise of warrants at an exercise price of $4.00 per share; and

- 23,332 shares of common stock issuable upon the exercise of warrants at an exercise price of $5.00 per share.

Unless otherwise indicated, all information in this prospectus:

- assumes no exercise by the underwriters of their option to purchase up to 900,000 shares of our common stock in this offering to cover over-allotments; and

gives effect to the one-for-four reverse stock split of our common stock effected on April 9, 2012.

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SUMMARY FINANCIAL DATA

We have derived the consolidated statements of operations data for the years ended December 31, 2009, 2010 and 2011 from our audited consolidated financial statements included in this prospectus. We have derived our consolidated balance sheet data as of September 30, 2012 and consolidated statement of operations data for each of the nine months ended September 30, 2011 and 2012 from our unaudited consolidated financial statements included in this prospectus. The unaudited consolidated financial statement data include, in our opinion, all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation in all material respects of our consolidated financial position and consolidated results of operations for these periods.

Our historical results are not necessarily indicative of future operating results, and the results for the first nine months of 2012 are not necessarily indicative of results expected for the full year or for any other period. You should read this summary consolidated financial data in conjunction with the sections entitled "Risk Factors," "Capitalization," "Selected Consolidated Financial Data" 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 prospectus.

	Year Ended December 31,			Nine Months Ended September 30,	
	2009	2010	2011	2011	2012
				(unaudited)	
	(in thousands, except share and per share information)				
Consolidated Statement of Operations Data:					
Revenues					
Development and milestone revenues	$ 1,050	$ 106	$ 803	$ 761	$ 391
Royalty revenues	36,875				
Total revenues	37,925	106	803	761	391
Costs and expenses					
Research and development	29,260	35,149	30,627	23,126	18,367
Selling, general and administrative	4,649	5,080	7,928	5,143	11,450
Total costs and expenses	33,909	40,229	38,555	28,269	29,817
Operating income (loss) from continuing operations	4,016	(40,123)	(37,752)	(27,508)	(29,426)
Other income (expense):					
Interest income	122	107	31	29	91
Interest expense			(1,866)	(1,357)	(2,771)
Other		542	117	30	(665)
Total other income (expense)	122	649	(1,718)	(1,298)	(3,345)
Income (loss) from continuing operations before income taxes	4,138	(39,474)	(39,470)	(28,806)	(32,771)
Income tax benefit		399	16,245		
Income (loss) from continuing operations	4,138	(39,075)	(23,225)	(28,806)	(32,771)
Discontinued operations:					
Income (loss) from discontinued operations, net of tax	(3,678)	612	2,188	646	

Gain on disposal of discontinued operations, net of tax			74,852		
Income (loss) from discontinued operations	(3,678)	612	77,040	646	
Net income (loss)	$ 460	$ (38,463)	$ 53,815	$ (28,160)	$ (32,771)
Cumulative dividends on Series A convertible preferred stock	$ (3,430)	$ (3,430)	(3,430)	(2,573)	(1,143)
Net income (loss) attributable to common stockholders	$ (2,970)	$ (41,893)	$ 50,385	$ (30,733)	$ (33,914)

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	Year Ended December 31,			Nine Months Ended September 30,	
	2009	2010	2011	2011	2012
				(unaudited)	
	(in thousands, except share and per share information)				
Income (loss) per common share					
Basic					
Continuing operations	$ 0.50	$ (26.77)	$ (16.60)	(19.68)	(2.36)
Discontinued operations	(2.60)	0.39	47.99	0.40	
Net income (loss)	(2.10)	(26.38)	31.39	(19.28)	(2.36)
Diluted					
Continuing operations	$ 0.29	$ (26.77)	$ (16.60)	(19.68)	(2.36)
Discontinued operations	(0.26)	0.39	47.99	0.40	
Net income (loss)	0.03	(26.38)	31.39	(19.28)	(2.36)
Weighted average number of common shares					
Basic	1,413,374	1,587,968	1,605,324	1,594,288	14,356,546
Diluted	14,081,186	1,587,968	1,605,324	1,594,288	14,356,546

The pro forma balance sheet data set forth below gives effect to the issuance and sale of 6,000,000 shares of our common stock in this offering at the assumed offering price of $12.05 per share, which was the last reported sale price of our common stock on The NASDAQ Global Market on November 23, 2012, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of September 30, 2012	
	Actual	Pro Forma
	(unaudited)	
	(in thousands)	
Consolidated Balance Sheet Data:		
Unrestricted cash and cash equivalents, and marketable securities	$ 62,472	$ 130,211
Restricted cash and cash equivalents, and marketable securities	275	275
Working capital	38,299	106,038
Total assets	67,014	134,753
Secured notes payable, including current portion	25,606	25,606
Accumulated deficit	(72,742)	(72,742)
Total stockholders' equity	$ 24,631	$ 92,370

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below with all of the other information included in this prospectus before deciding to invest in our common stock. 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 preparing for the commercial launch in the United States of our approved product, Oxtellar XR, in the first quarter of 2013 and our tentatively approved product, Trokendi XR, 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:

- establish commercial manufacturing arrangements with third-party manufacturers for 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 Oxtellar XR or 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.

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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 anticipation of the planned commercial launch of Oxtellar 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 material adverse impact on our anticipated revenues and liquidity.

Moreover, even if we are able to timely launch Oxtellar XR and 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 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 adverse events 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.

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We are rapidly expanding our operations to support commercial launch 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. 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 enter into commercial manufacturing arrangements with third parties for any approved product which, if delayed, could result in 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 planning for the commercialization of our approved product, Oxtellar XR, and 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, 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

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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 are building our commercial infrastructure to launch Oxtellar XR, our first approved product, and Trokendi XR, our tentatively approved product, in the United States. 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 this offering, together with cash on hand, will be sufficient to complete the development of and to fund the expected commercialization of Oxtellar XR and, upon final approval, Trokendi XR. We anticipate the commercial launch of Oxtellar XR will occur during the first quarter of 2013 and the commercial launch of Trokendi XR will occur during the third quarter of 2013 assuming the receipt of final approval by the FDA. If final FDA approval of Trokendi or the commercial launch of Oxtellar XR or 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;

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- 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 anti-epileptic drugs, or 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 a NCE) and risk a breakthrough seizure or tolerability issues in their patients. Although Oxtellar XR and Trokendi XR are not NCEs, if commercially launched, 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 a new drug application, or 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 (extended release topiramate), we submitted an NDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or 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 Drug Price Competition and Patent Term Restoration Act of 1984, or 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 file or approve our NDA submissions, request additional information before accepting our submissions for filing 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 controls 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

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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 active pharmaceutical ingredient, or 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

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

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. 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. 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.

In addition, 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, 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 Laboratories, Inc.'s, or Upsher-Smith, USL255 (extended release topiramate) is in Phase III clinical development for the treatment of epilepsy in adults. If Upsher-Smith's USL255 product is approved

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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. If we are unable to obtain marketing exclusivity for our products or product candidates, 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;

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- 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 institutional review board 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 institutional review board 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, 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

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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 15 were in late-stage (Phase II or later) clinical trials as of April 2010. 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. 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 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.

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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 current Good Manufacturing Practices, or 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

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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. In responding to the FDA's refusal-to-file letter for the Trokendi XR NDA, we had to address chemistry and manufacturing controls issues. 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, for our tentatively approved product, Trokendi XR, we are presently negotiating agreements with a leading contract manufacturing organization, or CMO, headquartered in North America for the manufacture of the final commercial product. If we fail to obtain the required commercial quantities on a timely basis 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 product candidates, the sales of those 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 abbreviated new drug application, or 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

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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 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.

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

If we are sued for infringing intellectual property rights of third parties, it 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.

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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 business as we have monetized the future revenues associated with Sanctura XR.

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. 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 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 business as we have monetized the future revenues associated with Oracea.

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

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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 business as we have monetized the future revenues associated with Intuniv.

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 U.S. Patent and Trademark Office, or 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 product candidate will not be subject to same risks.

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

We have a license agreement with United Therapeutics Corporation, or United Therapeutics, to use one of our proprietary technologies for an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension, or 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

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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 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. 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;

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- 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. For example, in responding to the FDA's refusal-to-file letter for the Trokendi XR NDA, we had to address chemistry and manufacturing controls issues. 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 a supply agreement for Oxtellar XR and are negotiating an agreement for 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 Pharmaceuticals, Inc., or Afecta, and Rune Healthcare Limited, or 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.

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

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

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

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

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

We 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,

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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 prospectus, as well as the trend toward programs aimed at reducing health care costs, 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;

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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 $5 million per occurrence, 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 intend to expand 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;

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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. This law, which we refer to as the PPACA, may have far reaching consequences for biopharmaceutical companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. 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

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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 PPACA 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 and motivate key members or if we lose 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.

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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 PPACA 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.

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

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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 were 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.

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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 perpetually refrain 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. In addition, we have agreed not to provide any services to, license any intellectual property rights to, or otherwise perform any work for certain pharmaceutical companies primarily engaged in the development and marketing of generic products through 2012. 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 or such companies.

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, TCD Royalty Sub LLC, or 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. We have incurred significant operating losses since our inception in 2005. We incurred net losses of approximately $17.3 million, $33.5 million, $38.5 million and $32.8 million in the years ended December 31, 2007, 2008 and 2010 and the nine months ended September 30, 2012, respectively. We incurred 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 September 30, 2012, we had an accumulated deficit of approximately $72.7 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 September 30, 2012 are approximately $52.3 million and $31.6 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,

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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, 2011 contains an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this public offering will eliminate this doubt. However, while we believe that the proceeds of this 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 not need additional capital 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 this 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, upon FDA approval, Trokendi XR, we may need to obtain additional capital through equity offerings, debt financing, payments under new or existing licensing and research and development collaboration agreements, or any combination thereof, in order to become cash flow positive and to develop and commercialize additional product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

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

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

- the 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;

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- 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. 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 generated 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 generated any 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 receive regulatory approval of our products and product candidates, including Oxtellar XR and Trokendi XR, and to successfully commercialize these products. Our ability to successfully commercialize our products depends on, among other things:

- our successful completion of ongoing and planned bioequivalence and clinical trials for our product candidates;

- our obtaining regulatory approvals for our product candidates, including final 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. Prior to commercializing any of our product candidates, we expect that any revenues we generate will fluctuate from quarter to quarter and year to year as a result of the timing and amount of development milestones and royalty revenues received under our collaboration license agreements, as our revenues from these arrangements are principally based on the achievement of clinical and commercial milestones outside of our control.

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;

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- 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 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. 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.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm 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. See "Summary Implications of being an Emerging Growth Company." 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 this offering.

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 transactions described in this offering, 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, 2011, we had approximately $37.5 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of approximately $5.0 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

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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 September 30, 2012, we had an accumulated deficit of $72.7 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

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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.

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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. Immediately after this offering, we will have outstanding 30,466,049 shares of common stock, based on the number of outstanding shares of common stock as of September 30, 2012, of which approximately 8,561,241 shares are currently freely tradeable and another 6,000,000 shares sold in this offering will be freely tradeable immediately after this offering unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities who are subject to lock-up agreements. Approximately 15,904,808 shares held by executive officers, directors and certain significant stockholders may be sold upon expiration of lock-up agreements 90 days after the date of this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. In addition, as of September 30, 2012, we had outstanding options to purchase 574,820 shares of common stock and warrants to purchase 143,749 shares of common stock, that, if exercised, will result in these additional shares becoming available for sale. Of the options to purchase 574,820 shares of common stock, a total of 415,500 of these shares would be subject to the lock-up agreements that expire 90 days after the date of this offering. A large portion of these shares and options are held by a small number of persons and investment funds. Moreover, after this offering, certain holders of shares of common stock will have rights, subject to some conditions, to 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 2,391,750 and 250,000 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, subject to the lock-up agreements referred to above. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock. See "Shares Eligible for Future Sale" for a more detailed description of sales that may occur in the future.

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

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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.

Following this proposed public offering of our common stock, our directors and their affiliated entities, and our executive officers will beneficially own, in the aggregate, approximately 74.3% 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

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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.

If you purchase shares of our common stock in this offering, you may not be able to resell those shares at or above the offering price. 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 September 30, 2012, we had options to purchase 574,820 shares of common stock outstanding, with exercise prices ranging from $0.40 to $12.92 per share and a weighted average exercise price of $4.89 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. Of the outstanding lender warrants to purchase 93,750 shares of common stock at an exercise price of $4.00 per share and 49,999 shares of common stock at an exercise price of $5.00 per share as of September 30, 2012, warrants to purchase 18,750 shares and 23,332 shares at exercise prices of $4 per share and $5 per share, respectively, remain outstanding following the October 2012 net exercise by one of the lenders.

The price of our common stock may fluctuate substantially.

Following this offering, 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;

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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.

Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return, if any.

