

SUPERNUS PHARMACEUTICALS INC

Form S-1/A

April 30, 2012

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As filed with the Securities and Exchange Commission on April 30, 2012

Registration No. 333-171375

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 7  
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**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)  
**1550 East Gude Drive**  
**Rockville, MD 20850**  
**(301) 838-2500**

**20-2590184**  
(I.R.S. Employer  
Identification Number)

(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)

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**Approximate date of commencement of proposed sale to public:**

As soon as practicable after this Registration Statement becomes effective.

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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. ☐

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. ☐

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. ☐

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. ☐

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 ☐      Accelerated filer ☐      Non-accelerated filer ☒      Smaller reporting company ☐

(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 it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED APRIL 30, 2012**

**PRELIMINARY PROSPECTUS**

**11,000,000 Shares**

**Supernus Pharmaceuticals, Inc.**

**Common Stock**  
**\$      per share**  

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This is the initial public offering of our common stock. We are selling 11,000,000 shares of our common stock. We currently expect the initial public offering price to be \$5.00 per share of common stock.

We have granted the underwriters an option to purchase up to 1,650,000 additional shares of common stock to cover over-allotments.

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "SUPN."  

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**Investing in our common stock involves risks. See "Risk Factors" on page 11.**

As an "emerging growth company," we are eligible for reduced public company reporting requirements. See "Summary Implications of being an Emerging Growth Company."

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.  

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	<b>Per Share</b>	<b>Total</b>
Public Offering Price	\$	\$
Underwriting Discount	\$	\$
Proceeds to Supernus (before expenses)	\$	\$

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2012 through the book-entry facilities of The Depository Trust Company.

Entities affiliated with New Enterprise Associates 11, Limited Partnership, OrbiMed Private Investments II LP and Abingworth Bioventures IV LP, each of which is a 5% stockholder, have indicated an interest in purchasing an aggregate of approximately \$33.0 million in

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shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering.

\_\_\_\_\_

**Citigroup**

**Piper Jaffray**

\_\_\_\_\_

**Cowen and Company**

**Stifel Nicolaus Weisel**

\_\_\_\_\_

, 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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Table of Contents**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 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" and "our" 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. We are developing several product candidates in neurology and psychiatry to address large market opportunities in epilepsy and attention deficit hyperactivity disorder, or ADHD, including ADHD patients with impulsive aggression. We intend to market our product candidates in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists.

We use our proprietary technologies to enhance the therapeutic benefits of approved antiepileptic drugs, or AEDs, through advanced extended release formulations. Our two epilepsy product candidates are SPN-538 (extended release topiramate), for which we submitted a new drug application, or NDA, that was accepted for filing by the U.S. Food and Drug Administration, or the FDA, in November 2011, and SPN-804 (extended release oxcarbazepine) for which we submitted an NDA that was accepted for filing by the FDA in February 2012. The Prescription Drug User Fee Act, or PDUFA, date for SPN-538 is in July 2012. The PDUFA date for SPN-804 is in October 2012. Our ADHD product candidates include SPN-810 (molindone hydrochloride), which is in 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 four lead 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. antidepressant 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.

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

<b>Product</b>	<b>Indication</b>	<b>Status</b>
<b>SPN-538</b>	Epilepsy	NDA accepted by FDA
<b>SPN-804</b>	Adjunctive therapy for epilepsy	NDA accepted by FDA
<b>SPN-810</b>	Impulsive Aggression in ADHD	Phase IIb
<b>SPN-812</b>	ADHD	Phase IIa
<b>SPN-809</b>	Depression	IND filed

***Our Late-Stage 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<sup>(1)</sup> and

(1)

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

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2 million people in the United States.<sup>(2)</sup> 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:

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(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*).

Extended release products have been shown to improve compliance and reduce breakthrough seizures.<sup>(3)</sup>

(3)

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

Extended release products have been shown to reduce side effects and improve tolerability.<sup>(4)</sup>

(4)

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

Managed care plans have not limited the success of extended release products.<sup>(5)</sup>

(5)

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

Extended release products generally have performed well in the market.<sup>(6)</sup>

(6)

IMS Health data.

*SPN-538 (extended release topiramate)*

Our most advanced product candidate, SPN-538, is a novel oral once-daily extended release topiramate product for the treatment of epilepsy. 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 and is indicated 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, blocking the sodium channel 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, somnolence and slowing of certain cognitive functions.

SPN-538 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. SPN-538'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 have conducted fourteen clinical trials in support of the development of SPN-538 and one additional clinical trial is ongoing. The NDA for SPN-538 was accepted for filing by the FDA in November 2011 and the PDUFA date is in July 2012. We are pursuing a regulatory strategy under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which allows us to rely in our submission on the existing data and knowledge the FDA has from the NDA of Topamax.

*SPN-804 (extended release oxcarbazepine)*

Our second late-stage product candidate, SPN-804, is a novel oral once-daily extended release formulation of oxcarbazepine for which we submitted an NDA that was accepted for filing by the FDA in February 2012. 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



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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, smoother and more consistent blood levels compared to immediate release products such as Trileptal, we believe SPN-804 has the potential of improving the tolerability of oxcarbazepine by reducing the side effects experienced by patients. We have conducted nine clinical trials, including bioequivalence trials and a Phase III trial, and we are conducting two ongoing clinical trials to support the development of SPN-804. The NDA for SPN-804 was accepted for filing by the FDA in February 2012 and the PDUFA date is in October 2012. We are pursuing a Section 505(b)(2) regulatory strategy, which allows us to rely in our filing on the existing data and knowledge the FDA has from the NDA of Trileptal.

***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.<sup>(7)</sup> 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.<sup>(8)</sup> In addition, approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.<sup>(9)</sup>

(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*.

***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 expect results in the second half of 2012. 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.

We have completed four clinical trials for SPN-810, including a Phase IIA trial in which we tested the safety and tolerability of immediate release molindone hydrochloride in children 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 results. SPN-810 also showed improvements on the primary and secondary outcome measures, such as conduct problem and ADHD scales, across all four treatment groups.

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*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. 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.

***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 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. In addition, we have used our proprietary technologies to develop an oral formulation of tadalafil diethanolamine, which is the subject of an NDA for pulmonary arterial hypertension submitted by United Therapeutics Corporation and accepted for filing by the FDA in February 2012 and for which the PDUFA date is in October 2012.

***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 SPN-538 and SPN-804.* We are currently focused on attaining regulatory approval for, and bringing to market, our two late-stage epilepsy product candidates, SPN-538 and SPN-804. As these product candidates progress towards U.S. regulatory approval, we intend to build our own targeted, specialty sales force to promote, if approved, SPN-538 and SPN-804 in the United States. We intend to direct our marketing efforts to high potential prescribers of both product candidates.

*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, in June 2011 we initiated a Phase IIb trial of SPN-810 for impulsive aggression in patients with ADHD for which we expect results in the second half of 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

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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.

***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:

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

Final marketing approval of SPN-538, SPN-804 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 have never generated any revenues from the sales of our own products, and we may never achieve or maintain profitability.

If other versions of extended or controlled release topiramate or oxcarbazepine are approved and successfully commercialized, especially if approved before SPN-538 or SPN-804, our business would 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.



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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.

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. We may choose to take advantage of some but not all of these reduced burdens. We have not taken advantage of any 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.

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®," 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	11,000,000 shares
Common stock to be outstanding after this offering	24,912,319 shares
Over-allotment option	We have granted the underwriters an option for a period of up to 30 days to purchase up to 1,650,000 additional shares of common stock at the initial public offering price.
Use of proceeds after expenses	We estimate that the net proceeds from this offering, without giving effect to any participation in this offering by existing stockholders, will be approximately \$47.8 million, or approximately \$55.5 million if the underwriters exercise their over-allotment option in full based on an assumed initial public offering price of \$5.00 per share. We expect to use the net proceeds from this offering to fund the expected commercial launch of SPN-538 and the preparation for the commercial launch of SPN-804, the continued clinical development of SPN-810 and SPN-812, the repayment of a portion of the principle 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 11 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

NASDAQ Global Market symbol SUPN

Certain of our existing stockholders, including entities affiliated with New Enterprise Associates 11, Limited Partnership, OrbiMed Private Investments II, LP and Abingworth Bioventures IV, LP, have indicated an interest in purchasing an aggregate of approximately \$33.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering. Any shares purchased by these stockholders will be subject to the lock-up agreements described in the "Underwriting" section of this prospectus.

The number of shares of our common stock to be outstanding after this offering is based on 13,912,319 shares of common stock outstanding as of December 31, 2011 after giving effect to the conversion of 49,000,000 shares of our preferred stock outstanding as of December 31, 2011 into 12,249,998 shares of our common stock at the closing of this offering.

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

598,109 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2011, with exercise prices ranging from \$0.40 to \$7.04 per share and a weighted average exercise price of \$2.75 per share (of which options to acquire 262,568 shares of common stock were vested as of December 31, 2011);

489,571 additional shares of common stock reserved for future grants under our 2005 Stock Plan as of December 31, 2011;

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2,500,000 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;

375,000 shares of preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2011 at an exercise price of \$1.00 per share which, upon the closing of this offering, will convert into warrants to purchase 93,750 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$4.00 per share; and

200,000 shares of preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2011 with an exercise price of \$1.50 per share which, upon the closing of this offering, will convert into warrants to purchase 49,999 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$6.00 per share.