The net proceeds from this offering will be used to fund the commercialization of Oxtellar XR and, upon FDA approval, Trokendi XR, research and development of our product candidates, to repay a portion of our indebtedness and for other general corporate purposes. Because of the number and variability of factors that will determine our use of the proceeds from the offering, their ultimate use may vary substantially from their currently intended use. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce significant income or investments that lose value. For a further description of our intended use of the proceeds of this offering, see "Use of Proceeds."

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this prospectus 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. These forward-looking statements include, among other things, statements about:

- our ability to commercialize our products and achieve profitability;
- the implementation of our corporate strategy;
- our future financial performance and projected expenditures;
- our ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies;
- our product research and development activities, including the timing and progress of our clinical trials, and projected expenditures;
- our ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize our product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidates;
- our ability to increase our manufacturing capabilities for our product candidates;
- our projected markets and growth in markets;

our product formulations and patient needs and potential funding sources;

our staffing needs;

our use of the proceeds from this offering; and

our plans for sales and marketing.

Any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. They may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in "Risk Factors" and elsewhere in this prospectus. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements. You should also review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission after the date of this prospectus. See "Where You Can Find Additional Information."

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of common stock that we are offering will be approximately $67.7 million. This projection is based upon an assumed public offering price of $12.05 per share, which was the last reported sale price on The NASDAQ Global Market on November 23, 2012, and after deducting underwriting discounts and commissions as well as estimated offering expenses payable by us.

We anticipate that we will use the net proceeds as follows:

- up to approximately $29.0 million for sales and marketing expenses to provide continued support of the commercial launch of Oxtellar XR and, after approval by the FDA, Trokendi XR;
- up to approximately $5.0 million for the manufacture and supply of commercial quantities of Oxtellar XR and Trokendi XR inventory to be sold in connection with such commercial launch;
- up to approximately $6.5 million to fund the continued clinical development of SPN-810, including: preclinical carcinogenicity testing; process development and scale up for commercial bulk active pharmaceutical ingredient;
- up to approximately $5.0 million to fund the continued clinical development of SPN-812, including preclinical carcinogenicity testing, process development for commercial bulk active pharmaceutical ingredient, continued Phase II testing and formulation development;
- up to approximately $6.0 million to fund Phase IV studies, and post-marketing formulation development and clinical work for Oxtellar XR and Trokendi XR;
- up to approximately $7.0 million to fund our payment obligations under the term loans under our secured credit facility; and
- the remainder, if any, for general corporate purposes including general and administrative expenses, capital expenditures and working capital.

We believe that net proceeds from this offering will be sufficient to fund the expected commercial launch of Oxtellar XR in the first quarter of 2013, to obtain the final FDA approval for Trokendi XR and to fund the expected commercial launch of Trokendi XR in the third quarter of 2013. In addition, our operating plan, including our planned commercialization of Oxtellar XR and Trokendi XR, may change as a result of many factors such as those described in the "Risk Factors" section of this prospectus.

As of September 30, 2012, we had $26.0 million of term loans outstanding under our secured credit facility, of which $11.9 million mature in August 2014 and $14.1 million mature in January 2015. The term loans bear interest at a fixed rate per annum of 11.0%. We used the proceeds of the term loans to fund ongoing clinical trials for Oxtellar XR, Trokendi XR and SPN-810, to prepare for manufacturing validation of Oxtellar XR and Trokendi XR, to support formulation for various clinical stage products, to prepare commercial marketing of Trokendi XR and for regulatory filing fees.

Although we currently anticipate that we will use the net proceeds as described above, there may be circumstances where a reallocation of funds may be necessary. The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our development and commercialization efforts, the progress of our clinical trials, whether or not we enter into strategic collaborations or partnerships and our operating costs and expenditures. Accordingly, our management will have significant flexibility in applying these net proceeds.

The costs and timing of drug development and commercialization and of regulatory approval, particularly conducting clinical studies, are highly uncertain, are subject to substantial risks and can often change. Accordingly, we may change the allocation of use of these proceeds as a result of contingencies such as the progress of research, progress of clinical trials, ability to secure approval of our products from the FDA, uptake of our products in the marketplace and competitive responses.

Pending use of the proceeds from this offering as described above or otherwise, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

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MARKET PRICE OF COMMON STOCK

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 (through November 23, 2012)	$ 14.98	$ 10.80

On November 23, 2012, the last reported sale price of our common stock on The NASDAQ Global Market was $12.05 per share. As of November 23, 2012, we had 47 holders of record of our common stock. The actual number of common stockholders is greater than these numbers 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.

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DIVIDEND POLICY

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.

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CAPITALIZATION

The following table sets forth our cash and capitalization as of September 30, 2012:

- on an actual basis; and
- on a pro forma basis to reflect our receipt of the estimated net proceeds from our sale of 6,000,000 shares of common stock offered hereby at the assumed offering price of $12.05 per share, which was the last reported sale price of our common stock on The NASDAQ Global Market on November 23, 2012, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table in conjunction with the sections of this prospectus entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and with our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	Actual	Pro Forma (unaudited)
	(in thousands, except share and per share information)	
Balance Sheet Data:		
Unrestricted cash and cash equivalents and marketable securities	$ 62,472	$ 130,211
Restricted cash and cash equivalents and marketable securities	275	275
Debt outstanding	$ 25,606	$ 25,606
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value 65,000,000 shares authorized, 0 shares issued and outstanding, actual		
Common stock, $0.001 par value 130,000,000 shares authorized, 24,466,049 shares issued and outstanding; and 130,000,000 shares authorized, 30,466,049 shares issued and outstanding, pro forma	24	30
Additional paid-in capital	97,378	165,111
Accumulated other comprehensive income (loss)	(29)	(29)
Accumulated deficit	(72,742)	(72,742)
Total stockholders' equity	24,631	92,370
Total capitalization	$ 50,237	$ 117,976

The table above does not include:

- 574,820 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2012 at a weighted average exercise price of $4.89 per share;
- 2,391,750 shares of common stock reserved for future issuance under our 2012 Equity Incentive Plan;
- 250,000 shares of common stock reserved for future issuance under our 2012 Employee Stock Purchase Plan;

49,137 shares of common stock issued in October 2012 upon the cashless net exercise of lender warrants with an exercise price of $4.00 per share;

15,172 shares of common stock issued in October 2012 upon the cashless net exercise of lender warrants with an exercise price of $5.00 per share;

18,750 shares of common stock issuable upon the exercise of warrants at an exercise price of $4.00 per share; and

23,332 shares of common stock issuable upon the exercise of warrants at an exercise price of $5.00 per share.

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SELECTED CONSOLIDATED 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 prospectus. The consolidated financial data as of December 31, 2010 and 2011 and for the fiscal years ended December 31, 2009, 2010 and 2011 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The consolidated financial data as of December 31, 2007, 2008 and 2009 and for the fiscal years ended December 31, 2007 and 2008 are derived from our audited consolidated financial statements not included in this prospectus. The consolidated financial data as of September 30, 2012 and for the nine months ended September 30, 2011 and 2012 are derived from our unaudited consolidated financial statements which are presented elsewhere in this prospectus, and have been prepared on the same basis as the audited consolidated financial statements and the notes thereto, and include, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the information for the unaudited interim periods. The operating results for the nine months ended September 30, 2012 may not be indicative of the operating results for the full year or any other period.

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 prospectus.

	Year Ended December 31,					Nine Months Ended September 30,	
	2007	2008	2009	2010	2011	2011	2012
						(unaudited)	
	(in thousands, except share and per share information)						
Consolidated Statement of Operations Data:							
Revenue:							
Development and milestone revenue	$ 1,405	$ 2,497	$ 1,050	$ 106	$ 803	$ 761	$ 391
Royalty revenue	2,828	1,512	36,875				
Total revenues	4,233	4,009	37,925	106	803	761	391
Operating Expenses:							
Research and development	19,269	30,463	29,260	35,149	30,627	23,126	18,367
Selling, general and administrative	4,011	4,287	4,649	5,080	7,928	5,143	11,450
Total operating expenses	23,280	34,750	33,909	40,229	38,555	28,269	29,817
Operating income (loss) from continuing operations	(19,047)	(30,741)	4,016	(40,123)	(37,752)	(27,508)	(29,426)
Other income (expense):							
Interest income	1,773	1,036	122	107	31	29	91
Interest expense					(1,866)	(1,357)	(2,771)
Other				542	117	30	(665)
Total other income (expense)	1,773	1,036	122	649	(1,718)	(1,298)	(3,345)
	(17,274)	(29,705)	4,138	(39,474)	(39,470)	(28,806)	(32,771)

Income (loss) from continuing operations before income taxes							
Income tax benefit				399	16,245		
Income (loss) from continuing operations	(17,274)	(29,705)	4,138	(39,075)	(23,225)	(28,806)	(32,771)
Discontinued operations:							
Income (loss) from discontinued operations, net of tax		(3,777)	(3,678)	612	2,188	646	
Gain on disposal of discontinued operations, net of tax					74,852		
Income (loss) from discontinued operations		(3,777)	(3,678)	612	77,040	646	
Net income (loss)	$ (17,274)	$ (33,482)	$ 460	$ (38,463)	$ 53,815	$ (28,160)	$ (32,771)
Cumulative dividends on Series A convertible preferred stock	(3,430)	(3,430)	(3,430)	(3,430)	(3,430)	(2,573)	(1,143)
Net income (loss) attributable to common stockholders	$ (20,704)	$ (36,912)	$ (2,970)	$ (41,893)	$ 50,385	$ (30,733)	$ (33,914)
Income (loss) per common share:							
Basic							
Continuing operations	$ (19.47)	$ (26.94)	$ 0.50	$ (26.77)	$ (16.60)	$ (19.68)	$ (2.36)
Discontinued operations		(3.07)	(2.60)	0.39	47.99	0.40	
Net income (loss)	(19.47)	(30.01)	(2.10)	(26.38)	31.39	(19.28)	(2.36)
Diluted							
Continuing obligations	$ (19.47)	$ (26.94)	$ 0.29	$ (26.77)	$ (16.60)	$ (19.68)	$ (2.36)
Discontinued obligations		(3.07)	(0.26)	0.39	47.99	0.40	
Net income (loss)	(19.47)	(30.01)	0.03	(26.38)	31.39	(19.28)	(2.36)
Weighted average number of common shares:							
Basic	1,063,433	1,229,956	1,413,374	1,587,968	1,605,324	1,594,288	14,356,546
Diluted	1,063,433	1,229,956	14,081,186	1,587,968	1,605,324	1,594,288	14,356,346

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	Year Ended December 31,					Nine Months Ended September 30,
	2007	2008	2009	2010	2011	2012
			(in thousands)			(unaudited)
Consolidated Balance Sheet Data:						
Unrestricted cash and cash equivalents and marketable securities	$ 25,592	$ 60,380	$ 66,524	$ 32,704	$ 48,544	$ 62,472
Restricted cash and cash equivalents and marketable securities(1)	281	6,281	2,076	1,714	245	275
Working capital	22,674	61,183	62,847	24,607	30,629	38,299
Total assets	31,907	77,134	79,899	47,009	53,730	67,014
Notes payable, including current portion					29,486	25,606
Non-current liabilities of discontinued operations		75,000	75,000	75,000		
Series A convertible preferred stock	49	49	49	49	49	
Accumulated deficit	(22,301)	(55,782)	(55,323)	(93,786)	(39,971)	(72,742)
Total stockholders' equity (deficit)	26,635	(6,747)	(6,156)	(44,320)	9,443	24,631

(1) Restricted cash and cash equivalents are included in assets of discontinued operations.

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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 appearing at the end of this prospectus. 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 prospectus.

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, Inc. We are planning for the commercial launch of two neurology products for the treatment of epilepsy in 2013 and are developing multiple product candidates in psychiatry to address the large market opportunity in the treatment of ADHD, including ADHD patients with impulsive aggression. We intend to market our products in the United States through our focused sales force targeting specialty physicians, including neurologists and psychiatrists, and to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

On October 19, 2012, the Food and Drug Administration, or FDA, granted final approval of Oxtellar XR (extended release oxcarbazepine), formerly known as SPN-804. We anticipate the commercial launch of Oxtellar XR to occur during the first quarter of 2013. On November 15, 2012, we received confirmation that the FDA granted Oxtellar XR a three year marketing exclusivity. On June 25, 2012, the FDA granted tentative approval of Trokendi XR (extended release topiramate), formerly known as SPN-538. The final approval for Trokendi XR may not be made effective until the expiration of the marketing exclusivity period that Topamax has regarding safety information of topiramate in a specific pediatric population. This marketing exclusivity expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. We anticipate the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA.

Our psychiatry product candidates include SPN-810 (molindone hydrochloride), which completed a Phase IIb trial that showed positive topline results as a novel treatment for impulsive aggression in patients with ADHD, and SPN-812 which completed a Phase IIa trial as a novel non-stimulant treatment for ADHD.

In addition to Oxtellar XR, Trokendi XR, SPN-810 and SPN-812, we have several additional product candidates in various stages of development, including SPN-809 for which we submitted an 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 products and 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. Immediate release formulations of oxcarbazepine and topiramate are available in generic form and are marketed 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

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2008, respectively. 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,[1] reduce side effects and improve tolerability as compared to immediate release products.[2]

We are also developing treatments for new indications in diseases such as ADHD and its coexisting disorders. We are developing SPN-810, which completed a Phase IIb trial as a novel treatment for impulsive aggression in patients with ADHD. We are in the process of evaluating the results of this Phase IIb trial. 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] In addition, we have a number of other product candidates in various stages of development such as SPN-809, which would represent a novel mechanism of action for the U.S. anti-depressant market.

Historically, our revenues have been generated through research and development agreements, which included fees for development services provided to customers and payments for achievement of specified development, regulatory and sales milestones, as well as royalties on product sales of licensed products, Oracea, Sanctura XR, and Intuniv. Since our inception in 2005, we have generated no revenue from our own sales of our products and have incurred significant operating losses. As of September 30, 2012, we had an accumulated deficit of approximately $72.7 million and a total stockholders' equity of approximately $24.6 million. We expect to incur net losses and negative cash flow from operating activities for the foreseeable future in connection with our planned commercialization of Oxtellar XR and Trokendi XR assuming we receive final FDA approval, and as we continue to develop and seek marketing approval for other product candidates.

History of our Company

We have a successful track record of developing novel products by applying proprietary technologies to known drugs to improve existing therapies and to 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), each of which is marketed by Shire; Equetro (carbamazepine), marketed by Validus Pharmaceuticals Inc.; Sanctura XR (trospium chloride), marketed by Allergan; and Oracea (doxycycline), marketed by Galderma. Throughout our 20-year history, we have continued our commitment to innovation with a focus for the past six years on developing our own product candidates in neurology and psychiatry.

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

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

(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.*

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We have historically raised capital through venture capital equity financings, the monetization of certain future royalty streams under our existing licenses for Oracea, Sanctura XR and Intuniv, and our initial public offering. In connection with the commencement of our operations, in December 2005 and February 2006, we raised approximately $45.0 million through the sale of 45 million shares of Series A convertible preferred stock. We raised approximately $63.3 million in net proceeds in April 2008 through the monetization of future royalty payment rights and other license rights for both Oracea and Sanctura XR. In that deal, we transferred the license rights to both Oracea and Sanctura XR to Royalty Sub, which issued $75.0 million in non-recourse notes in a private placement to institutional investors. All milestone and royalty revenues due from net sales of Oracea and Sanctura XR were required to be used to satisfy the payment of principal and interest on the non-recourse notes. The non-recourse notes were non-recourse to our Company and were secured by Royalty Sub's assets, which include the royalty payment rights and other rights related to net sales of Oracea and Sanctura XR. In addition, we entered into an agreement with an affiliate of Shire plc in May 2009, whereby the Shire affiliate paid us a one-time, lump-sum payment of approximately $36.9 million as consideration for a royalty-free, fully paid-up license for Intuniv.

Pursuant to a Unit Purchase Agreement executed on December 14, 2011, we sold 100% of our equity ownership interests in Royalty Sub to an entity affiliated with OrbiMed Advisors LLC, one of our stockholders, hereafter referred to as the "Purchase Transaction." The purchase price consisted of $27.0 million 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 Royalty Sub, 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 non-recourse notes, plus (c) the aggregate redemption price paid, if any, to redeem any of the non-recourse notes, from any transaction that refinances or liquidates the equity interests in Royalty Sub or the non-recourse 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 us. We entered into the Purchase Transaction with an entity affiliated with OrbiMed Advisors LLC, which offered the highest purchase price.

Pursuant to the Purchase Transaction, we retained duties and obligations under the non-recourse notes and related agreements, including the Purchase and Sale Agreement, the Residual License Agreements and the Servicing Agreement, for so long as the non-recourse notes remain outstanding. For example, pursuant to the Purchase Transaction, 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.

We also retained certain duties and obligations under the ongoing Servicing Agreement. We 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. Specifically, we are 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 non-recourse 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 us the assignment and transfer of

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all the licensed intellectual property and all of our rights and obligations under the license agreements subject to certain conditions described in the Unit Purchase Agreement.

We accounted for the Purchase Transaction as a sale of a subsidiary and recorded the resulting gain of approximately $74.9 million as "gain on disposal of discontinued operations, net of tax" in our consolidated statements of operations. The gain on disposal of discontinued operations was calculated as the aggregate of the fair value of the consideration and the carrying value of Royalty Sub's assets and liabilities, less our fees and expenses. Since the assets and liabilities of Royalty Sub had identifiable operations and cash flows that are independent from the Company and we do not have a significant continuing involvement with Royalty Sub's operations, the sale of Royalty Sub is reported as discontinued operations in our consolidated statements of operations. Accordingly, the gain on the sale of Royalty Sub, as well as any results of operations related to Royalty Sub, are presented as discontinued operations for all periods presented. If we receive the milestone payment, the fair value of amounts received, less any related fees and expenses, will be recorded as "gain on disposal of discontinued operations, net of tax," a component of discontinued operations.

We also have a license agreement with United Therapeutics Corporation, or United Therapeutics, to use one of our proprietary technologies for an oral formulation of treprostinil for the treatment of PAH, as well as for other indications. Remaining milestone payments to us could total up to approximately $6.0 million, which includes milestone payments that could total $2.0 million for the satisfaction of development milestones of oral treprostinil in PAH. This oral formulation of treprostinil diethanolamine, or treprostinil, is the subject of an NDA for PAH for which the FDA issued on October 23, 2012 a complete response letter declining to approve the product. We do not expect to receive any royalties for this oral formulation in this indication until United Therapeutics launches this product after receiving final marketing approval from the FDA. We are also entitled to receive milestones and royalties for use of this formulation in other indications.

In January 2011, we 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, we drew down $15.0 million and a second $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%. The initial $15.0 million of term loans drawn down in January 2011 will mature on August 1, 2014. The second $15.0 million of term loans drawn down in December 2011 will mature on January 1, 2015. In connection with the initial drawdown in January 2011, we issued to the lenders warrants that are exercisable for an aggregate of 93,750 shares of common stock at an exercise price of $4.00 per share. In connection with the drawdown of the second $15.0 million under our secured credit facility on December 31, 2011, we issued the lenders warrants that are exercisable for an aggregate of 49,999 shares of common stock at an exercise price of $5.00 per share. The warrants expire on December 30, 2021. In October 2012, one of the lenders exercised both tranches of its warrants for an aggregate of 101,667 shares of common stock using a cashless net share settlement, resulting in the issuance of 64,309 shares of common stock to this lender.

These warrants are accounted for as a derivative liability, and as such, we reflect the liability at its estimated 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 May 1, 2012, we completed our initial public offering, in which 10,000,000 shares of our common stock were sold at a price of $5.00 per share. Additionally, the underwriters of our initial public offering exercised the full amount of their over-allotment option resulting in the sale of an additional 449,250 shares of our common stock at a price of $5.00 per share, resulting in net proceeds of $47.6 million after expenses of approximately $4.7 million from the initial public. Upon consummation of the initial public offering, 49,000,000 outstanding shares of Series A preferred stock automatically converted to 12,249,998 shares of common stock.

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See "Liquidity and Capital Resources Financing History and Future Capital Requirements" for additional details regarding the foregoing transactions.

Financial Overview

Revenue

Our historical revenues have been generated through collaboration and research and development agreements. These agreements included fees for development services provided to customers and payments for achievement of specified development, regulatory and sales milestones, which comprise our development and milestone revenues, as well as royalties on product sales of licensed products (i.e., Oracea, Sanctura XR, and Intuniv), which comprise our royalty revenues. Until such time that we begin generating revenues from the sales of our own approved product candidates, we expect that development, milestone and royalty revenues from licensed products other than Oracea, Sanctura XR, and Intuniv will continue to represent our primary sources of revenues.

We recognize development and milestone revenues related to research and development agreements pursuant to which various third parties have accessed our proprietary technologies. These arrangements generally provided for fees for research and development services rendered, including milestone payments at the conclusion of the research period upon achieving specified events. Over time, we do not expect these historical revenues relating to development and milestone revenues to be significant as we continue to focus on the development and potential commercialization of our own product candidates.

We recognize royalty revenues from our collaboration agreements. Royalty revenues consist of payments received from our various collaborative partners related to the sales of products that utilize our proprietary technologies under these collaboration agreements.

The table below summarizes the revenues that we have recognized from our collaboration arrangements.

	Year Ended December 31,			Nine Months Ended September 30,	
	2009	2010	2011	2011	2012
				(unaudited)	
		(in thousands)			
Continuing operations:					
Development and milestone revenues collaboration arrangements	$ 1,050	$ 106	$ 803	$ 761	$ 391
Royalty revenues Intuniv	36,875				
Total continuing operations revenues	37,925	106	803	761	391
Discontinued operations:					
Development and milestone revenues Oracea & Sanctura XR	500				
Royalty revenues Oracea & Sanctura XR	8,088	13,404	14,398	9,887	
Total discontinued operations revenues	8,588	13,404	14,398	9,887	
Total revenues	$ 46,513	$ 13,510	$ 15,201	$ 10,648	$ 391

From and after April 15, 2008, all development and milestone revenues and royalty revenues due from net sales of Oracea and Sanctura XR were required to be used to satisfy the payment of principal and interest on the non-recourse notes of Royalty Sub. After the closing of the Purchase Transaction in December 2011, we no longer receive any revenues from such sales nor are we required to satisfy the payment of principal and interest on the non-recourse notes. We also received in May 2009, a one-time payment of approximately $36.9 million from Shire plc as consideration for a royalty-free, fully paid-up license to

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Shire plc for Intuniv and, as a result, we no longer will receive any royalty payments with respect to the net sales of Intuniv.

If we commercialize Oxtellar XR and Trokendi XR, which we expect to commercially launch in the first quarter of 2013 and, upon FDA approval, third quarter 2013, respectively, or obtain approval for any of our other product candidates, we would expect to begin to generate revenues from product sales and, over time, we expect that our future revenues would begin to be principally derived from product sales as compared to development and milestone revenues and royalty revenues.

Prior to commercializing any of our product candidates, we expect that any revenues we generate will fluctuate from quarter to quarter as a result of the timing and amount of development and milestone revenues and royalty revenues received under our collaboration license agreements, as our revenues from these arrangements are principally based on the achievement of clinical and commercial milestones outside of our control. If we fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expense

Research and development expenses consist of costs incurred in connection with the development of our and our collaborators' product candidates. These expenses consist primarily of:

- employee-related expenses, which include salaries and benefits;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial materials;
- the cost of manufacturing validation tests, if these materials are manufactured prior to obtaining regulatory approval;
- costs related to facilities, depreciation and other allocated expenses;
- license fees for, and milestone payments related to, in-licensed products and technology;
- stock-based compensation expense to employees and consultants engaged in research and development activities; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used in future research and development activities are initially recorded as prepaid expenses and expensed as the activity is performed or when the goods have been received.

Since our founding, we have developed and evaluated a series of CNS product candidates through Phase I pharmacokinetic trials. In 2008, we conducted a review of our portfolio of product candidates and rationalized the programs based on clinical profiles, expected required resources to complete development, intellectual property, existing treatment options and commercial opportunity. As a result of that review, we elected to concentrate on our two epilepsy product candidates and the product candidates that comprise our psychiatry portfolio. We intend to continue to strategically invest in our pipeline, and the commitment of funding for each subsequent stage of our development programs is dependent upon, among other things, the receipt of clear, positive data.

The majority of our external costs relate to later-stage product candidates, as costs associated with later-stage clinical trials are, in most cases, more significant than those incurred in earlier stages of our pipeline. For example, the external costs related to our Oxtellar XR program were higher than our other programs in 2009 through 2011 because Oxtellar XR completed Phase III clinical trials in 2011 that began in late 2008.

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We track external development expenses and direct personnel expense on a program-by-program basis. Costs related to facilities, depreciation, employee benefits and bonuses, stock-based compensation, research and development management and research and development support services and supplies are not charged to specific programs, because the number of clinical and preclinical product candidates or development projects tends to vary from period to period and internal resources are utilized across and benefit multiple programs over any given period of time. The following table is a summary of our research and development expenses for the years ended December 31, 2009, 2010 and 2011 and the nine months ended September 30, 2011 and 2012 and from our inception in late 2005 to September 30, 2012.