Unless otherwise indicated, all information in this prospectus:

assumes the automatic conversion of all outstanding shares of our preferred stock into 12,249,998 shares of common stock upon the closing of this offering; and

assumes no exercise by the underwriters of their option to purchase up to 1,650,000 shares of our common stock in this offering to cover over-allotments.

In addition, unless otherwise indicated, all information in this prospectus gives effect to the one-for-four reverse stock split of our common stock effected on April 9, 2012.

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We have derived the consolidated statements of operations data for the years ended December 31, 2009, 2010 and 2011 and the consolidated balance sheet data as of December 31, 2011 from our audited consolidated financial statements appearing elsewhere in this prospectus.

Our historical results are not necessarily indicative of future operating results. You should read this summary consolidated financial data in conjunction with the sections entitled "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,		
	2009	2010	2011
	(in thousands of dollars, except share and per share data)		
Consolidated Statement of Operations Data:			
Revenues			
Development and milestone revenues	\$ 1,050	\$ 106	\$ 803
Royalty revenues	36,875		
Total revenues	37,925	106	803
Costs and expenses			
Research and development	29,260	35,149	30,627
General and administrative	4,649	5,080	7,928
Total costs and expenses	33,909	40,229	38,555
Operating income (loss) from continuing operations	4,016	(40,123)	(37,752)
Other income (expense):			
Interest income	122	107	31
Interest expense			(1,866)
Other		542	117
Total other income (expense)	122	649	(1,718)
Income (loss) from continuing operations before income taxes	4,138	(39,474)	(39,470)
Income tax benefit		399	16,245
Income (loss) from continuing operations	4,138	(39,075)	(23,225)
Discontinued operations:			
Income (loss) from discontinued operations, net of tax	(3,678)	612	2,188
Gain on disposal of discontinued operations, net of tax			74,852
Income (loss) from discontinued operations	(3,678)	612	77,040
Net income (loss)	\$ 460	\$ (38,463)	\$ 53,815
Cumulative dividends on Series A convertible preferred stock			
	\$ (3,430)	\$ (3,430)	(3,430)



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Net income (loss) attributable to common stockholders	\$	(2,970)	\$	(41,893)	\$	50,385
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## Income (loss) per common share

Basic						
Continuing operations	\$	0.50	\$	(26.77)	\$	(16.60)
Discontinued operations		(2.60)		0.39		47.99
Net income (loss)		(2.10)		(26.38)		31.39
Diluted						
Continuing operations	\$	0.29	\$	(26.77)	\$	(16.60)
Discontinued operations		(0.26)		0.39		47.99
Net income (loss)		0.03		(26.38)		31.39
Weighted average number of common shares						
Basic		1,413,374		1,587,968		1,605,324
Diluted		14,081,186		1,587,968		1,605,324

Net income (loss) used to compute pro forma net income (loss) per common share basic and diluted (unaudited)<sup>(1)</sup>

Continuing operations	\$	(23,225)
Discontinued operations	\$	77,040
Net income	\$	53,815

Weighted-average number of shares used in calculating pro forma net income (loss) per share basic and diluted (unaudited)<sup>(1)</sup>

13,855,322

Pro forma net income (loss) per share basic and diluted<sup>(1)</sup>

Continuing operations	\$	(1.68)
Discontinued operations	\$	5.56
Net income	\$	3.88

(1)

Pro forma net income (loss) per share basic and diluted have been calculated assuming the conversion of all outstanding shares of our Series A convertible preferred stock into an aggregate of 12,249,998 shares of common stock upon completion of this offering, as if they had converted at the beginning of the period. Pro forma net income (loss) per share basic and diluted do not give effect to the sale of 11,000,000 shares of common stock that we are offering pursuant to this prospectus or any related estimated net proceeds therefrom. See Note 3 to our consolidated financial statements for an explanation of the method used to calculate the pro forma basic and diluted net income (loss) per common share and the per share amounts.

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The pro forma balance sheet data set forth below gives effect to the conversion of all outstanding shares of our Series A convertible preferred stock into an aggregate of 12,249,998 shares of common stock upon completion of this offering. The pro forma as adjusted balance sheet data set forth below gives further effect to the issuance and sale of 11,000,000 shares of our common stock in this offering at an assumed initial public offering price of \$5.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and without giving effect to any participation in this offering by existing stockholders.

	As of December 31, 2011		
	Actual	Pro Forma	Pro Forma as Adjusted
	(unaudited)		
	(in thousands of dollars)		
Consolidated Balance Sheet Data:			
Unrestricted cash and cash equivalents, and marketable securities	\$ 48,544	\$ 48,544	\$ 96,346
Restricted cash and cash equivalents, and marketable securities	245	245	245
Working capital	30,629	30,629	78,431
Total assets	53,730	53,730	101,532
Secured notes payable, including current portion	29,486	29,486	29,486
Series A convertible preferred stock	49		
Accumulated deficit	(39,971)	(39,971)	(39,971)
Total stockholders' equity	9,443	9,443	57,245
	10		

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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 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 seeking marketing approval for and planning for potential commercialization of our two most advanced product candidates, SPN-538 and SPN-804, 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 obtain marketing approval for and commercialize SPN-538 and SPN-804. Neither SPN-538 nor SPN-804 are approved for marketing in any jurisdiction and, therefore, unless they obtain regulatory approval, they may never be commercialized.

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

successfully complete our clinical trials;

produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;

receive marketing approvals from the FDA and similar foreign regulatory authorities;

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; and

manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

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 SPN-538, SPN-804 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, although we believe that we have already incurred the majority of the costs related to the development of SPN-538 and SPN-804, if we experience unanticipated delays or problems, these costs could substantially increase and our business, financial condition and results of operations will be adversely affected.



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***Final marketing approval of SPN-538, SPN-804 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.***

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. We cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any.

With respect to our two most advanced product candidates, SPN-538 (extended release topiramate) and SPN-804 (extended release oxcarbazepine), we are pursuing a regulatory strategy pursuant to 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 NDAs of Topamax and Trileptal, respectively. 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 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 SPN-538 in January 2011, but the FDA refused to file the NDA and raised questions relating to chemistry and manufacturing controls issues. The FDA accepted the NDA for filing in November 2011. In addition, in late December 2011, Upsher-Smith Laboratories, Inc., or Upsher-Smith, submitted a citizen petition to the FDA requesting that the FDA refrain from approving any application for extended-release topiramate that does not include an adequate and well-controlled clinical study demonstrating the safety and efficacy of the extended-release formulation. The citizen petition states that the FDA required Upsher-Smith to conduct such a study for its extended-release topiramate candidate and that it would be inequitable, in Upsher-Smith's opinion, for the FDA not to require other applicants for extended-release topiramate to conduct similar studies. To our knowledge, the FDA has not yet substantively responded to the citizen petition. If the FDA grants the petition and requires us to conduct a clinical study to demonstrate the safety or efficacy of SPN-538, the commercialization of SPN-538 could be delayed or prevented.

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, irrespective of Upsher-Smith's citizen petition with respect to SPN-538, the FDA:

could determine that we cannot rely on Section 505(b)(2) for SPN-538 or SPN-804;

could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of SPN-538, SPN-804 or 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;

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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 SPN-538, SPN-804 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 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 and efficacy of our product candidates, which could prevent or significantly delay regulatory approval.***

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

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

***Our 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 topiramate and oxcarbazepine, drug compounds upon which our SPN-538 and SPN-804 product candidates are based, respectively, are known to cause various side effects, including dizziness, paresthesia, headaches, cognitive deficiencies such as memory loss and speech impediment, digestive



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problems, somnolence, double vision, gingival enlargement, nausea, weight gain, and fatigue. The use of SPN-538 and SPN-804 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 product candidates 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 product candidates and could substantially increase commercialization costs.

***If other versions of extended or controlled release topiramate or oxcarbazepine are approved and successfully commercialized, especially if approved before SPN-538 or SPN-804, our business would be materially harmed.***

Other third parties may seek approval to manufacture and market their own versions of extended release topiramate or oxcarbazepine in the United States. If any of these parties obtain FDA approval before we do, they may be entitled to three years of marketing exclusivity. Such exclusivity would delay the commercialization of SPN-538 and SPN-804 and, as a result, we may never achieve significant market share for these product candidates. Consequently, revenues from product sales of these product candidates would be similarly delayed and our business, including our development programs, and growth prospects would suffer. For example, we are aware that Upsher-Smith is currently conducting a Phase III clinical trial for USL255 (extended release topiramate) and, in connection with our NDA submission for SPN-538, has filed a citizen petition with the FDA alleging that it would be inequitable, in Upsher-Smith's opinion, for the FDA not to require other applicants for extended-release topiramate to conduct similar studies. If the FDA grants the petition and requires us to conduct another clinical study of SPN-538, the approval of SPN-538 by the FDA could be delayed. If Upsher-Smith's USL255 product is approved by the FDA before SPN-538, 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 SPN-538 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 outside of the United States modified-release oxcarbazepine products, such as Apydan, which is developed by Desitin Arzneimittel GmbH and requires twice-daily administration. If companies with modified-release oxcarbazepine products outside





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of the United States pursue or obtain approval of their products within the United States before we do, such competing products may be granted three year marketing exclusivity, which would significantly delay SPN-804's entry into the U.S. market. Such a delay would limit the potential success of SPN-804 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 topiramate or oxcarbazepine in the United States, we may not be able to recover expenses incurred in connection with the development of our product candidates or realize revenues from SPN-538 or SPN-804.