	Year Ended December 31,			Nine Months Ended September 30,		From Inception to September 30
	2009	2010	2011	2011	2012	2012
				(unaudited)		(unaudited)
	(in thousands)					
Trokendi XR	$ 6,464	$ 9,864	$ 6,262	$ 5,675	$ 3,205	$ 31,642
Oxtellar XR	10,027	12,664	10,959	8,475	3,458	52,252
SPN-810	3,333	2,150	4,152	2,919	3,970	17,995
SPN-812 and SPN-809	680	2,042	1,166	623	1,461	10,705
Other research and development programs	426	690	204	3	37	7,491
Development expenses general	8,330	7,739	7,884	5,431	6,236	52,086
Total research and development expenses	$ 29,260	$ 35,149	$ 30,627	$ 23,126	$ 18,367	$ 172,171

The successful development of our product candidates is highly uncertain and subject to a number of risks including, but not limited to:

- The duration of clinical trials varies substantially according to the type, complexity and novelty of the product candidate;
- The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- The duration and cost of nonclinical studies and clinical trials may vary significantly over the life of a product candidate and are difficult to predict;
- The costs, timing and outcome of regulatory review of a product candidate are uncertain; and
- The emergence of competing technologies and products and other adverse market developments could impede our commercial efforts.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as ongoing assessments of such product candidate's commercial potential. Although we have received tentative FDA approval of Trokendi XR and anticipate receiving final FDA approval of

Trokendi XR in June 2013, the uncertainties surrounding the timing and outcome of final approval of Trokendi XR or other product candidates still exist and make it

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difficult to estimate precisely when, if ever, Trokendi XR or any other product candidates will generate revenues and cash flows. Additionally, with respect to our other product candidates, we cannot currently estimate with any degree of certainty the amount of time or money that we will be required to expend in the future on our other product candidates to complete current or future clinical or pre-commercial stages prior to their regulatory approval, if such approval is ever granted, or when, if ever, the other product candidates will generate revenues and cash flows.

We expect our research and development costs to continue to be substantial for the foreseeable future 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 may elect to expand existing collaborative relationships or to seek new partnerships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, marketing, information technology, legal and human resources functions. Other selling, general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, prosecution and defense costs, professional fees for legal, consulting, auditing and tax services, and stock compensation expense for the personnel identified above.

We expect that our selling, general and administrative expenses in 2012 will be higher than in 2010 and 2011 as we plan to continue to increase spending related to the build-out of our commercial infrastructure for the anticipated launch of both Oxtellar XR and Trokendi XR (upon receiving FDA final approval) in the United States. We are internally developing a sales force to market Oxtellar XR, initially consisting of a certain number of field sales representatives to support the commercial launch of the product. We would then seek to expand our sales force to proceed with the commercial launch of Trokendi XR once we receive final FDA approval of this product. Having two epilepsy products that can be promoted to the same physician audience by the same sales force would allow us to leverage our commercial infrastructure with these prescribers. Subsequent to the completion of our initial public offering in May 2012, we have incurred and expect to continue to incur greater expenses relating to our operations as a public company, including increased payroll and increased consulting, legal and compliance, accounting, insurance and investor relations costs.

Other Income and Expense

Other income and expense is comprised of interest income and expense, and other miscellaneous items.

Interest income consists of interest earned on our cash and cash equivalents and marketable securities. The primary objective of our investment policy is capital preservation.

Interest expense consists of interest on the notes issued under our secured credit facility, as well as the amortization of the related deferred financing costs and debt discounts. The balance of the secured notes payable was $30.0 million and $26.0 million as of December 31, 2011 and September 30, 2012, respectively. Interest expense for the year ended December 31, 2011 and the nine months ended September 30, 2011 and 2012 was approximately $1.9 million, $1.4 million, and $2.8 million, respectively. Interest expense on the non-recourse notes includes amortization of the related deferred financing costs and was $12.3 million, $12.4 million, $11.7 million, $9.2 million, and zero for the years ended December 31, 2009, 2010 and 2011 and the nine months ended September 30, 2011 and 2012, respectively, and is included as an element of discontinued operations (see Note 7 to our consolidated financial statements).

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Net Operating Losses and Tax Carryforwards

As of December 31, 2011, we had approximately $37.5 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of approximately $5.0 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. 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. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

Net Income and Loss

We have incurred significant net losses since our inception in 2005, with the exception of 2009 and 2011, when we generated net income of $0.5 million and $53.8 million, respectively, due to one-time items. The net income in 2009 was principally due to the one-time payment of $36.9 million that we received from Shire plc as consideration for a royalty-free, fully-paid-up license to Shire plc for Intuniv. The net income in 2011 was principally due to a gain on the sale of Royalty Sub of $74.9 million, which was reported as discontinued operations. We expect to continue to incur net losses for the foreseeable future as we commercialize Oxtellar XR and, upon FDA approval, Trokendi XR, and as we continue to develop our product portfolio, seek regulatory approval, and, upon final FDA approval, if obtained, commercialize our other product candidates.

Results of Operations

Comparison of the Nine Months Ended September 30, 2011 and September 30, 2012

	Nine Months Ended September 30,		Increase/ (decrease)
	2011	2012	
	(unaudited) (in thousands)		
Revenues:			
Development and milestone revenues	$ 761	$ 391	$ (370)
Total revenues	761	391	
Operating Expenses:			
Research and development	23,126	18,367	(4,759)
Selling, general and administrative	5,143	11,450	6,307
Total operating expenses	28,269	29,817	
Operating loss from continuing operations	(27,508)	(29,426)	
Interest income and other income (expense), net	59	(574)	(633)
Interest expense	(1,357)	(2,771)	1,414
Total other income (expense)	(1,298)	(3,345)	
Loss from continuing operations	$ (28,806)	$ (32,771)	
Income from discontinued operations, net of tax	646		(646)
Net Loss	$ (28,160)	$ (32,771)	

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Revenues

Our revenues were approximately $0.4 million for the nine months ended September 30, 2012 compared to $0.8 million for the same period in 2011, representing a decrease of $0.4 million. This decrease was principally attributable to a one-time milestone payment of $0.8 million received in 2011 under our license agreement with United Therapeutics offset by recognition of revenue under our agreement with Stendhal in 2012.

Research and Development Expense

Our research and development expenses were $18.4 million for the nine months ended September 30, 2012, compared to $23.1 million for the same period in 2011, a decrease of $4.7 million or 21%. This decrease was attributable to a decrease in clinical trial costs for Oxtellar XR of approximately $5.0 million as the Phase III trial for Oxtellar XR was substantially completed by the first quarter of 2012, offset by increases in clinical trial costs for SPN-810 and general expenses.

Selling, General and Administrative Expense

Our selling, general and administrative expenses were $11.5 million for the nine months ended September 30, 2012 compared to $5.1 million for the same period in 2011, representing an increase of approximately $6.4 million or approximately 123%. This increase is mainly due to an increase in marketing costs associated with preparing for commercial launches of Oxtellar XR and Trokendi XR which are now expected to occur during the first and, subject to obtaining marketing approval, third quarter of 2013, respectively.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net was approximately $0.6 million for the nine months ended September 30, 2012 compared to $0.1 million for the same period in 2011, representing an decrease of $0.7 million. The decrease is primarily the result of an increase in warrant income valuations during the nine months ended September 30, 2012 offset by fluctuations in foreign currency rates.

Interest Expense

Interest expense was approximately $2.8 million for the nine months ended September 30, 2012, compared to $1.4 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.

Loss from continuing operations

Loss from continuing operations was $32.8 million for the nine months ended September 30, 2012, compared to a loss of $28.8 million for the same period in 2011. This increase is primarily due to the increase in sales and marketing costs offset by the decrease in clinical trial costs.

Income from discontinued operations

Income from discontinued operations was $0.6 million for the nine months ended September 30, 2011. There were no activities related to discontinued operations in 2012, as we sold our membership interests in TCD Royalty Sub, LLC in December 2011.

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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 of dollars)		
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	
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 $750,000 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 is 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 is 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.

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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 is 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 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 of $16.2 million in 2011, which was utilized to reduce income tax expense from discontinued operations income.

Income from discontinued operations

Income from discontinued operations was $2.2 million for the year ended December 31, 2011 compared to $0.6 million for the same period in 2010, representing an increase of approximately $1.6 million. This increase is mainly due to increased royalty revenues of approximately $1.0 million from Oracea and Sanctura XR for the year ended December 31, 2011. Additionally, in 2011, we realized a gain on sale of 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. Results for prior years have been restated for discontinued operations. For additional details on our discontinued operations, refer to Note 8 to our consolidated financial statements.

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Comparison of Year Ended December 31, 2010 and Year Ended December 31, 2009

	Year Ended December 31, 2009	2010	Increase/ (decrease)
	(in thousands of dollars)		
Revenues:			
Development and milestone revenues	$ 1,050	$ 106	$ (944)
Royalty revenues	36,875		(36,875)
Total revenues	37,925	106	
Operating Expenses:			
Research and development	29,260	35,149	5,889
Selling, general and administrative	4,649	5,080	431
Total operating expenses	33,909	40,229	
Operating income (loss) from continuing operations	4,016	(40,123)	
Interest income and other income (expense), net	122	649	527
Income (loss) from continuing operations before income taxes	4,138	(39,474)	
Income tax benefit		399	
Income (loss) from continuing operations	4,138	(39,075)	(43,213)
Discontinued operations:			
Income (loss) from discontinued operations, net of tax	(3,678)	612	
Income (loss) from discontinued operations	(3,678)	612	4,296
Net income (loss)	$ 460	$ (38,463)	

Revenues

Our revenues were approximately $0.1 million for the year ended December 31, 2010 compared to approximately $37.9 million for the same period in 2009, representing a decrease of $37.8 million. This decrease was principally attributable to the one-time, lump-sum payment of approximately $36.9 million that we received in May 2009 from Shire plc as consideration for a royalty-free, fully paid-up license to Shire plc for Intuniv. We also generated lower development and milestone revenues for the year ended December 31, 2010 of approximately $106,000 as compared to approximately $1.1 million in the same period in 2009 due to our focus on the development of our own product candidates as opposed to developing product candidates for third parties.

Research and Development

Our research and development expenses were $35.1 million for the year ended December 31, 2010 compared to $29.3 million for the same period in 2009, representing an increase of approximately $5.9 million, or approximately 20%. This increase is primarily attributable to an increase in clinical trial costs of approximately $4.6 million, the largest portion of which was due to the costs for our Phase III clinical trial for Oxtellar XR, and higher manufacturing costs of approximately $0.9 million principally associated with pre-validation work performed by our commercial manufacturers for both Oxtellar XR and Trokendi XR.

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Selling, General and Administrative

Our selling, general and administrative expenses were $5.1 million for the year ended December 31, 2010 compared to $4.6 million for the same period in 2009, representing an increase of approximately $0.5 million or approximately 11%. This increase is primarily the result of costs incurred in connection with the development of our sales and marketing infrastructure and higher compensation expenses resulting from higher stock compensation expense and the hiring of additional employees, partially offset by lower patent and outside consulting fees incurred during the year ended December 31, 2010.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net was $0.6 million for the year ended December 31, 2010 compared to $0.1 million for the same period in 2009, representing an increase of $0.5 million. The $0.5 million increase is primarily the result of our receipt of approximately $0.5 million in November 2010 for qualifying 2009 development expenses under the federal Qualifying Therapeutic Discovery Project Program.

Income (Loss) from continuing operations

Loss from continuing operations was $39.1 million for the year ended December 31, 2010 compared to net income of $4.1 million for the same period in 2009, representing a decrease of approximately $43.2 million. This decrease is principally a result of approximately $36.9 million that we received in May 2009 from Shire plc as consideration for a royalty-free, fully paid-up license for Intuniv as well as higher research and development costs of approximately $5.9 million incurred in 2010 associated with the continued development of our most advanced product candidates, Trokendi XR and Oxtellar XR.

Income (loss) from discontinued operations

Income from discontinued operations was $0.6 million for the year ended December 31, 2010 compared to a loss of $3.7 million for the same period in 2009, representing an increase of approximately $4.3 million. This increase is mainly due to increased royalty revenues of approximately $5.3 million from Oracea and Sanctura XR for the year ended December 31, 2010.

Liquidity and Capital Resources

In December 2005, we acquired substantially all of the assets of Shire Laboratories Inc. from Shire plc in exchange for a cash payment of approximately $0.8 million and the issuance of 4 million shares of our Series A convertible preferred stock at a value of $1.00 per share. In connection with the commencement of our operations, in December 2005 and February 2006, we raised approximately $45.0 million through the sale of 45 million shares of Series A convertible preferred stock. To date, we have not generated any revenues from product sales. Since our inception in 2005, we have funded our operations largely through venture capital equity and other financings, such as the monetization of future royalties due to us from existing license agreements with Endo Pharmaceuticals Solutions Inc., Galderma Laboratories, L.P. and Shire plc pursuant to which we have received net proceeds of approximately $100.2 million through December 31, 2011. Additionally, in each of January 2011 and December 2011, we drew down $15.0 million under our secured credit facility, which charges interest at a fixed rate of 11.0% per annum. The initial $15.0 million of term loans drawn down in January 2011 will mature in August 2014. The second $15.0 million of term loans drawn down in December 2011 will mature in January 2015. In May 2012, we completed our initial public offering in which we sold 10,449,250 shares of our common stock and received net proceeds of $47.6 million, net of offering and financing costs. As of September 30, 2012, we had unrestricted cash, cash equivalents and marketable securities of approximately $62.5 million.

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Financing History and Future Capital Requirements

Non-recourse Notes

In April 2008, we raised approximately $63.3 million in net proceeds (i.e., net of financing costs and a required interest reserve of $8.0 million) through a private placement to institutional investors of $75.0 million aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due April 15, 2024 (the "Non-recourse Notes") issued by Royalty Sub. As part of the transaction, pursuant to a Purchase and Sale Agreement and Residual License Agreements executed by us and Royalty Sub, we transferred to Royalty Sub our payment rights until the Non-recourse Notes are paid in full and other license rights related to two products that utilize our proprietary technologies: Oracea, which is marketed by Galderma as a treatment for rosacea; and Sanctura XR, which is marketed by Allergan as a treatment for overactive bladder. The Non-recourse Notes are secured by these royalty payments and other license rights, as well as by the pledge of the outstanding equity interest in Royalty Sub. While the Non-recourse Notes are outstanding, all royalty and milestone payments due from net sales of Oracea and Sanctura XR go to the payment of interest, and when available, to the principal on such Non-recourse Notes. Pursuant to the Unit Purchase Agreement executed on December 14, 2011, where we sold 100% of our equity ownership interests in Royalty Sub for a purchase price consisting of $27.0 million, assumption of all assets and liabilities and a milestone payment of $3.0 million payable upon certain events, we retained certain duties and obligations under the Non-recourse Notes and related agreements, including the Purchase and Sale Agreement, the Residual License Agreements and the Servicing Agreement.

Until the Purchase Transaction, Royalty Sub made quarterly debt service payments on the Non-recourse Notes. Applicable royalties received by Royalty Sub on net sales of Oracea and Sanctura XR for any quarter that exceeded the interest payments and expenses due for that quarter were applied to the repayment of principal on the Non-recourse Notes. In April 2011 and October 2011, Royalty Sub paid approximately $182,000 and $364,000, respectively, in principal on the Non-recourse Notes. As of December 14, 2011, the date of the sale of Royalty Sub, the principal balance outstanding on the Non-recourse Notes was approximately $74.5 million.

In connection with the Non-recourse Note transaction, an $8.0 million interest reserve was established to fund potential interest shortfalls or, if none, for repayment of principal due under the Non-recourse Notes. These funds came out of the debt proceeds and were restricted. In the first quarter of 2010, the $8.0 million interest reserve was exhausted. As a result, all subsequent interest payments were made by Royalty Sub solely from royalty payments received. Under the terms of the Non-recourse Notes, Royalty Sub was not in default for payment of interest unless it failed to make payment in full on the interest payment by the next succeeding payment date. Through December 14, 2011, Royalty Sub was able to make up all interest shortfalls in full before the next succeeding payment date. In the event of a default for failure to pay interest on a timely basis, the holders of the Non-recourse Notes do not have recourse to our Company as the Non-recourse Notes are non-recourse beyond Royalty Sub, are not convertible into any other of our securities, and have not been guaranteed by our Company.

The syndication costs to complete the Non-recourse Note transaction were approximately $4.4 million for investment banking, legal, consulting, accounting, and printing fees. These costs were funded from the debt proceeds and were being amortized to interest expense over 16.2 years, the term of the Non-recourse Notes. In connection with the Purchase Transaction, the remaining balance of $3.4 million in deferred financing costs was eliminated from our consolidated balance sheets. See Note 7 to our consolidated financial statements for further information.

In connection with the Non-recourse Note transaction, we executed a Servicing Agreement with Royalty Sub. The Servicing Agreement provided for a servicing fee of $10,000 per quarter to be paid to us for performance of services. We retained certain duties under the Servicing Agreement following the Purchase Transaction, including taking commercially reasonable steps to collect the royalty amounts due and

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enforcing the related provisions under the license agreements. Specifically, we are 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.

Sale of Intuniv Royalties

In May 2009, we entered into an agreement with an affiliate of Shire plc, whereby a Shire affiliate paid us a one-time, lump-sum payment of approximately $36.9 million as consideration for a royalty-free, fully paid-up license for Intuniv, which is a novel ADHD product marketed by Shire plc which utilizes one of our proprietary technologies. As a result, we will not receive any future royalty payments from Shire plc with respect to Intuniv.

Secured Credit Facility

In January 2011, we 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 initial drawdown of $15.0 million under our secured credit facility on January 26, 2011, the lenders received from us ten-year warrants that are exercisable for an aggregate of 93,750 shares of our common stock at an exercise price of $4.00 per share. The warrants expire on January 26, 2021. In December 2011, in connection with the drawdown of the second $15.0 million under our secured credit facility, as amended, we issued to the lenders warrants that are exercisable for an aggregate of 49,999 shares of our common stock at an exercise price of $5.00 per share. The warrants expire on December 30, 2021. In October 2012, one of the lenders exercised both tranches of its warrants to purchase an aggregate of 101,667 shares using cashless net share method. As a result of this exercise, we issued 64,309 shares of common stock to this warrant holder. We have primarily used the proceeds of the term loans under our secured credit facility to fund ongoing clinical trials for Oxtellar XR, Trokendi XR and SPN-810, to prepare for manufacturing validation of Oxtellar XR and Trokendi XR, to support formulation for various clinical stage products, to prepare commercial marketing of Oxtellar XR and Trokendi XR and for regulatory filing fees. The term loans bear interest at a fixed rate per annum of 11.0%. The initial $15.0 million of term loans drawn down in January 2011 will mature in August 2014. The second $15.0 million of term loans drawn down in December 2011 will mature in January 2015. In March 2011, we made the first of twelve monthly interest-only payments on the initial $15.0 million of term loans drawn down in January 2011. Thereafter, beginning in March 2012, which is the amortization date for these term loans, we will make principal and interest payments to fully amortize the balance over the term of these term loans. In February 2012, we made the first of six monthly interest-only payments on the second $15.0 million of term loans drawn down in December 2011. Thereafter, beginning in August 2012, which is the amortization date for these term loans, we will make principal and interest payments to fully amortize the balance over the term of these term loans.

We may voluntarily prepay all, but not less than all, outstanding term loans under our 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, 2.0% if such 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, we will also be required to make a final payment equal to 2.5%, or $750,000, of the aggregate principal amount of the term loans borrowed under our secured credit facility. This payment is being recorded as additional interest expense over the life of the loan.

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. Our secured credit facility includes negative covenants that, subject to certain exceptions, limit our ability and the ability of our subsidiaries to, among

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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 or engage in certain transactions with affiliates. Our secured credit facility also includes certain customary representations and warranties, affirmative covenants and events of default, which, among other things, include payment defaults, covenant defaults, a material adverse change in our business, certain events of bankruptcy, cross-defaults to certain indebtedness, material judgments, breach of representations and warranties and the revocation, rescission, suspension or other adverse modification of a governmental approval. Upon the occurrence of an event of default, the lenders under our secured credit facility will be entitled to 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.

We incurred debt financing costs of approximately $498,000, which included the payment of an upfront fee and the reimbursement of certain of the lenders' related expenses, and these expenses have been recorded as deferred financing costs in our consolidated balance sheet. Additionally, the fair value of the warrants upon issuance of $612,000 has been recognized as a discount on the term loan as of December 31, 2011. The deferred financing costs and the debt discount are being amortized to interest expense over the term of the related loans.

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 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 September 30, 2012, $456,000 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 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 of deferred revenue that will be recognized as revenue in a straight-line basis over its substantive obligation period of twelve years. As of September 30, 2012, $0.5 million of this amount has been 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 $1.8 million in future milestone payments, based on certain milestones defined in the Stendhal License Agreement.

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United Therapeutics License

We have a license agreement with United Therapeutics to use one of our proprietary technologies for an oral formulation of Remodulin for the treatment of PAH, and potentially for additional indications. 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. United Therapeutics has stated that this oral formulation of treprostinil diethanolamine, or treprostinil, is the subject of an NDA for PAH that was submitted in December 2011, 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. 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. Through September 30, 2012, we have received $1.5 million in pre-commercial milestone payments under the agreement. If United Therapeutics receives approval to market and sell oral treprostinil for additional indications and/or any additional combination products that utilizes our technologies, we will receive royalties in the single digits based on net sales worldwide. Any revenues received under this agreement will fluctuate as a result of the timing and amount of milestone and other payments received under this agreement, and the amount and timing of payments that we receive upon the sale of covered products, to the extent any are successfully commercialized by United Therapeutics or its sub licensees. 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 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 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.

Funding Requirements

As of September 30, 2012, we had unrestricted cash, cash equivalents and marketable securities of $62.5 million, an increase of $14.0 million from $48.5 million at December 31, 2011. This increase is primarily due to the proceeds received from our initial public offering in May 2012, offset by ongoing losses from operations as we continue to build towards two product launches in 2013. 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. 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, 2011 contains an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. Furthermore, since the completion of our initial public offering in May 2012, we have incurred additional costs associated with operating as a public company. We believe that the successful completion of this public offering will eliminate this doubt. However, while we believe that the proceeds of this offering, together with our cash, cash equivalents and marketable securities and anticipated future product revenues will be sufficient to commercialize both Oxtellar XR and Trokendi XR, there can be no assurance that we 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.

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As of September 30, 2102, our expected principal repayments over the next four years are (in thousands):

Year	Principal
2012	$ 2,756
2013	11,809
2014	10,847
2015	569
Total	$ 25,981

We expect to continue to incur substantial additional operating losses for the foreseeable future as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of Oxtellar XR, Trokendi XR and our other product candidates. With regards to Oxtellar XR and, if we obtain marketing approval for Trokendi XR, with regards to Trokendi XR, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

Even after giving consideration to the net proceeds of this public offering, we may need to obtain additional financing through equity offerings, debt financings, payments under new or existing licensing and research and development collaboration agreements or any combination thereof. For instance, although we expect the net proceeds from this offering will be sufficient to fund the commercial launch of Oxtellar XR and Trokendi XR, assuming we receive final FDA approval, there can be no assurance that we become cash flow positive. Our anticipated cash burn for calendar year 2012 is in the range of $55 million to $60 million.

In this regard, the report of our independent registered public accounting firm with respect to our consolidated financial statements as of and for the year ended December 31, 2011 contains an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- The receipt of marketing approval from the FDA for Trokendi XR;
- The costs of our commercialization activities for Oxtellar XR and Trokendi XR, if it receives final approval from the FDA;
- The cost of building and maintaining a wide variety of internal sales, distribution and marketing capabilities for the commercial launch of our products;
- The terms of third-party commercial manufacturing arrangements and cost of purchasing manufacturing and other capital equipment for our potential products;
- The cost and availability of active chemical ingredients and other manufacturing components required to supply a finished product;
- The scope, progress, results and costs of development for our other product candidates;
- The cost, timing and outcome of regulatory review of our other product candidates;

The extent to which we acquire or invest in products, businesses and technologies;

The extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for product candidates; and

The costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

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Cash Flows

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

	Years Ended December 31,			Nine Months Ended September 30,	
	2009	2010	2011	2011	2012
				(unaudited)	
			(in thousands)		
Net cash provided by (used in):					
Operating activities:					
From continuing operations	$ 6,845	$ (32,192)	$ (38,206)	$ (30,068)	$ (31,022)
From discontinuing operations	(4,211)	(352)	2,021	2,141	
Investing activities:					
From continuing operations	(28,385)	25,823	8,295	8,471	(39,613)
From discontinuing operations			25,607		
Financing activities:					
From continuing operations	20	(1,341)	29,054	14,296	45,503
From discontinuing operations	4,260	397	(1,967)	(2,096)	
Net increase (decrease) in cash and cash equivalents	$ (21,471)	$ (7,665)	$ 24,804	$ (7,256)	(25,132)

Operating Activities

Net cash used in operating activities from continuing operations for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 increased by $1.0 million. This change in cash flows from operating activities was primarily the result of an increase in loss of $4.6 million for the nine months ended September 30, 2012 offset by increases of approximately $1.9 million between the two periods related to net changes in working capital and approximately $1.1 million in non-cash items. The largest portion of the net changes in working capital related to a $512,000 increase in cash reimbursements for tenant improvements, which are recorded as deferred rent in 2011, and $3.1 million increase in account payables and accrued expense balances in 2012.

Net cash used in operating activities from continuing operations for the year ended December 31, 2011 compared to the same period in 2010 increased by $6.0 million. This change in cash flows from operating activities was primarily the result of a decrease of $5.7 million between the two periods related to net changes in working capital and a decrease of approximately $0.4 million in non-cash items. The largest portion of the net changes in working capital related to a $5.2 million increase in cash provided by higher account payables and accrued expenses in 2010 as compared to a $1.1 million decrease in cash provided due to lower account payables and accrued expenses in 2011. This was partially offset by recognition of deferred revenue under the Stendhal License Agreement as well as cash reimbursements for tenant improvements which are recorded as deferred rent.