***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 provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active pharmaceutical ingredient, or active moiety. 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. If we are unable to obtain marketing exclusivity for our product candidates including SPN-538, our competitors may obtain approval of competing products more easily than if we had such marketing exclusivity, and our future revenues could be reduced, possibly materially.

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

Delays or failures in the completion of clinical trials for our product candidates could significantly raise our product development costs. We do not know whether current or planned trials will be completed on schedule, if at all. The commencement and completion of clinical development can be delayed or halted for a number of reasons, including:

difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;

delays in reaching or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

insufficient or inadequate supply or quantity of a product candidate for use in trials;

difficulties obtaining institutional review board or ethics committee approval to conduct a trial at a prospective site;

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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. 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 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 product candidates that are commercialized unless we are able to differentiate them. We anticipate that we will face intense competition when and if our product candidates are approved by regulatory authorities and we begin the commercialization process. 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 attention deficit hyperactivity disorder, or ADHD, market in the United States has increased with the launch of several products in recent years, including the launch of generic versions of branded drugs such as Adderall XR. As a result, we may not be able to recover expenses incurred in connection with the development of our product candidates or realize revenues from any commercialized product.

In addition to already marketed competing products, we believe certain companies are developing other products which could compete with our product candidates should they be approved by



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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 announced the initiation of a Phase III clinical trial for USL255 (extended release topiramate) for the management of epilepsy in adults. If successful, such competing product could limit the potential success of SPN-538, 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. If companies with modified-release oxcarbazepine products outside of the United States obtain approval for their products within the United States prior to us, such competing products may obtain three years of marketing exclusivity, which would significantly delay our entry into the U.S. market and limit the potential success of SPN-804. 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.

***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



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product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our product candidates.

***We have limited sales and marketing experience and resources, and we may not be able to effectively market and sell our product candidates in the United States, if approved.***

We are preparing the build-out of our commercial infrastructure to launch our product candidates within the United States. We have limited sales or marketing experience. To develop internal sales and marketing capabilities, we will have to invest 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 SPN-538, SPN-804 or any other of our product candidates will be approved. We believe that net proceeds from this offering will be sufficient to complete the development of SPN-538 and SPN-804 and to fund the expected commercial launch of SPN-538 and the preparation for the commercial launch of SPN-804, assuming FDA approval on their respective PDUFA dates. Accordingly, we will need to obtain additional funds beyond the proceeds of this offering to complete the commercial launch of SPN-804. If the commercial launch of SPN-538 or SPN-804 is delayed for a protracted period of time as a result of FDA requirements or other reasons, we would 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;

the cost of establishing a marketing or sales force may not be justifiable in light of the revenues generated by any of our product candidates, if approved; and

our direct sales and marketing efforts may not be successful.

If we are unable to establish adequate sales and marketing capabilities, we may not be able to generate product revenues and may never become profitable.

***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. Any 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.

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***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.

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 our product candidates including SPN-538 and SPN-804, which could prevent us from being able to commercialize these product candidates. 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.



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

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. For example, we are involved in the following matters related to Paragraph IV Certification Notice Letters that we have received in connection with our collaborators' products. In connection with an ANDA, a Paragraph IV Certification Notice Letter notifies the FDA that one or more patents listed in the FDA's Approved Drug Product List (Orange Book) is alleged 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

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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. have filed an appeal and we intend to support them in their 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 Sanctura XR.

*Oracea Litigation.* We are involved in a patent infringement matter filed in response to four Paragraph IV Certification Notice Letters that we received in November 2010, January 2011, April 2011 and September 2011 regarding an ANDA, submitted to the FDA by each of Lupin Limited, Sandoz Inc., Impax Laboratories, Inc. and Amneal Pharmaceuticals LCC, respectively, requesting approval to market and sell generic versions of Oracea doxycycline, a product that is manufactured and sold by Galderma Laboratories, L.P. The ANDA filers alleged in their respective original notice letters that the U.S. Patent Number 7,749,532 issued to us is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product described in their ANDA submissions. In addition, we have received in October 2010, a complaint for Declaratory Judgment from Mylan alleging invalidity of the 7,749,532 patent. This matter was tried in July 2011. The District Court for the District of Delaware held that Mylan infringed certain claims of the patent, and that the claims are valid. Our patent covers once-daily formulations of doxycycline, including methods of their use in treating rosacea and processes regarding their preparation, and expires on December 19, 2027, and is licensed to Galderma Laboratories, L.P. We intend to support Galderma Laboratories, L.P. in 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 Oracea.

*Intuniv Litigation.* We are involved in several patent infringement actions filed in response to Paragraph IV Certification Notice Letters that we received in March, April and October 2010, and February, March and October 2011, regarding ANDAs submitted to the FDA requesting approval to market and sell generic versions of Intuniv, a product that is manufactured and sold by Shire LLC. The defendants in these cases are Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd; Actavis Elizabeth LLC and Actavis Inc.; Anchen Pharmaceuticals, Inc. and Anchen, 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 Numbers 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. Our patents cover extended-release formulations containing guanfacine hydrochloride, with the latest patent expiration in 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

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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.

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

Even if our product candidates are approved for sale by the appropriate regulatory authorities, physicians may not prescribe our approved product candidates, in which case we would not generate the revenues we anticipate. Market acceptance of any of our 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 candidate as a safe and effective treatment;

perceived advantages of our product candidates over alternative treatments;

relative convenience and ease of administration of our product candidates compared to existing treatments;

any labeling restrictions placed upon each product candidate in connection with its approval;

the prevalence and severity of the adverse side effects of each of our product candidates;

the clinical indications for which each of our product candidates is approved, including any potential additional restrictions placed upon each product candidate in connection with its approval;

prevalence of the disease or condition for which each product candidate is approved;

the cost of treatment in relation to alternative treatments, including generic products;

the extent to which each product is approved for inclusion on formularies of hospitals and managed care organizations;

any negative publicity related to our or our competitors' products, including as a result of any related adverse side effects;

the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;

pricing and cost effectiveness; and

the availability of adequate reimbursement by third parties.

For example, new AEDs that were introduced in the market as new chemical entities, or NCEs, historically have not quickly gained significant market share against existing molecules in the epilepsy

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market, because physicians are often reluctant to change a stable patient's existing therapy (even for a NCE) and risk a breakthrough seizure in their patients. Although our epilepsy product candidates are not NCEs, if approved, they would be subject to the risk that they will not be able to gain significant market share against existing AEDs. If our 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 product candidates to become or remain profitable on a timely basis, if at all.

***Even if our product candidates receive regulatory approval, they 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 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 GMP, 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, our collaborators, our collaborators' approved products or our product candidates, or the manufacturing facilities for our collaborators' approved products or our 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, if any of our product candidates are approved, our product labeling, advertising and promotion would be 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. If we receive marketing approval for our product candidates, physicians may nevertheless prescribe 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.

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***If we fail to produce our 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 product candidates.***

We do not currently own or operate manufacturing facilities for the production of any of our product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently depend on third-party contract manufacturers for the supply of the active pharmaceutical ingredients for our product candidates, including drug substance for our preclinical research and clinical trials. For SPN-538 and SPN-804, we currently rely on single suppliers for raw materials including drug substance and single manufacturers for the product candidates, and expect to rely on third-party suppliers and manufacturers for the final commercial products. 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 production, 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 SPN-538 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 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 GMP 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 product candidates may be unable to comply with these GMP 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 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 product candidate, 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 product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates. Furthermore, for our two most advanced product candidates, SPN-538 and SPN-804, we are presently negotiating agreements with leading contract manufacturing organizations, or CMOs, headquartered in North America for the manufacture of the final commercial products. 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 product candidates, if any, and would lose potential revenues.

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

We have a license agreement with United Therapeutics to use one of our proprietary technologies for an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension, or PAH, as well as for other indications. This oral formulation is the subject of an NDA for PAH submitted by United Therapeutics and accepted for filing by the FDA in February 2012 and for which the PDUFA date is in October 2012. If United Therapeutics receives approval to market and sell this product candidate, we are entitled to receive single digit gross royalties based on worldwide net sales. We are also entitled to receive milestones and royalties for use of this formulation in other indications. If we materially breach any of our obligations under the license agreement, however, we could lose the potential to receive any future royalty payments thereunder, which could be financially significant to us.

We also have a license agreement 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 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 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 candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or

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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;

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 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 SPN-538 and SPN-804, we currently rely on single suppliers for raw materials including drug substance and single manufacturers for the product candidates, 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 manufacturing 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 SPN-538 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 do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates. For our two most advanced product candidates, SPN-538 and SPN-804, we are presently negotiating agreements with leading CMOs headquartered in North America for the manufacture of the final commercial products. 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.



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***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.

***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 product candidates.***

Government agencies promulgate regulations and guidelines directly applicable to us and to our 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 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 product candidates.

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

Our ability or our collaborators' ability to commercialize our product candidates, including SPN-538 and SPN-804, successfully 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 product candidates, including SPN-538 and SPN-804, less attractive to patients and prescribing physicians. We also may be required to sell our product candidates at a discount, which would adversely affect our ability to realize an appropriate return on our investment in our 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 product candidates, including SPN-538 and SPN-804, in determining whether to approve reimbursement for such 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 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 product candidates from private insurers on a timely or satisfactory basis. Our approved product candidates, if any, may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our 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 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 product candidates to other available therapies. If reimbursement for our 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 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.