Net cash used in operating activities from continuing operations for the year ended December 31, 2010 compared to the same period in 2009 decreased by $39.0 million. This difference was driven by the recognition of royalty revenues in 2009 of approximately $36.9 million related to a license agreement with Shire plc for Intuniv. In addition, we incurred higher research and development costs of approximately $5.9 million for the year ended December 31, 2010 compared to the same period in 2009 primarily to support our clinical programs relating to Oxtellar XR and Trokendi XR. This decrease in cash flows from operating activities was partially offset by an increase of $4.3 million between the two periods related to net changes in working capital. The largest portion of the increase in working capital related to a $3.4 million year-over-year increase in cash provided by higher account payables and accrued expenses, principally

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relating to the increased clinical trial and pre-validation manufacturing expenses for Oxtellar XR and Trokendi XR incurred during the 2010 period.

Net cash used in operating activities from discontinued operations for the year ended December 31, 2011 compared to the same period in 2010 increased by $2.4 million. This change in cash flows from operating activities was primarily the result of $1.6 million in increased income between the two periods, offset by decreased interest payable of $0.5 million in 2011. This was augmented by year over year increase in receivables of $1.3 million. Net cash used in operating activities from discontinued operations for the year ended December 31, 2010 compared to the same period in 2009 increased by $3.9 million. This change in cash flows from operating activities was primarily the result of $4.7 million in increased income between the two periods offset by increased receivables of $0.8 million.

Net cash used in operating activities from discontinued operations for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011, decreased by $2.1 million. This change in cash flows was primarily the result of our sale of Royalty Sub.

Investing Activities

Our investing activities from continuing operations are principally driven by cash provided by our financing activities and cash generated by operations, if any. We invest excess cash in accordance with our investment policy. Marketable securities consist of investments in U.S. Treasuries and various government agency debt securities, as well as investment grade securities in industrial and financial institutions which generally mature in twelve months or less. Fluctuations in investing activities between periods relate exclusively to the timing of marketable security purchases and the related sale and maturities of these securities.

Net cash used in investing activities from continuing operations for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 decreased by $48.0 million. This decrease was primarily the result of using cash and cash equivalents received in our initial public offering to purchase marketable securities.

Net cash provided by investing activities from continuing operations for the year ended December 31, 2011 compared to the same period in 2010 decreased by $17.5 million. This decrease was primarily the result of a $32.0 million decrease in the cash received from the sales and maturities of marketable securities, partially offset by a $14.9 million decrease in the cash used to purchase marketable securities. We also used an additional $0.4 million to purchase property and equipment for the year ended December 31, 2011 compared to the same period in 2010.

Cash provided by investing activities from discontinued operations of $25.6 million in 2011 relates to cash proceeds net of transaction costs from the sale of Royalty Sub.

The increase of $54.2 million in net cash provided by investing activities for the year ended December 31, 2010 compared to the same period in 2009 was primarily the result of a $30.3 million increase in cash received from the sales and maturities of marketable securities, partially offset by a $23.5 million decrease in cash used to purchase marketable securities. This increase in cash provided by investing activities was augmented by a $0.4 million decrease in cash used for the purchase of property and equipment for the year ended December 31, 2010 compared to the same period in 2009.

Financing Activities

Our net cash provided by financing activities from continuing operations was $45.5 million for the nine months ended September 30, 2012, as compared to $14.3 million for the nine months ended September 30, 2011. This increase is due to the receipt of proceeds from our initial public offering of common stock in May 2012.

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Net cash provided in financing activities from continuing operations for the year ended December 31, 2011 compared to the same period in 2010 increased by $30.4 million. This increase was primarily due to the drawdown of $30.0 million under our secured credit facility in 2011, as well as a decrease in deferred financing costs of $0.4 million.

Net cash provided by financing activities from continuing operations decreased by $1.4 million for the year ended December 31, 2010 compared to the same period in 2009. This decrease was primarily due to $1.3 million of deferred financing costs incurred in 2010 in connection with our initial public offering.

Net cash used in financing activities from discontinued operations decreased by $2.4 million in 2011, compared to the same period in 2010. This decrease was mainly due to lower balances of restricted cash and cash equivalents of $1.5 million used to fund interest and $0.5 million in principal payments on the Non-recourse Notes. This was offset by an increase in restricted cash of $0.4 million in 2010. Net cash used in financing activities from discontinued operations decreased by $3.9 million in 2010, compared to net cash used in financing activities for the same period in 2009. This decrease was primarily due to the drawdown in 2009 of approximately $4.3 million in the interest reserve account that was established to fund potential shortfalls in interest payments for the Non-recourse Notes. This was offset by an increase in restricted cash of $0.4 million in 2010.

Net cash used in financing activities from discontinued operations for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011, increased by $2.1 million. This change in cash flows was primarily the result of our sale of Royalty Sub.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 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]	$ 11,490	$ 14,491	$	$	$ 25,981
Interest on Secured Credit Facility[1]	2,161	1,762			3,923
Operating leases[2]	964	1,979	2,059	618	5,620
Purchase obligations[3]	8,144				8,144
Total[4]	$ 22,759	$ 18,232	$ 2,059	$ 618	$ 43,668

(1) Annual interest expense is currently $2.2 million on $26.0 million of principal outstanding currently.

(2) Our commitments for operating leases relate to our lease of copiers and office and laboratory space as of September 30, 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

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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

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and amounts recorded as revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While a summary of significant accounting policies are more fully described in Note 3 to our consolidated financial statements appearing at the end of this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

Revenue Recognition

Our revenues have been generated through collaboration and research and development agreements. These agreements included fees for development services provided to customers and payments for achievement of specified development, regulatory and sales milestones, which comprise our development and milestone revenues, as well as royalties on product sales of licensed products, Oracea, Sanctura XR, and Intuniv, which comprise our royalty revenue. We record any amounts received in advance of services performed as deferred revenue and recognize them as revenue if and when earned.

Multiple Element Arrangements

For multiple element arrangements, we evaluate the components of each arrangement as separate elements based on certain criteria. Accordingly, revenues from collaboration agreements are recognized based on the performance requirements of the agreements. We recognize revenues 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.

Our development revenues have been earned under contracts that were less than one year in duration. Development contracts generally take the form of fee-for-service arrangements based on an annual contractual full time equivalent billing rate. In cases where performance spanned multiple accounting

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periods, we recognized revenue as services were performed, measured on a proportional-performance basis. We used output measures, specifically labor hours, to measure performance as they reflect our pattern of performance over the contractual term.

In January 2011, we adopted 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 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 our consolidated financial statements, as we did not enter into any multiple element arrangements during 2011. We will evaluate new or materially modified multiple element arrangements pursuant to the guidance in ASU No. 2009-13.

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. In January 2011, we adopted ASU 2010-17, *Revenue Recognition-Milestone Method*. 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 identified in 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 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 recognized as revenue when services have been rendered and there are no further performance obligations. The adoption of ASU 2010-17 did not have a material impact on our consolidated results of operations, financial position, or liquidity.

Royalty Revenues

We record royalty revenues based on estimates of the sales that occurred during the relevant period. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties received (adjusted for any changes in facts and circumstances, as appropriate). We maintain regular communication with licensees in order to obtain information to develop reasonable estimates. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they are collected, typically the following quarter. Historically, adjustments have not been material based on actual amounts received from licensees. To the extent we do not have sufficient ability to accurately estimate revenue, we record revenue when received.

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In 2009, we recognized approximately $36.9 million in royalty revenues related to an amendment to a license agreement with Shire plc for Intuniv, which is a novel ADHD product marketed by Shire plc and utilizes one of our proprietary technologies. Under the terms of the license amendment, the parties agreed to delete all provisions regarding milestone and royalty payments and replaced those provisions with, among other things, (1) a commitment by Shire plc to make a one-time payment of $36.9 million within 15 days of signing the amendment, (2) an acknowledgement by us that no other sums would be payable to us, then or in the future, under the amended license; and (3) a statement that the amended license was permanent, irrevocable and fully paid. We concluded that immediate revenue recognition was appropriate because (1) the executed contract constituted persuasive evidence of an arrangement, (2) the delivery of the license amendment had occurred and Shire plc had assumed all risks and rewards regarding Intuniv, and we had no current or future performance obligations, (3) the total consideration for the license amendment was fixed and known at the time of its execution and there were not any extended payment terms or rights of return, and (4) collection was reasonably assured as we determined that Shire plc was creditworthy and had the financial ability to make the payment in accordance with the terms of the license amendment.

Inventories

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. We capitalize 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 commercialization of the product. Following the receipt of tentative approval for Trokendi XR from the FDA on June 25, 2012, and the receipt of approval of Oxtellar XR from the FDA on October 19, 2012, we will capitalize validation batch manufacturing costs, to the extent the product is expected to be sold commercially after the product launch.

Accrued Expenses

As part of the process of preparing our consolidated financial statements, we may be required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each consolidated balance sheet date in our consolidated financial statements based on facts and circumstances known to us. We confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to CROs in connection with clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial materials; and
- professional service fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing the related service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services

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performed or the costs of these services, our actual expenses could differ from our estimates. We do not anticipate the future settlement of existing accruals to differ materially from our estimates.

Stock-Based Compensation

We recognize as compensation expense the estimated fair value of stock options and non-vested stock awards over the requisite service periods, which are typically the vesting periods. Equity instruments issued to non-employees are recorded at their estimated fair value and are re-measured each reporting period as the equity instruments vest and the related expense is recognized ratably over the related service period.

Stock-based compensation expense includes stock options and non-vested stock granted to employees and non-employees and has been reported in our consolidated statements of operations as follows:

	Years Ended December 31,			Nine Months Ended September 30,	
	2009	2010	2011	2011	2012
				(unaudited)	
	(in thousands)				
Research and development	$ 28	$ 53	$ 63	$ 44	$ 133
Selling, general and administrative	83	244	(145)	(88)	139
Total	$ 111	$ 297	$ (82)	$ (44)	$ 272

Historically, stock-based compensation has not been material to our consolidated results of operations or financial position. Because the determination of the estimated fair value of share-based payments inherently includes the use of subjective assumptions and the potential that the related expense may be material in the future, we have included stock-based compensation as a significant accounting policy.

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the input of subjective assumptions, including stock price volatility, assumed dividend yield, the expected term of stock options and a risk-free interest rate. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies, or our guideline peer group, for which historical information is available. We will continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants. The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future. We determine the average expected term 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 contractual term. We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected term assumed at the date of grant. The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2009, 2010 and 2011 and the nine months ended September 30, 2011 and 2012 are set forth in our consolidated financial statements appearing at the end of this prospectus.

Forfeitures are not an assumption that impacts the Black-Scholes option-pricing model; however, it is an estimate that impacts the amount of stock compensation expense recognized. We estimate forfeiture rates based on our historical analysis of actual stock option forfeitures.

There is a high degree of subjectivity involved when using option-pricing models to estimate stock-based compensation. There are currently no market-based mechanisms or other practical applications to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the estimated fair value of employee stock-based awards is determined using an option-pricing model, the value may not be indicative of the fair value

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observed in a market transaction between a willing buyer and willing seller. If factors change and we employ different assumptions when valuing our options, the compensation expense that we record in the future may differ significantly from what we have historically reported.

For all stock options granted after the completion of our initial public offering, the fair value for our underlying common stock was determined using the quoted market value on the date of grant.

For all stock options granted prior to the completion of our initial public offering, our board of directors, with input from management, estimated the fair value for our underlying common stock on each of the stock option grant dates. Given the absence of an active market for our common stock, our board of directors contemporaneously estimated the fair value of our common stock with the assistance of a third-party valuation firm on the dates of grant. These contemporaneous valuations were performed in accordance with applicable methodologies, approaches and assumptions of the technical practice aid issued by the American Institute of Certified Public Accountants Practice Aid entitled *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (AICPA Practice Aid), considering numerous objective and subjective factors to determine common stock fair market value at each option grant date, including but not limited to the following factors:

our stage of development and business strategy;

our financial condition, operating results and book value;

economic and competitive elements affecting us, our industry and our target markets;

our projected operating results;

a comparative analysis of our financial condition and operating results with those of publicly-owned companies engaged in similar lines of business;

the current and historical relationship between the reported stock prices and revenues and earning levels of selected publicly traded companies engaged in similar lines of business;

important developments relating to the results of our clinical trials;

the likelihood of achieving a liquidity event for our outstanding shares of stock; and

the price per share at which our Series A convertible preferred stock was issued to investors including the rights, preferences and privileges of the preferred stock relative to the common stock. In considering the rights and preferences of our Series A convertible preferred stock relative to our common stock, we considered the following rights and preferences:

The holders of our Series A convertible preferred stock were entitled to receive a cumulative annual dividend of $0.07 per share, when and if declared by the board of directors; and

The holders of our Series A convertible preferred stock were entitled to a liquidation preference. The aggregate amount of liquidation preferences, increased from $55.8 million as of December 31, 2007 to $69.5 million as of December 31, 2011. In the event of liquidation, dissolution or winding up of our Company, the liquidation preference for each Series A convertible preferred share equaled the original purchase price of $1.00 per share,

plus accumulated unpaid dividends.