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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 product candidates for which we may obtain marketing approval 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 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 candidate that has received approval and is being commercialized;

impairment of our business reputation and exposure to adverse publicity;

withdrawal of bioequivalence and/or clinical trial participants;

initiation of investigations by regulators;

costs of related litigation;

distraction of management's attention from our primary business;

substantial monetary awards to patients or other claimants;

loss of revenues; and

the inability to commercialize any of our product candidates for which we obtain marketing approval.

Our product liability insurance coverage for our clinical trials is limited to \$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. If and when we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain this product liability insurance on commercially reasonable terms. 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 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.



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The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

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

exposure to unknown liabilities;

disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;

incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

higher than expected acquisition and integration costs;

difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

increased amortization expenses;

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

inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

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

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any 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 candidate profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our potential 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



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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 product candidates. If reimbursement for our approved product candidates, if any, 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. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of any approved product candidates.

Future federal and state proposals and health care reforms could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the PPACA by the possible effect of such current or future legislation on 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 need to effectively execute our growth strategy requires that we:

manage our regulatory approval 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





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revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

***We may not be able to manage our business effectively if we are unable to attract and motivate key personnel or if we lose any 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 any members of our management team, we may not be able to find suitable replacements in a timely fashion, if at all. For instance, following the resignation of our Senior Vice President, Chief Medical Officer, Dr. Paolo Baroldi, in March 2012, we intend to manage such responsibilities through existing personnel and services provided by Dr. Baroldi under a consulting arrangement. 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. For instance, since the October 2011 resignation of Russell P. Wilson, our Chief Financial Officer since 2009, we have had two Chief Financial Officers, including Gregory S. Patrick, our Chief Financial Officer since November 2011.

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

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

***We 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 U.S. Patent and Trademark Office. 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.

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***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 manufacturer 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 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

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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.

***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

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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 product candidates, with the goal of 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, and the sale of our subsidiary, TCD Royalty Sub LLC, or Royalty Sub, which held the license rights to Oracea and Sanctura XR. We have incurred significant operating losses since our inception in 2005. We incurred net losses of approximately \$17.3 million, \$33.5 million and \$38.5 million in the years ended December 31, 2007, 2008 and 2010, 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 December 31, 2011, we had an accumulated deficit of approximately \$40.0 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs and from general and administrative costs associated with our operations. For example, the expenses that we have incurred relating to the research and development of SPN-538 and SPN-804 from inception to December 31, 2011 are approximately \$28.4 million and \$48.8 million, respectively. We expect our research and development costs to continue to be substantial and to increase with respect to our product candidates as we advance those product candidates through preclinical studies, clinical trials, manufacturing scale-up and other pre-approval activities. 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, upon the closing of this offering, we expect to incur 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 offering will eliminate this doubt and enable us to continue as a going concern. However, even after giving effect to the expected net proceeds in this offering, we may need to obtain capital through equity offerings, debt financing and/or payments under new or existing licensing and research and development collaboration agreements. For instance, the net proceeds from this offering will be sufficient to fund the preparation for the commercial launch of SPN-804, assuming timely FDA approval. Accordingly, we will need to obtain additional funds beyond the proceeds of this offering to complete the commercial launch of SPN-804. 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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***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 it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing unrestricted cash, cash equivalents and marketable securities and anticipated future product revenues, will be sufficient to fund our operations for at least the next 12 months. However, we will need to obtain additional funds beyond the proceeds of this offering to complete the commercial launch of SPN-804, if approved by the FDA. We may need to obtain additional capital through equity offerings, debt financing and/or payments under new or existing licensing and research and development collaboration agreements prior to any future profitability. 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;

the costs of establishing sales, marketing and distribution capabilities; 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 the sales of our own 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 product candidates. To date, we have not generated any revenues from product sales of our own 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 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.

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Our ability to generate product revenues is dependent on our ability to receive regulatory approval of our product candidates, including SPN-538 and SPN-804, and to successfully commercialize these products. Our ability to successfully commercialize our product candidates 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 SPN-538 and SPN-804; and

if regulatory approvals are received, our manufacturing of commercial quantities of our product candidates at acceptable cost levels.

Even if any of 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 quarterly operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. 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 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 product candidates, our net loss and other operating results will be affected by numerous factors, including:

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

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

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

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

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

our ability to establish an effective sales and marketing infrastructure;

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

competition from existing products or new products that may emerge;

regulatory developments affecting our product candidates;

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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 periods 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

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stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

***We have operated as a private company and have no experience attempting to comply with public company obligations. Attempting to comply with these requirements will increase our costs and require additional management resources, and we still may fail to comply.***

We will 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, will result 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 Exchange Act will require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage.

As a public company, we expect to become 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.

***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, 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 will be required to disclose changes made in our internal control and procedures on a quarterly basis and our management will be 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



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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 beginning in 2025, if not utilized. We have not 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. 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,

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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, 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; and

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.

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

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

Since our inception in 2005, we have generated no revenue from product sales and have incurred significant operating losses. As of December 31, 2011, we had an accumulated deficit of \$40.0 million. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to develop and seek marketing approval for our product candidates. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our secured credit facility. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations would be significantly limited, and we may be required to delay, significantly curtail or eliminate one or more of our programs.

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

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

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

dispose of certain assets;

change our lines of business;

engage in mergers or consolidations;

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incur additional indebtedness;

create liens on assets, including our intellectual property;

pay dividends and make distributions on or repurchase our capital stock; and

engage in certain transactions with affiliates.

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

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

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

**Risks Related to Securities Markets and Investment in Our Stock**

***The concentration of our capital stock ownership with our directors, executive officers and current holders of our preferred stock (and their affiliates) will limit your ability to influence certain corporate matters.***

Upon completion of this offering and after giving effect to the conversion of the Series A convertible preferred stock into common stock, our directors, executive officers and the current holders of our Series A convertible preferred stock will, in the aggregate, beneficially own 56.0% of our outstanding common stock (or approximately 52.6% if the underwriters exercise their over-allotment option in full) assuming no participation in the offering by these stockholders. As a result, these stockholders will collectively be able to significantly influence and may be able to 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. In addition, certain current holders of our Series A convertible preferred stock and their affiliated entities have indicated an interest in purchasing an aggregate of approximately \$33.0 million in shares of our common stock in this offering at the initial public offering price. To the extent these existing stockholders are allocated

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and purchase shares in this offering, the concentration of voting power in our executive officers, directors and current holders of our Series A convertible preferred stock would increase, which may negatively impact the liquidity 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 and restated upon the completion of this offering, may have the effect of delaying or preventing a change of control. These provisions include the following:

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

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

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

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

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

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

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

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

***There may not be a viable public market for our common stock.***

Prior to this offering, there has been no public market for our common stock, and a regular trading market may not develop and continue after this offering. Furthermore, the market price of our common stock may decline below the initial public offering price. The initial public offering price has been determined through negotiations between us and the representatives of the underwriters and may



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not be indicative of the market price of our common stock following this offering. Among the factors considered in such negotiations were prevailing market conditions, certain of our financial information, market valuations of other companies that we and the representatives of the underwriters believed were comparable to us, estimates of our business potential and the present state of our business. See "Underwriting" for additional information.

If you purchase shares of our common stock, you may not be able to resell those shares at or above the initial public offering price. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the Nasdaq Global Market or otherwise or how liquid that market might become. Certain of our existing stockholders and their affiliated entities, including holders of more than 5% of our common stock, have indicated an interest in purchasing an aggregate of approximately \$33.0 million in shares of our common stock in this offering at the initial public offering price. To the extent these existing stockholders are allocated and purchase shares in this offering, such purchases would reduce the available public float for our shares because these stockholders will be restricted from selling the shares by restrictions under applicable securities laws and the lock-up agreements described in the "Shares Eligible for Future Sale" and "Underwriting" sections of this prospectus. As a result, the liquidity of our common stock could be significantly reduced from what it would have been if these shares had been purchased by investors that were not affiliated with us.

An active public market for our common stock may not develop or be sustained after the offering. If an active public market does not develop or 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.

***As a new investor, you will experience immediate and substantial dilution in the net tangible book value of your shares.***

The initial public offering price of our common stock in this offering is considerably more than the net tangible book value per share of our common stock. Investors purchasing shares of common stock in this offering will pay a price that substantially exceeds the value of our tangible assets after subtracting liabilities. As a result, these investors will, as of December 31, 2011:

incur immediate dilution of \$2.83 per share of common stock, based on an assumed initial public offering price of \$5.00 per share of common stock; and

contribute 53% of the total amount invested to date to fund our company based on an assumed initial offering price of \$5.00 per share of common stock, but will own only 44% of the outstanding shares of common stock after the offering.

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

As of December 31, 2011, we had options to purchase 598,109 shares of common stock outstanding, with exercise prices ranging from \$0.40 to \$7.04 per share and a weighted average exercise price of \$2.75 per share. Upon the vesting of each of these options, the holder may exercise his or her options, which would result in further dilution to investors.

As of December 31, 2011, we had outstanding warrants to purchase (i) 375,000 shares of Series A convertible preferred stock at an exercise price of \$1.00 per share and (ii) 200,000 shares of Series A convertible preferred stock at an exercise price of \$1.50 per share. Upon completion of this offering, the respective lender warrants will convert into (i) warrants to purchase 93,750 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$4.00 per share and

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(ii) warrants to purchase 49,999 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$6.00 per share. You may experience dilution if we issue additional shares of common stock under the warrants that we issued to our 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 not been previously traded publicly. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, including:

plans for, progress in and results from clinical trials of our product candidates generally;

the results from our bioequivalence trials for SPN-538 and our bioequivalence and/or clinical trials, including our current Phase III clinical trials for SPN-804;

FDA or international regulatory actions, including actions on regulatory applications for any of our product candidates;

the commercial performance of any of our product candidates that receive marketing approval;

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 continued development, commercialization and research and development of our product candidates, to repay 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



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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."

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

While we do not currently anticipate making additional offers of common stock, such sales, 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 and impair our ability to raise adequate capital through the sale of additional equity securities. Immediately after this offering, we will have outstanding 24,912,319 shares of common stock, based on the number of outstanding shares of common stock as of December 31, 2011 and after giving effect to the conversion of 49,000,000 shares of our preferred stock outstanding as of December 31, 2011 into 12,249,998 shares of our common stock at the completion of this offering. Of these outstanding shares, 11,000,000 shares are being sold in this offering and will be freely tradable immediately after this offering, except for shares purchased in this offering by affiliates or by existing stockholders who are subject to lock-up agreements, and the remaining shares may be sold upon expiration of lock-up agreements 180 days after the date of this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. In addition, as of December 31, 2011, we had outstanding options and warrants to purchase 741,858 shares of common stock that, if exercised, will result in these additional shares becoming available for sale upon expiration of the lock-up agreements. 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 also intend to register 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. Effective upon the closing of this offering, an aggregate of 2,500,000 and 250,000 shares of our common stock will be reserved for future issuance under the 2012 Equity Incentive Plan and the 2012 Employee Stock Purchase Plan, respectively. Once we register these shares, which we plan to do shortly after the closing of this offering, they can 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.

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***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 do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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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 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;

the respective PDUFA dates for 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;

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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

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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, without giving effect to any participation in this offering by existing stockholders, will be approximately \$47.8 million, or \$55.5 million if the underwriters exercise their over-allotment option in full. This projection is based upon an assumed initial public offering price of \$5.00 per share and after deducting estimated underwriting discounts and commissions as well as estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$5.00 per share would increase (decrease) the net proceeds from this offering by \$10.2 million, after deducting underwriting discounts, commissions, and estimated offering expenses payable by us, assuming that the number of shares offered, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase (decrease) of one million shares in the number of shares of common stock offered by us would increase (decrease) the net proceeds from this offering by \$4.7 million, after deducting underwriting discounts, commissions, and estimated offering expenses payable by us, assuming that the assumed initial public offering price, remains the same.

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

Approximately \$27.0 million for sales and marketing expenses in conjunction with the expected commercial launch of SPN-538 and the preparation for the commercial launch of SPN-804, assuming timely approval by the FDA.

Approximately \$2.5 million to fund the continued clinical development of SPN-810, including: preclinical carcinogenicity testing; process development for commercial bulk active pharmaceutical ingredient; and completion of current Phase II testing.

Approximately \$1.4 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.

Approximately \$5.8 million to repay a portion of the principle of the term loans under our secured credit facility.

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 complete the development of SPN-538 and SPN-804 through FDA approval and to fund the expected commercial launch of SPN-538 and preparation for the commercial launch of SPN-804, assuming FDA approval on their respective PDUFA dates. In addition, our operating plan, including our planned commercialization of SPN-538 and SPN-804, may change as a result of many factors such as those described in the "Risk Factors" section of this prospectus.

As of December 31, 2011, we had \$30.0 million of term loans outstanding under our secured credit facility, of which \$15.0 million mature in August 2014 and \$15.0 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 terms loans to fund ongoing clinical trials for SPN-538, SPN-804 and SPN-810, to prepare for manufacturing validation of SPN-538 and SPN-804, to support formulation for various clinical stage products, to prepare commercial marketing of SPN-538 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

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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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**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.



Table of Contents**CAPITALIZATION**

The following table sets forth our cash and capitalization as of December 31, 2011:

on an actual basis;

on a pro forma basis, reflecting the conversion of all of our outstanding preferred stock into an aggregate of 12,249,998 shares of common stock upon the closing of this offering; and

on a pro forma as adjusted basis to further reflect our receipt of the estimated net proceeds from our sale of 11,000,000 shares of common stock offered hereby at an assumed public offering price of \$5.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and without giving effect to any participation in this offering by existing stockholders.

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.

	As of December 31, 2011					
	Actual		Pro Forma (unaudited)		Pro Forma as Adjusted <sup>(1)</sup> (unaudited)	
	(in thousands of dollars, except share and per share data)					
<b>Balance Sheet Data:</b>						
Unrestricted cash and cash equivalents and marketable securities	\$	48,544	\$	48,544	\$	96,346
Restricted cash and cash equivalents and marketable securities		245		245		245
Debt outstanding	\$	29,486	\$	29,486	\$	29,486
<b>Stockholders' equity:</b>						
Series A convertible preferred stock, \$0.001 par value 49,625,000 shares authorized, 49,000,000 shares issued and outstanding, actual; none, pro forma and pro forma as adjusted		49		14		25
Common stock, \$0.001 par value 62,625,000 shares authorized, 1,662,321 shares issued and outstanding, actual; 62,625,000 shares authorized, 13,912,319 shares issued and outstanding, pro forma; and 130,000,000 shares authorized, 24,912,319 shares issued and		2				

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outstanding, pro forma as adjusted			
Additional paid-in capital	49,362	49,399	97,190
Accumulated other comprehensive income (loss)	1	1	1
Accumulated deficit	(39,971)	(39,971)	(39,971)
Total stockholders' equity	9,443	9,443	57,245
Total capitalization	\$ 38,929	\$ 38,929	\$ 86,731

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$5.00 per share would increase (decrease) each of additional unrestricted cash, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$10.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of one million shares in the number of shares offered by us would increase (decrease) each of unrestricted cash, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$4.7 million, assuming that the assumed initial public offering price remains the same.

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The table above does not include:

598,109 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2011 at a weighted average exercise price of \$2.75 per share;

489,571 additional shares of common stock reserved for future issuance under our 2005 Stock Plan;

2,500,000 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;

375,000 shares of preferred stock issuable upon the exercise of warrants outstanding at an exercise price \$1.00 per share which, upon the closing of this offering, will convert into warrants to purchase 93,750 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$4.00 per share; and

200,000 shares of preferred stock issuable upon the exercise of warrants outstanding as of December, 31, 2011 at an exercise price of \$1.50 per share which, upon the closing of this offering, will convert into warrants to purchase 49,999 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$6.00 per share.

Table of Contents**DILUTION**

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share you will pay in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of December 31, 2011 was approximately \$6.3 million, or \$3.81 per share of common stock. Net tangible book value per share is equal to our total tangible assets, which excludes patents and deferred financing costs, minus total liabilities, all divided by the number of shares of common stock outstanding as of December 31, 2011.

Our pro forma net tangible book value per share as of December 31, 2011 was approximately \$0.46 per share. Pro forma net tangible book value per share gives effect to the conversion of all outstanding shares of our preferred stock as of December 31, 2011 into 12,249,998 shares of our common stock, upon the closing of this offering.

After giving effect to the sale of the 11,000,000 shares of common stock we are offering based on the assumed initial public offering price of \$5.00 per share, less estimated underwriting discounts and commissions and our estimated offering expenses, our pro forma as adjusted net tangible book value as of December 31, 2011 would have been approximately \$54.1 million, or \$2.17 per share. This represents an immediate increase in pro forma net tangible book value of \$1.71 per share and an immediate dilution of \$2.83 per share to new investors. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by a new investor. The following table illustrates this calculation on a per share basis (without giving effect to the over-allotment option granted to the underwriters):

Assumed initial public offering price per share <sup>(1)</sup>	\$ 5.00
Net tangible book value per share as of December 31, 2011	3.81
Effect on net tangible book value per share attributable to conversion of preferred stock outstanding at December 31, 2011	(3.35)
Pro forma net tangible book value per share of common stock as of December 31, 2011	0.46
Increase per share attributable to the offering	1.71
Pro forma as adjusted net tangible book value per share of common stock after this offering	2.17
Pro forma dilution per share to new investors	\$ 2.83

(1) The assumed initial public offering price set forth on the cover page of this prospectus.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$5.00 per share would increase (decrease) the pro forma as adjusted net tangible book value per share after giving effect to this offering by \$0.41 per share and would increase (decrease) the dilution in pro forma net tangible book value per share to investors in this offering by \$0.59 per share. This calculation assumes that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and is after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their over-allotment option in full, pro forma as adjusted net tangible book value will increase to \$2.33 per share, representing an increase to existing holders of \$1.87 per share, and there will be an immediate dilution of \$2.67 per share to new investors.

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The following table summarizes, on a pro forma as adjusted basis as of December 31, 2011, after giving effect to this offering and the pro forma adjustments referred to above, the total number of shares of our common stock purchased from us and the total consideration and average price per share paid by existing stockholders and by new investors:

	Total Shares		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
(in thousands of dollars, except share and per share data)					
Existing stockholders	13,912,319	56%	\$ 49,398	47%	\$ 3.55
New Investors	11,000,000	44	55,000	53	5.00
Total	24,912,319	100%	\$ 104,398	100%	

If the underwriters exercise their over-allotment option in full, the following will occur:

the pro forma as adjusted percentage of shares of our common stock held by existing stockholders will decrease to approximately 52% of the total number of pro forma as adjusted shares of our common stock outstanding after this offering; and

the pro forma as adjusted number of shares of our common stock held by new public investors will increase to approximately 48% of the total pro forma as adjusted number of shares of our common stock outstanding after this offering.