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The following table includes stock option grant information from January 1, 2009 through the date of our initial public offering in May 2012, including the estimated fair value of the option grant as determined by the Black-Scholes option-pricing model.

Grant Date	Number of Options	Exercise Price	Estimated Fair Value	Intrinsic Value
January 19, 2009	56,250	$ 1.60	$ 0.93	$
December 15, 2009[(1)]	64,300	$ 7.04	$ 4.13	$
February 10, 2010	13,125	$ 3.36	$ 1.96	$
April 16, 2010	8,186	$ 3.36	$ 1.95	$
July 20, 2010	9,625	$ 3.36	$ 1.93	$
October 15, 2010	3,750	$ 2.56	$ 1.48	$
November 2, 2010	220,000	$ 2.56	$ 1.64	$
November 16, 2010	8,750	$ 2.56	$ 1.65	$
October 14, 2011	8,750	$ 4.24	$ 2.68	$
December 30, 2011	136,000	$ 5.88	$ 3.68	$
January 17, 2012 (unaudited)	5,686	$ 5.88	$ 3.68	$
Total	534,422			

(1) On November 2, 2010, 63,750 of these options were repriced from $7.04 to $2.56 per share.

Our board of directors has made only one grant of non-vested stock. This grant was made in December 2005 for 875,000 shares of common stock. The estimated fair value of those shares as of the date of grant was $0.40 per share.

In November 2010, our board of directors repriced 63,750 of the options granted on December 15, 2009 from a per share exercise price of $7.04 to $2.56. In addition, our board of directors approved the modification of the performance vesting requirements related to 39,424 employee stock options and 102,941 shares of non-vested stock awarded to our chief executive officer. The vesting of all of these share-based awards was contingent upon the filing and the FDA's acceptance of the Company's first NDA on or before December 22, 2010, and the board of directors extended the deadline for the achievement of this performance condition to March 31, 2011. As a result of the board of directors' actions, there was no immediate charge related to the repriced and modified options. We recognized approximately $190,000 of stock-based compensation related to the modified performance vesting options during the period January 1, 2010 through February 2011. As of March 31, 2011, the performance condition was not met and all performance vesting options expired. As a result, all previously recorded compensation expense related to the performance vesting options was reversed during 2011.

All contemporaneous valuations were prepared consistent with the AICPA Practice Aid. For valuations dated January 19, 2009 through November 16, 2010, we considered the use of market, income and asset valuation approaches. We lacked relevant financial metrics to utilize the market approach and the asset approach was not utilized because the majority of our assets are intangible, accordingly we used an income approach for each valuation. The income approach values a business based upon the future benefits that will accrue to it with the value of the future economic benefits discounted back to a present value at some appropriate discount rate. Implicit in the market price of all publicly traded securities is a consensus forecast of earnings and financial condition. The consensus forecast results from the information made available to the investing public by us and from the numerous forecasts prepared by financial analysts. We have replicated this approach through the preparation of an operating forecast and the use of discounted cash flow analysis. The discount rate reflects all the risk of ownership and the associated risks of realizing the prospective economic income stream. Given that we had Series A convertible preferred stock outstanding, it was also necessary to allocate our Company's value to the various classes of stock. As

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provided in the AICPA Practice Guide, there are several approaches for allocating equity value of a privately-held company among the securities in a complex capital structure, including the current value method, the probability weighted expected return method, or PWERM, and the option pricing method. The current value method was not employed because a liquidity event, in the form of an acquisition or dissolution, was not imminent. The PWERM was not utilized because of the nature of drug development and our stage of development estimating the probability and value of various liquidity events is highly speculative. We used the option-pricing method to allocate the estimated value of our equity to the classes of securities. The value of our common stock was then discounted for lack of marketability, or the inability to readily sell shares, which increases the owner's exposure to changing market conditions and increases the risk of ownership. The discount for lack of marketability was derived using a protective put calculation using the Black-Scholes option pricing model.

For the valuations performed as of September 30, 2011 and December 30, 2011, we used the PWERM described in the AICPA Practice Aid to allocate the enterprise values to the common stock. Under this method, the value of our common stock is estimated based upon an analysis of future values for our Company assuming various future outcomes, the timing of which is based on the plans of our board of directors and management. Under this approach, share value is based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the rights of each share class.

Stock Option Grants on January 19, 2009

Our board of directors granted stock options on January 19, 2009, with each having an exercise price of $1.60 per share. In addition to considering the objective and subjective factors listed above, our board of directors considered the valuation as of December 31, 2007 provided by management in determining the fair value of our common stock on January 19, 2009. We considered this valuation relevant in our determination of the estimated fair value of the common stock primarily because the deterioration of the overall financial markets in the second half of 2008 overshadowed progress on our clinical pipeline and the financing from the Non-recourse Notes. Our board of directors considered that in the face of the credit and liquidity crisis and the resulting uncertainties, the prospects for a liquidity event in the foreseeable future were significantly lower.

In the December 31, 2007 valuation, we used the income approach, specifically a discounted cash flow analysis, to estimate our Company's equity value. The first step in that process was to calculate the present value of our discrete net cash flows for the periods projected. Next, the present value of our terminal net cash flow was calculated. The sum of these two present values, utilizing a cost of capital discount rate of 21.2%, determined the total market value capitalization on a minority basis to approximate $59.5 million. We added free cash (cash remaining after all investments and commitments that could potentially be available for debt service or shareholders dividends without impairing operations) in the amount of $25.9 million to estimate the market value of the total equity on a minority interest basis to approximate $85.4 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using the option-pricing method. A discount of 25.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at December 31, 2007 of $1.60 per share. Our board determined this valuation analysis to be reasonable and, on the basis of the factors described above, that the estimated fair value of our common stock on January 19, 2009 was $1.60 per share.

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Stock Option Grants on December 15, 2009

Our board of directors granted stock options on December 15, 2009, with each having an exercise price of $7.04 per share. In addition to considering the objective and subjective factors listed above, our board of directors considered the valuation as of July 16, 2009 provided by management in determining the fair value of our common stock on December 15, 2009. We utilized the income approach, specifically a discounted cash flow analysis, to estimate the equity value of our Company. In addition, to the non-risk adjusted forecast, we also considered a risk-adjusted forecast using various probabilities to reflect the risks of achieving commercialization based on our product candidates' clinical stage of development. We utilized non-risk adjusted and risk adjusted costs of capital of 25.0% and 18.9%, respectively. These discount rates were applied to our discrete net cash flows to determine the present value. This present value was combined with the present value of our terminal cash flow to determine the total market value of capitalization for us on a minority interest basis of approximately $122.9 million. We added free cash in the amount of $80.6 million to estimate the market value of the total equity, on a minority interest basis, to be approximately $203.5 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using the option-pricing method. A discount of 30.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at July 16, 2009 of $7.04 per share. Based on the foregoing, we concluded the fair value of our common stock as of December 15, 2009 was $7.04 per share. No significant changes had come to our attention between July 16, 2009 and the December 15, 2009 grant date to warrant a revaluation of the stock. We therefore concluded there was no basis for a change in the fair value during such period.

The increase in the estimated fair value of the common stock relative to the December 31, 2007 valuation relates to several items. First, we had an additional $55.0 million of free cash on hand as a result of the monetization of certain future royalty streams under our licenses for Oracea, Sanctura XR and Intuniv. In addition, we had completed in-depth market research in mid-2009 that indicated a substantially greater commercial potential for our two epilepsy product candidates.

Stock Option Grants on February 10, April 16 and July 20, 2010

Our board of directors granted stock options on February 10, April 16 and July 20, 2010, with each having an exercise price of $3.36 per share. In addition to considering the objective and subjective factors listed above, our board of directors considered the valuation as of December 31, 2009 provided by management in determining the fair value of our common stock on each of February 10, April 16 and July 20, 2010. We utilized the income approach, specifically a discounted cash flow analysis, to estimate the equity value of our Company. We considered a non-risk adjusted forecast and risk-adjusted forecast using various probabilities to reflect the risks of achieving commercialization based on our product candidates' clinical stage of development. We utilized non-risk adjusted and risk adjusted costs of capital of 25.0% and 15.7%, respectively. These discount rates were applied to our discrete net cash flows to determine the present value. This present value was combined with the present value of our terminal cash flow to determine the total market value of capitalization for us, on a minority interest basis, of approximately $53.0 million. We added free cash in the amount of $66.7 million to estimate the market value of the total equity on a minority interest basis to be approximately $119.7 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using the option-pricing method. A discount of 30.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at December 31, 2009 of $3.36 per share. Based on the foregoing, we concluded the fair value of our common stock as of February 10, 2010 was $3.36 per share. We further determined the fair value of the common stock as of April 16 and July 20, 2010 to be $3.36 per share. No significant changes had come to our attention between December 31, 2009 and each of the foregoing grants date to warrant a revaluation of the stock. We therefore concluded there was no basis for a change in the fair value during such period.

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The decrease in the estimated fair value of the common stock as compared to the July 16, 2009 valuation principally relates to information regarding the announcement in December 2009 by a competitor of the initiation of a Phase III clinical trial for a once-a-day, extended-release topiramate product to treat epilepsy that could compete head-to-head with Trokendi XR, and, if approved before Trokendi XR, would have had three years of market exclusivity.

Stock Option Grants on October 15, November 2 and November 16, 2010

Our board of directors granted stock options on October 15, November 2 and November 16, 2010, with each having an exercise price of $2.56 per share. In addition to considering the objective and subjective factors listed above, our board of directors considered the valuation as of October 1, 2010 provided by management in determining the fair value of our common stock on each of October 15, November 2 and November 16, 2010. We utilized the income approach, specifically a discounted cash flow analysis, to estimate the equity value of our Company. We utilized a non-risk adjusted forecast and a risk-adjusted forecast using various probabilities to reflect the risks of achieving commercialization based on our product candidates' clinical stage of development. We utilized non-risk adjusted and risk adjusted costs of capital of 22.0% and 14.2%, respectively. These discount rates were applied to our discrete net cash flows to determine the present value. This present value was combined with the present value of our terminal cash flow to determine our total market value of capitalization on a minority interest basis of approximately $64.0 million. We added free cash in the amount of $45.8 million to estimate the market value of the total equity on a minority interest basis to be approximately $109.8 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using the option-pricing method. A discount of 20.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at October 1, 2010 of $2.56 per share. Based on the foregoing, we concluded the fair value of our common stock as of October 15, November 2 and November 16, 2010 was $2.56 per share. No significant changes had come to our attention between October 1, 2010 and each of the foregoing grant dates to warrant a revaluation of the stock. We therefore concluded there was no basis for a change in the fair value during such period.

The decrease in the estimated fair value of the common stock as compared to the December 31, 2009 valuation principally relates to a reduction of $20.8 million of free cash and a further refinement in the market estimates for our two epilepsy products based on additional market research on the dynamics of the market for epilepsy products and our expected product profiles upon approval.

Stock Option Grants on October 14, 2011

Our board of directors granted stock options on October 14, 2011 having an exercise price of $4.24 per share. Our board of directors considered the valuation performed as of September 30, 2011 provided by management in determining the fair value of our common stock on October 14, 2011. In the September 30, 2011 valuation, we used the PWERM to value our common stock. We estimated the fair value of our common stock using a probability-weighted analysis of the present value of the returns afforded to our stockholders under each of five possible future scenarios. All five of the scenarios assumed a shareholder exit, either through an initial public offering or a merger/acquisition of our Company. The five scenarios and their respective probabilities as assigned by management:

Scenario	Probability
1. An initial public offering in late 2011	0%
2. Royalty monetization in 2011 with an initial public offering in the first half of 2012	5%
3. Preferred equity financing in 2011, royalty monetization 2011, and an initial public offering in the second half of 2012	5%
4. Preferred equity financing in 2011 with an initial public offering in the first half of 2012	60%
5. Merger or other sale transaction in late 2011	30%

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We indicated scenario 4 was most likely given our greater control over the timing of a preferred equity financing (compared to a royalty monetization) and since scenario 4 provided more flexibility regarding the timing of an initial public offering. Management also considered that the initial public offering would occur after the NDA for Trokendi XR was accepted for filing by the FDA and after the NDA was submitted for Oxtellar XR in 2011.

The merger or other sale transaction scenario was weighted strongly as well given the increased volatility in the public markets which made a merger or other sales transaction more probable.

The lowest probability was applied to scenario 1. Due to timing of SEC filings and initiating a road show, as well as given the limited initial public offering activity for life sciences companies in the third quarter, increased volatility, and ongoing economic concerns, the prospect of an initial public offering in late 2011 was not considered likely.