The tables and calculations above are based on 13,912,319 shares of our common stock outstanding as of December 31, 2011 after giving effect to the conversion of 49,000,000 shares of our preferred stock outstanding as of December 31, 2011 into 12,249,998 shares of our common stock at the closing of this offering and exclude:

598,109 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2011 with exercise prices ranging from \$0.40 to \$7.04 per share and a weighted average exercise price of \$2.75 per share (of which options to acquire 262,568 shares of common stock were vested as of December 31, 2011);

489,571 shares of our common stock available for future grants under our 2005 Stock Plan as of December 31, 2011;

2,500,000 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;

375,000 shares of preferred stock issuable upon the exercise of warrants outstanding as of December 31, 2011 at an exercise price of \$1.00 per share which, upon the closing of this offering, will convert into warrants to purchase 93,750 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$4.00 per share; and

200,000 shares of preferred stock issuable upon the exercise of warrants outstanding as of December, 31, 2011 at an exercise price of \$1.50 per share which, upon the closing of this offering, will convert into warrants to purchase 49,999 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$6.00 per share.

If all of our outstanding options and warrants as of December 31, 2011 were exercised, the pro forma as adjusted net tangible book value per share after this offering would be \$2.20 per share, representing an increase to existing holders of \$1.74 per share, and there will be an immediate dilution of \$2.80 per share to new investors. In addition, we will need to obtain additional capital, and we may choose to raise such

additional capital through equity offerings, debt financing and/or payments under new or existing licensing and research and development collaboration agreements. To the extent that

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additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities would result in further dilution to our stockholders.

Certain of our existing stockholders, including entities affiliated with New Enterprise Associates 11, Limited Partnership, OrbiMed Private Investments II, LP and Abingworth Bioventures IV, LP, have indicated an interest in purchasing an aggregate of approximately \$33.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering. The foregoing discussion and tables do not reflect any potential purchases by these existing stockholders or their affiliated entities.

Table of Contents**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, 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 for the fiscal years ended December 31, 2007 and 2008 are derived from our audited consolidated financial statements not included in this prospectus.

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,				
	2007	2008	2009	2010	2011
	(in thousands of dollars, except share and per share data)				
Consolidated Statement of Operations Data:					
Revenue:					
Development and milestone revenue	\$ 1,405	\$ 2,497	\$ 1,050	\$ 106	\$ 803
Royalty revenue	2,828	1,512	36,875		
Total revenues	4,233	4,009	37,925	106	803
Operating Expenses:					
Research and development	19,269	30,463	29,260	35,149	30,627
General and administrative	4,011	4,287	4,649	5,080	7,928
Total operating expenses	23,280	34,750	33,909	40,229	38,555
Operating income (loss) from continuing operations	(19,047)	(30,741)	4,016	(40,123)	(37,752)
Other income (expense):					
Interest income	1,773	1,036	122	107	31
Interest expense					(1,866)
Other				542	117
Total other income (expense)	1,773	1,036	122	649	(1,718)
Income (loss) from continuing operations before income taxes	(17,274)	(29,705)	4,138	(39,474)	(39,470)
Income tax benefit				399	16,245
Income (loss) from continuing operations	(17,274)	(29,705)	4,138	(39,075)	(23,225)
Discontinued operations:					
Income (loss) from discontinued operations, net of tax		(3,777)	(3,678)	612	2,188
Gain on disposal of discontinued operations, net of tax					74,852
Income (loss) from discontinued operations		(3,777)	(3,678)	612	77,040
Net income (loss)	\$ (17,274)	\$ (33,482)	\$ 460	\$ (38,463)	\$ 53,815



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Cumulative dividends on Series A convertible preferred stock	(3,430)	(3,430)	(3,430)	(3,430)	(3,430)
Net income (loss) attributable to common stockholders	\$ (20,704)	\$ (36,912)	\$ (2,970)	\$ (41,893)	\$ 50,385

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	Year Ended December 31,				
	2007	2008	2009	2010	2011
	(in thousands of dollars, except share and per share data)				
Income (loss) per common share:					
Basic					
Continuing operations	\$ (19.47)	\$ (26.94)	\$ 0.50	\$ (26.77)	\$ (16.60)
Discontinued operations		(3.07)	(2.60)	0.39	47.99
Net income (loss)	(19.47)	(30.01)	(2.10)	(26.38)	31.39
Diluted					
Continuing obligations	\$ (19.47)	\$ (26.94)	\$ 0.29	\$ (26.77)	\$ (16.60)
Discontinued obligations		(3.07)	(0.26)	0.39	47.99
Net income (loss)	(19.47)	(30.01)	0.03	(26.38)	31.39
Weighted average number of common shares:					
Basic	1,063,433	1,229,956	1,413,374	1,587,968	1,605,324
Diluted	1,063,433	1,229,956	14,081,186	1,587,968	1,605,324
Income (loss) used to compute pro forma income (loss) per common share basic and diluted <sup>(1)</sup>					
Continuing operations				\$ (23,225)	
Discontinued operations					77,040
Net income					53,815
Weighted-average number of shares used in calculating pro forma income (loss) per share basic and diluted <sup>(1)</sup>					13,855,322
Pro forma net income (loss) per common share basic and diluted <sup>(1)</sup>					
Continuing operations				\$ (1.68)	
Discontinued operations				\$ 5.56	
Net income				\$ 3.88	

(1)

Pro forma income (loss) per share basic and diluted have been calculated assuming the conversion of all outstanding shares of the Company's Series A convertible preferred stock into an aggregate of 12,249,998 shares of common stock upon completion of this offering, as if they had converted at the beginning of the period. Pro forma income (loss) per share basic and diluted do not give effect to the sale of 11,000,000 shares of common stock that we are offering pursuant to this prospectus or any related estimated net proceeds therefrom. See Note 3 to our consolidated financial statements for an explanation of the method used to calculate the pro forma basic and diluted net income (loss) per common share and the per share amounts.

	Year Ended December 31,				
	2007	2008	2009	2010	2011
	(in thousands of dollars)				
<b>Consolidated Balance Sheet Data:</b>					
Unrestricted cash and cash equivalents and marketable securities	\$ 25,592	\$ 60,380	\$ 66,524	\$ 32,704	\$ 48,544
Restricted cash and cash equivalents and marketable securities <sup>(1)</sup>	281	6,281	2,076	1,714	245
Working capital	22,674	61,183	62,847	24,607	30,629
Total assets	31,907	77,134	79,899	47,009	53,730
Notes payable, including current portion					29,486
Liabilities of discontinued operations		75,000	75,000	75,000	

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Series A convertible preferred stock	49	49	49	49	49
Accumulated deficit	(22,301)	(55,782)	(55,323)	(93,786)	(39,971)
Total stockholders' equity (deficit)	26,635	(6,747)	(6,156)	(44,320)	9,443

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(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. We are developing several product candidates in neurology and psychiatry to address large market opportunities in epilepsy, attention deficit hyperactivity disorder, or ADHD, including ADHD patients with impulsive aggression. Our two epilepsy product candidates are SPN-538 (extended release topiramate), for which we have submitted a new drug application, or NDA, that was accepted for filing by the FDA in November 2011, and SPN-804 (extended release oxcarbazepine), for which we submitted an NDA that was accepted for filing by the FDA in February 2012. The Prescription Drug User Fee Act, or PDUFA, date for SPN-538 is in July 2012. The PDUFA date for SPN-804 is in October 2012. Our ADHD product candidates include SPN-810 (molindone hydrochloride), which is in 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 four lead product candidates, we have several additional product candidates in various stages of development. We intend to market our product candidates in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists. 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 anti-epileptic drugs, or AEDs through advanced extended release formulations. Our most advanced product candidates, SPN-538 and SPN-804, are novel oral once-daily extended release formulations of topiramate and oxcarbazepine, respectively, for the treatment of epilepsy. Immediate release formulations of topiramate and oxcarbazepine are available in generic form and are marketed under the brand names of Topamax and Trileptal, respectively. According to IMS Health, peak sales of Topamax and Trileptal represented an estimated 25.8% and 8.1% of the total seizure disorder market in 2008 and 2006, respectively. We are pursuing a Section 505(b)(2) regulatory strategy for SPN-538 and SPN-804, which allows us to rely on the existing data from the NDAs of Topamax and Trileptal, respectively. The once-per-day dosing of SPN-538 and SPN-804 is designed to improve patient compliance and to have a better tolerability profile compared to the current immediate release AEDs that are taken multiple times per day to maintain therapeutic drug concentrations over the dosing interval. We believe there is a significant unmet need for extended release products, such as SPN-538 and SPN-804, for the treatment of epilepsy. Extended release products have been shown to improve

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compliance, increase seizure control,<sup>(1)</sup> reduce side effects and improve tolerability as compared to immediate release products.<sup>(2)</sup>

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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 Scandinavica*.

We are also developing treatments for new indications in diseases such as ADHD and its coexisting disorders. We are developing SPN-810, which is currently in a Phase IIb trial 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 antidepressant in Europe, this product candidate, if studied in that specific patient population and is shown to be effective, may provide increased benefit to an estimated 40% of ADHD patients who suffer from depression.<sup>(3)</sup> In addition to these four lead product candidates, 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. antidepressant market.

(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*.