Considering scenarios 2 and 3, management had projected a monetization of Trokendi XR royalties and an initial public offering. However, as mentioned, we had no control over the timing of a royalty monetization, and the valuation of the royalty monetization is dependent on the terms for including Trokendi XR and/or Oxtellar XR in any proposal.

In the September 30, 2011 valuation, we applied a discount for lack of marketability of 12.1% to reflect the fact that our shares have no immediate path to liquidity and there is no market mechanism to sell these shares. A common stockholder would have to wait for a liquidity event such as an initial public offering or a sale of our Company to enable the sale of the common stock. We used an option pricing model to determine the value of this lack of marketability.

Stock Option Grants on December 30, 2011 and January 17, 2012

Our board of directors granted stock options on December 30, 2011 and January 17, 2012 having an exercise price of $5.88 per share. Our board of directors considered the valuation performed as of December 30, 2011 provided by management in determining the fair value of our common stock on December 30, 2011 and January 17, 2012. In the December 30, 2011 valuation, we used the PWERM to value our common stock. We estimated the fair value of our common stock using a probability-weighted analysis of the present value of the returns afforded to our stockholders under each of five possible future scenarios. All five of the scenarios assumed a shareholder exit, either through an initial public offering or a merger/acquisition of our Company. The five scenarios and their respective probabilities as assigned by management:

Scenario	Probability
1. An initial public offering in early 2012	50%
2. Preferred equity financing in the second quarter of 2012 with an initial public offering in the third quarter of 2012	30%
3. Preferred equity financing in the second quarter of 2012, royalty monetization in the fourth quarter of 2012, and an initial public offering in the third quarter of 2013	10%
4. Preferred equity financing in the second quarter of 2012, royalty monetization in the fourth quarter of 2012, SPN-810 Partnership in the first quarter of 2013, and an initial public offering in the second quarter of 2013	5%
5. Merger or other sale transaction in early 2012	5%

Management had indicated scenario 1 was most likely given we had more control over the timing of an initial public offering and given the recent positive trends in the U.S. initial public offering and equity markets. The initial public offering would be occurring as we prepared to commercially launch Trokendi XR and as the NDA for Trokendi XR and Oxtellar XR were under review. Moreover, given that the number and

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size of initial public offering transactions had increased to the highest level since May 2011 and the volatility in the market had decreased, the prospects of an initial public offering improved.

We applied the second highest weighting to scenario 2, in which we would complete a Series B financing in June 2012 and then undertake an initial public offering in the third quarter of 2012. Management had indicated our investors would be willing to commit to a Series B financing, which would bridge the short-term funding gap until an initial public offering and provide more flexibility regarding the timing of the initial public offering.

The lowest probability was applied to scenarios 4 and 5 (5%). Scenario 4 consisted of a Series B financing in June 2012, an oral Remodulin royalty monetization in October 2012, a partnership with a large cap pharma or biotech company for SPN-810 in February 2013 and finally an initial public offering in June 2013. While we had more control over the timing of a Series B financing and the financing can provide more flexibility regarding the timing of a royalty monetization and initial public offering, we cannot control the timing of a royalty monetization and we cannot control the timing of a partnership for the development of SPN-810 through Phase III trials. In addition, management indicated there were no discussions pending and therefore the probability or occurrence at this juncture is low.

In the December 30, 2011 valuation, we applied a discount for lack of marketability of 13.5% to reflect the fact that our shares have no immediate path to liquidity and there is no market mechanism to sell these shares. A common stockholder would have to wait for a liquidity event such as an initial public offering or a sale of our Company to enable the sale of the common stock. We used an option pricing model to determine the impact of lack of marketability.

Lender Warrants

In connection with the initial $15.0 million drawdown under our secured credit facility, the lenders received from us ten-year warrants to purchase an aggregate of 375,000 shares of our Series A convertible preferred stock at an exercise price of $1.00 per share. The warrants became exercisable upon issuance and will expire on January 26, 2021. In December 2011, in connection with the drawdown of the second $15.0 million under our secured credit facility, the lenders received from us ten-year warrants to purchase 200,000 shares of our Series A convertible preferred stock at an exercise price of $1.50 per share. The warrants became exercisable upon issuance and will expire on December 30, 2021. Upon completion of our initial public offering on May 1, 2012, the respective lender warrants converted into (i) warrants to purchase 93,750 shares of common stock at an exercise price of $4.00 per share and (ii) warrants to purchase 49,999 shares of common stock at an exercise price of $5.00 per share.

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 will continue to be classified as derivative liabilities.

The warrants are classified as liabilities in accordance with ASC 815-40 *Derivatives and Hedging Contracts in an Entity's Own Equity*. The value of the warrants has been recorded as a derivative liability at a discount to the notes payable, and will be marked to market at each reporting period. The discount attributable to the notes will be amortized to interest expense over the expected term of the loans. Change in fair value of warrant liability represents non-cash (expense) income associated with changes in the fair value of the warrants to purchase common stock issued to the lenders under our secured credit facility. The warrant obligation is adjusted to fair value at the end of each reporting period.

Prior to completion of our initial public offering, the fair value of the preferred stock warrants was estimated in accordance with the AICPA Practice Aid. Several objective and subjective factors were considered when

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valuing each equity security and related warrant at a valuation date. With assistance from a third party valuation firm, we utilized the PWERM to estimate the fair value of the preferred stock warrants. Under the PWERM, the value of each equity security and warrant was estimated based upon an analysis of future values for the entire equity instrument assuming various future outcomes. Share value was based upon the probability-weighted present value of the expected outcomes, as well as the rights of each class of preferred and common stock. A probability was estimated for each possible event based on the facts and circumstances as of the valuation date.

Subsequent to the completion of our initial public offering, which occurred on May 1, 2012, we have calculated the fair value of the common stock warrants 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 our issuance of additional common stock in future financings. 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. In October 2012, a lender exercised both tranches of its warrants to purchase an aggregate of 101,667 shares of common stock using a cashless net share settlement. As a result of this exercise, we issued 64,309 shares of common stock to this lender.

Recent Accounting Pronouncements

We have evaluated all Accounting Standards Updates through the date the unaudited condensed consolidated financial statements were issued and believe the adoption of these will not have a material impact on our results of operations or finaicial position.

Jumpstart Our Business Startups Act of 2012

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing 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.

Quantitative and Qualitative Disclosure 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 September 30, 2012, we had unrestricted cash, cash equivalents, marketable securities and long term investments of $62.5 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, marketable securities and long term investments, 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 $540,000 for the nine months ended September 30, 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 $540,000 for the nine months ended September 30, 2012. We do not believe that inflation and changing prices over the years ended December 31, 2009, 2010 and 2011 or the nine months ended September 30, 2011 and 2012 had a significant impact on our consolidated results of operations.

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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 stand alone 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 are planning for the commercial launch of two neurology products in 2013 for the treatment of epilepsy 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, including 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 an approved product and a tentatively approved product. On October 19, 2012, the FDA granted final approval of Oxtellar XR (extended release oxcarbazepine), formerly known as SPN-804, 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. On June 25, 2012, the FDA granted tentative approval of Trokendi XR (extended release topiramate), formerly known as SPN-538, 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 has regarding safety information of topiramate in a specific pediatric population. This marketing exclusivity expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. We anticipate the commercial launch of Oxtellar XR to occur during the first quarter of 2013 and the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA.

Our psychiatry product candidates include SPN-810 (molindone hydrochloride), which completed a Phase IIb trial that showed positive topline results as a novel treatment for impulsive aggression in patients with ADHD and SPN-812, which completed a Phase IIa trial as a novel non-stimulant treatment of ADHD.

In addition, 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. We believe that these will be the first extended release formulations for the treatment of these indications available 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 allows us to rely on the existing data from the new drug application, or NDA, of Trileptal. The once-per-day dosing of each of Oxtellar XR and Trokendi XR is designed to improve patient compliance and to provide a better tolerability profile compared to the current immediate release anti-epileptic drugs, or AEDs, that are taken multiple times per day to maintain

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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 are also developing 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. 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	Final approval by FDA
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; and Oracea (doxycycline), marketed by Galderma. 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 six years on successfully developing our own product candidates in neurology and psychiatry.

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(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*.

(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*.

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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 are currently focused on building our own targeted specialty sales force and marketing capabilities in the United States to launch, Oxtellar XR and, once approved, Trokendi XR.

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. For example, we recently completed a Phase IIb trial of SPN-810 for impulsive aggression in patients with ADHD for which we received positive topline results in November 2012.

Develop differentiated products by applying our technologies to known drug compounds. We intend to continue to focus our development activities on known drug compounds and compounds with established mechanisms of action and thereby reduce the risks, costs and time typically associated with pharmaceutical product development. We intend to leverage our proprietary and in-licensed technologies and expand our patent portfolio to 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 product candidates 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 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, if 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]

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

(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.

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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 epileptic patients. 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 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.

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

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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.

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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 after a missed dose by 43%. 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]

Immediate Release Products Have Serious Side Effects and Lack of Tolerability

The FDA has recognized AEDs as being "critical dose drugs," 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 drug 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

(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.

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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 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)]

A number of epilepsy advocacy groups such as the Epilepsy Foundation, 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

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

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

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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 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

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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

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

(14)

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

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Oxtellar XR and Trokendi XR are novel extended release formulations of two well known and approved AEDs, oxcarbazepine and topiramate, respectively. Both product candidates 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. 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. We anticipate the commercial launch of Oxtellar XR to occur during the first quarter of 2013 and the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA. 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 of the last 15 years.

Oxtellar XR (extended release oxcarbazepine)

Oxtellar XR is a novel oral once-daily extended release formulation of oxcarbazepine, for which we received approval from the FDA on October 19, 2012 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 three year marketing exclusivity to 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.[(16)] With approximately 3.4 million total oxcarbazepine prescriptions in 2011 and trending at 3.5 million prescriptions in 2012, oxcarbazepine represents a portion of prescriptions with approximately 2.8% of total 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 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.

(16) 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.

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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 the product candidate at our commercial contract manufacturing facility, which produced clinical supplies to conduct our Phase III trial.

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.

In this trial, the adverse events 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 adverse events reported for Trileptal, while Oxtellar XR generated a total of only 120 adverse events, a reduction of 37%. Of these, a total of 197 adverse events 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 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 (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

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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 1200mg or 2400mg 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

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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. Adverse Event, or 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 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.

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Commercialization Strategy

We expect Oxtellar XR to be the only once-daily oxcarbazepine product indicated for the treatment of epilepsy as an adjunctive therapy and to compete 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. To support the commercial launch of Oxtellar XR, which was granted three years of market exclusivity by the FDA, we plan to build a small specialty sales force 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. 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.[(15)] With approximately 10.0 million total topiramate prescriptions in 2011 and trending at 10.7 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 avoids 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 products with total daily regimen that ranged from 200mg-400mg. Patients were first converted to

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

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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?

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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, 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. We plan to expand our sales force that will commercially launch Oxtellar XR and will subsequently be used to commercially launch Trokendi XR in the third quarter of 2013. We expect to finalize the terms of the commercial manufacture and supply of Trokendi XR with the CMO as the tentatively approved product gets closer to a final approval by the FDA.

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 60% to 80% of children with ADHD continue to meet criteria for ADHD into adolescence.[18] In 2008, the U.S. market for ADHD prescription drugs was more than $4 billion, according to data from IMS Health.

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.[19]

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

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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.[20] 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.[21] 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.

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.[22] In addition, it has been estimated that approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.[23] 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.

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(20) 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*.

(21) 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*.

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

(23) 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*.

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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,[(24)] 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.

Our Psychiatry Portfolio

Our psychiatry portfolio includes three product candidates for the treatment of 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 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 12mg per day to 54mg 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 (molindone hydrochloride extended release formulation) 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.

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

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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, 6-12 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 known 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 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.

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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 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 will be 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 Retrospective Modified Overt Aggression Scale, or 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,

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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 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.

Statistical Significance in Patients ≥ 30 kg on Low to Medium Doses

Primary Efficacy Endpoints (Treatment vs. placebo in ITT population)	Low Dose P-value	Medium Dose P-value	High Dose P-value
R-MOAS Change Overall	0.071	0.115	0.943
Patients (<30kg)	0.729	0.643	0.997
Patients (≥30kg)	0.024	0.049	0.966
R-MOAS Remission Overall	0.009	0.043	0.276
Patients (<30kg)	0.648	0.738	0.623
Patients (≥30kg)	0.004	0.021	0.086

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)

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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 (PK) and pharmacodynamic (PD) relationship from the PK 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 adverse events that occurred were not drug related. One patient in the low dose arm and two patients in the medium dose arm had severe adverse events that were considered either possibly or definitely related to the drug. Six patients in total discontinued the study because of adverse events 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.

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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 a new chemical entity. 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.[25] 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.

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

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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 Clinical Global Impressions 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.[(26)] 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.

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

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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 customized product profiles designed to meet efficacy needs, more convenient and less frequent 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 fille