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 product sales and have incurred significant operating losses. As of December 31, 2011, we had an accumulated deficit of approximately \$40.0 million and a total stockholders' equity of approximately \$9.4 million. We expect to incur net losses and negative cash flow from operating activities 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 SPN-538 and SPN-804, as well as our 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.

We have historically raised capital through private equity and the monetization of certain future royalty streams under our existing licenses for Oracea, Sanctura XR and Intuniv. In connection with the commencement of our operations, in December 2005 and February 2006, we raised approximately

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\$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 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.

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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 pulmonary arterial hypertension, or PAH, as well as for other indications. United Therapeutics has stated that this oral formulation of treprostinil diethanolamine, or treprostinil, is the subject of an NDA for PAH that it submitted in December 2011 and that was accepted for filing by the FDA in February 2012 and for which the PDUFA date is in October 2012. 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. If United Therapeutics receives approval to market and sell this product candidate, we are entitled to receive single digit royalties based on worldwide net sales. 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 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 are immediately exercisable and expire on January 26, 2021. 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 to purchase an aggregate of 200,000 shares of our Series A convertible preferred stock at an exercise price of \$1.50 per share. The warrants are immediately exercisable and expire on December 30, 2021. Upon completion of this offering, the respective lender warrants will convert into (i) warrants to purchase 93,750 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$4.00 per share and (ii) warrants to purchase 49,999 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$6.00 per share.

All of our warrant holders are subject to lock-up agreements with the underwriters in this offering. 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).

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

Table of Contents**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,		
	2009	2010	2011
	(in thousands of dollars)		
Continuing operations:			
Development and milestone revenues			
collaboration arrangements	\$ 1,050	\$ 106	\$ 803
Royalty revenues Intuniv	36,875		
Total continuing operations revenues	37,925	106	803
Discontinued operations:			
Development and milestone revenues			
Oracea & Sanctura XR	500		
Royalty revenues Oracea & Sanctura XR	8,088	13,404	14,398
Total discontinued operations revenues	8,588	13,404	14,398
Total revenues	\$ 46,513	\$ 13,510	\$ 15,201

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 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 obtain regulatory approval for SPN-538, SPN-804 or 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.



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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 SPN-804 program have been higher than our other programs in recent years because SPN-804 recently completed Phase III clinical trials that began in late 2008.

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



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a summary of our research and development expenses for the years ended December 31, 2009, 2010 and 2011 and from our inception in late 2005 to December 31, 2011.

	Year Ended December 31,			From Inception to December 31,
	2009	2010	2011	2011
	(in thousands of dollars)			(unaudited)
SPN-538	\$ 6,464	\$ 9,864	\$ 6,262	\$ 28,436
SPN-804	10,027	12,664	10,959	48,794
SPN-810	3,333	2,150	4,152	14,025
SPN-812 and SPN-809	680	2,042	1,166	9,245
Other research and development programs	426	690	204	7,919
Development expenses general	8,330	7,739	7,884	45,383
Total research and development expenses	\$ 29,260	\$ 35,149	\$ 30,627	\$ 153,802

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. Accordingly, 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 product candidates to complete current or future clinical or pre-commercial stages prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, SPN-538, SPN-804 or any of our 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



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diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

***General and Administrative Expenses***

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 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 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 SPN-538 and SPN-804 in the United States. Upon approval of SPN-538, we would internally develop a sales force, initially consisting of a certain number of field sales representatives to support the launch of the product. We would then seek to expand our sales force in connection with an approval and commercial launch of SPN-804. 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. Additionally, once we complete this offering, we would also expect to have 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 as of December 31, 2011. Interest expense for the year ending December 31, 2011 was approximately \$1.9 million. Interest expense on the non-recourse notes includes amortization of the related deferred financing costs and was \$12.3 million, \$12.4 million and \$11.7 million for fiscal years 2009, 2010 and 2011, respectively, and is included as an element of discontinued operations (see Note 7 to our consolidated financial statements).

***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

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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 continue to develop our product portfolio, seek regulatory approval, and, if such approval is obtained, commercialize SPN-538 and SPN-804 as well as our other product candidates.

## Results of Operations

### 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)		
<b>Revenues:</b>			
Development and milestone revenues	\$ 106	\$ 803	\$ 697
<b>Total revenues</b>	<b>106</b>	<b>803</b>	
<b>Operating Expenses:</b>			
Research and development	35,149	30,627	(4,522)
General and administrative	5,080	7,928	2,848
<b>Total operating expenses</b>	<b>40,229</b>	<b>38,555</b>	
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)
<b>Loss from continuing operations before income taxes</b>	<b>(39,474)</b>	<b>(39,470)</b>	
Income tax benefit	399	16,245	
<b>Loss from continuing operations</b>	<b>\$ (39,075)</b>	<b>\$ (23,225)</b>	<b>15,850</b>
<b>Discontinued operations:</b>			
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
<b>Income from discontinued operations</b>	<b>612</b>	<b>77,040</b>	
<b>Net income (loss)</b>	<b>\$ (38,463)</b>	<b>\$ 53,815</b>	

**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 SPN-804 was substantially completed by the first quarter of 2011.

**General and Administrative.** Our 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 associated with preparing for launches of SPN-538 and SPN-804 during the year ended December 31, 2011.



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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.

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

	Year Ended December 31,		Increase/ (decrease)
	2009	2010	
	(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
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





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\$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 \$1.0 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 \$35.2 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 SPN-804, and higher manufacturing costs of approximately \$0.9 million principally associated with pre-validation work performed by our commercial manufacturers for both SPN-538 and SPN-804.

**General and Administrative.** Our 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, SPN-538 and SPN-804.

**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

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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. As of December 31, 2011, we had unrestricted cash, cash equivalents and marketable securities of approximately \$48.5 million.

***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 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

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\$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 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 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 are immediately exercisable and 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 to purchase an aggregate of 200,000 shares of our Series A convertible preferred stock at an exercise price of \$1.50 per share. The warrants are immediately exercisable and expire on December 30, 2021. Upon completion of an initial public offering, the respective lender warrants will convert into (i) warrants to purchase 93,750 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$4.00 per share and (ii) warrants to purchase 49,999 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$6.00 per share. We have primarily used the proceeds of the term loans under our secured credit facility to fund ongoing clinical trials for SPN-538, SPN-804 and SPN-810, to prepare for manufacturing validation of SPN-538 and SPN-804, to support formulation for various clinical stage products, to prepare commercial marketing of SPN-538 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.

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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 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.

***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. 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 and for which the PDUFA date is in October 2012. Through December 31, 2011, we have received \$1.5 million in pre-commercial milestone payments under the agreement. Remaining milestone payments to us could total up to approximately \$6.0 million, which includes milestone payments that could total \$2.0 million based on the satisfaction of development milestones of oral treprostinil in PAH and up to approximately \$4.0 million for the development of additional treprostinil products for a second indication. If United Therapeutics receives approval to market and sell 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.

***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 SPN-804 product, in Mexico, Venezuela, Colombia and other select

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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 SPN-804 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 2014. We monitor this estimate on a quarterly basis to determine if facts and circumstances may have changed that would require a prospective adjustment of the recognition period. We may receive up to \$3.0 million in additional milestone payments, based on certain regulatory and commercial milestones defined in the agreement. As of December 31, 2011, \$697,000 remained recorded as deferred revenue.

***Funding Requirements***

As of December 31, 2011, we had unrestricted cash, cash equivalents and marketable securities of \$48.5 million. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing unrestricted cash, cash equivalents and marketable securities, and anticipated future product revenues, will be sufficient to fund our operations for at least the next 12 months. Successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure, which we do not expect in the near term, if at all. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

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 SPN-538, SPN-804 and our other product candidates. If we obtain marketing approval for SPN-538 or SPN-804, 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 following the closing of this offering. 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. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern. However, even after giving effect to the net expected net proceeds of this offering, we may need to obtain additional financing through equity offerings, debt financings and/or payments under new or existing licensing and research and development collaboration agreements. For instance, the net proceeds from this offering will be sufficient to fund the preparation for the commercial launch of SPN-804, assuming timely FDA approval. Accordingly, we will need to obtain additional funds beyond the proceeds of this offering to complete the commercial launch of SPN-804.

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

The timing and outcome of the FDA's review of the NDA for SPN-538;

The timing and outcome of the FDA's review of the NDA for SPN-804;

The extent to which the FDA may require us to perform additional clinical trials or pre-commercial manufacturing activities for SPN-538 or SPN-804;

The timing and success of this offering;

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The costs of our commercialization activities for SPN-538 and/or SPN-804, if either is approved by the FDA;

The cost of purchasing manufacturing and other capital equipment for our potential products;

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.

We may need to obtain additional capital through equity offerings, debt financing and/or payments under new or existing licensing and research and development collaboration agreements, including to complete the commercial launch of SPN-804. We expect that our progress in the development of our product candidates may provide sufficient value inflection milestones, based on which we will be able to seek additional funding. The type, timing, and terms of financing will depend upon our cash needs, the availability of financing sources and the prevailing conditions in the financial markets. There can be no assurance that such financing will be available to us at any given time or available on favorable terms, if at all. 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, additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

## ***Cash Flows***

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

	Years Ended December 31,		
	2009	2010	2011
	(in thousands)		
Net cash provided by (used in):			
Operating activities:			
From continuing operations	\$ 6,845	\$ (32,192)	\$ (38,206)
From discontinuing operations	(4,211)	(352)	2,021
Investing activities:			
From continuing operations	(28,385)	25,823	8,295
From discontinuing operations			25,607
Financing activities:			
From continuing operations	20	(1,341)	29,054
From discontinuing operations	4,260	397	(1,967)
Net increase (decrease) in cash and cash equivalents	\$ (21,471)	\$ (7,665)	\$ 24,804





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***Operating Activities***

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 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 SPN-538 and SPN-804. 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 relating to the increased clinical trial and pre-validation manufacturing expenses for SPN-538 and SPN-804 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.

***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, which generally mature in one year 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 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.

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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***

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 this 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.

***Contractual Obligations and Commitments***

The following table summarizes our contractual obligations and commitments as of December 31, 2011 (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 <sup>(1)</sup>	\$ 6,775	\$ 23,225	\$	\$	\$ 30,000
Interest on Secured Credit Facility <sup>(1)</sup>	3,013	3,150			6,163
Operating leases <sup>(2)</sup>	971	1,951	2,029	1,399	6,350
Purchase obligations <sup>(3)</sup>	6,247				6,247
<b>Total<sup>(4)</sup></b>	<b>\$ 17,006</b>	<b>\$ 28,326</b>	<b>\$ 2,029</b>	<b>\$ 1,399</b>	<b>\$ 48,760</b>

(1) Annual interest expense is currently \$3.0 million on \$30.0 million of principal outstanding currently.

(2) Our commitments for operating leases relate to our lease of copiers and office and laboratory space as of December 31, 2011.

(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.



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

**Off-Balance Sheet Arrangements**

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

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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 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

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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.

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.

***Accrued Expenses***

As part of the process of preparing the 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 contract research organizations, or 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

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overestimate the level of services 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,		
	2009	2010	2011
	(In Thousands)		
Research and development	\$ 28	\$ 53	\$ 63
General and administrative	83	244	(145)
Total	\$ 111	\$ 297	\$ (82)

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 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 is currently no market-based mechanism or other practical application 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

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employee stock-based awards is determined using an option-pricing model, that value may not be indicative of the fair value 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.

Our board of directors estimated the fair value for our common stock, with input from management. 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 are 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 are entitled to a liquidation preference. The aggregate amount of liquidation preferences, has 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 equals 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 this prospectus, including the estimated fair value of the option grant as determined by the

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Black-Scholes option-pricing model for options granted in 2009 and 2010, or by the probability-weighted expected return method, or PWERM, for options granted in 2011 and 2012.

Grant Date	Number of Options	Exercise Price	Estimated Fair Value	Intrinsic Value
January 19, 2009	56,250	\$ 1.60	\$ 0.93	\$
December 15, 2009 <sup>(1)</sup>	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	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.

The intrinsic value of all outstanding vested and unvested options as of December 31, 2011 based on the assumed initial public offering price of \$5.00 per share and the exercise price of the outstanding options are as follows:

	Number of Options	Intrinsic Value
Unvested	335,541	\$ 488,755
Vested	262,568	\$ 975,306

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.

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

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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 have Series A convertible preferred stock outstanding, it was also necessary to allocate our company's value to the various classes of stock. As 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 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 probability weighted expected return method 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

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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 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 SPN-538, and, if approved before SPN-538, would have 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

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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%

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 SPN-538 was accepted for filing by the FDA and after the NDA was submitted for SPN-804 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 SPN-538 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 SPN-538 and/or SPN-804 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

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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 launch SPN-538 and as the NDA for SPN-538 and SPN-804 were under review. Moreover, given that the number and 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.

### *Offering Price*

The assumed initial public offering price of \$5.00 per share was determined based on discussions with the underwriters, the general condition of the securities markets and the recent market prices of, and the demand for, publicly-traded common stock of generally comparable companies.

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***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 an initial public offering, the respective lender warrants will convert into (i) warrants to purchase 93,750 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$4.00 per share and (ii) warrants to purchase 49,999 shares of common stock at an exercise price equal to the lesser of the initial public offering price or \$6.00 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 upon completion of an initial public offering (at which time the shares underlying the warrants are converted from Series A Preferred Stock to common stock).

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. Upon consummation of this offering, the warrants will continue to be recorded as a derivative liability.

Change in fair value of warrant liability represents non-cash (expense) income associated with changes in the fair value of the warrants to purchase preferred 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. The fair values of the preferred stock warrants are estimated in accordance with the AICPA Practice Aid. Several objective and subjective factors are considered when 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 is estimated based upon an analysis of future values for the entire equity instrument assuming various future outcomes. Share value is 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 is estimated for each possible event based on the facts and circumstances as of the valuation date. We will continue to adjust the warrant liability for changes in fair value until the earlier of the exercise or expiration of the warrants. Subsequent to the completion of an initial public offering, the fair value of the warrants will be determined using either a risk-neutral lattice methodology within a Monte-Carlo analysis or 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 until the warrants are exercised or they expire to reflect conditions at each such valuation date. Under either methodology, 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.



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**Recent Accounting Pronouncements**

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income*, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of stockholders' equity. Instead, a company must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. We intend to adopt ASU 2011-05 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-05 will have a material impact on our condensed consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. ASU 2011-04 created a uniform framework for applying fair value measurement principles and clarified existing guidance in GAAP. ASU 2011-04 will be effective for the first annual reporting period beginning after December 15, 2011 and must be applied prospectively. We will adopt ASU 2011-04 in the first quarter of fiscal year 2012. We do not believe that the adoption of ASU 2011-04 will have a material impact on our condensed consolidated financial statements.

**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 December 31, 2011, we had unrestricted cash, cash equivalents and marketable securities of \$48.5 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, 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 \$488,000 for the year ended December 31, 2011. 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 \$488,000 for the year ended December 31, 2011. We do not believe that inflation and changing prices over the years ended December 31, 2009, 2010 and 2011 had a significant impact on our consolidated results of operations.

Table of Contents**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 developing several product candidates in neurology and psychiatry to address large market opportunities in epilepsy and attention deficit hyperactivity disorder, or ADHD, including ADHD patients with impulsive aggression. Our two epilepsy product candidates are SPN-538 (extended release topiramate), for which our submitted NDA was accepted for filing by the U.S. Food and Drug Administration, or FDA, in November 2011, and SPN-804 (extended release oxcarbazepine), for which we submitted an NDA that was accepted for filing by the FDA in February 2012. The Prescription Drug User Fee Act, or PDUFA, date for SPN-538 is in July 2012. The PDUFA date for SPN-804 is in October 2012. Our ADHD product candidates include SPN-810 (molindone hydrochloride), which is in 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 of ADHD. Both of these programs are in Phase II. In addition to these four lead product candidates, we have several additional product candidates in various stages of development. We intend to market our product candidates in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists. We believe our diversified and broad 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 anti-epileptic drugs, or AEDs through advanced extended release formulations. Our most advanced product candidates, SPN-538 and SPN-804, are novel oral once-daily extended release formulations of topiramate and oxcarbazepine, respectively, for the treatment of epilepsy. Immediate release formulations of topiramate and oxcarbazepine, are available in generic form and are marketed by Johnson & Johnson and Novartis under the brand names of Topamax and Trileptal, respectively. According to IMS Health, peak sales of Topamax and Trileptal represented an estimated 25.8% and 8.1% of the total seizure disorder market in 2008 and 2006, respectively. We are pursuing a Section 505(b)(2) regulatory strategy for SPN-538 and SPN-804, which allows us to rely on the existing data from the NDAs of Topamax and Trileptal, respectively. The once-per-day dosing of each of SPN-538 and SPN-804 is designed to improve patient compliance and to provide a better tolerability profile compared to the current immediate release AEDs that are taken multiple times per day to maintain therapeutic drug concentrations over the dosing interval. We believe there is a significant unmet need for extended release products, such as SPN-538 and SPN-804, for the treatment of epilepsy. Extended release products have been shown to improve compliance, reduce side effects and improve tolerability<sup>(1)</sup> as compared to immediate release products, which can lead to increased seizure control.<sup>(2)</sup>

(1)

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

(2)

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

We are also developing treatments for new indications in diseases such as ADHD and its coexisting disorders. We are developing SPN-810, which is in a Phase IIb trial, 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

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other non-stimulant treatments for ADHD. In addition, because the active ingredient of SPN-812 has demonstrated efficacy as an antidepressant in Europe, this product candidate, if studied in that specific patient population and is shown to be effective, may provide increased benefit to an estimated 40% of ADHD patients who suffer from depression.<sup>(3)</sup>

(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*.

In addition to these four lead product candidates, we have a number of other product candidates in various stages of development such as SPN-809, for which we submitted an investigational new drug application, or IND, in 2008 and which would represent a novel mechanism of action for the U.S. antidepressant market.

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

Product	Indication	Status
SPN-538	Epilepsy	NDA accepted by FDA
SPN-804	Adjunctive therapy for epilepsy	NDA accepted by FDA
SPN-810	Impulsive Aggression in ADHD	Phase IIb
SPN-812	ADHD	Phase IIa
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.

### 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 SPN-538 and SPN-804.* We are currently focused on attaining regulatory approval for, and bringing to market our two late-stage epilepsy products, SPN-538 and SPN-804, to market. As these product candidates progress towards U.S. regulatory approval, we intend to build our own targeted, specialty sales force to promote, if approved, SPN-538 and SPN-804 in the United States. We intend to direct our marketing efforts to high potential prescribers of both products.

*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, in June 2011 we initiated a Phase IIb trial for SPN-810 for impulsive aggression in patients with ADHD for which we expect results in the second half of 2012.

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*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<sup>(4)</sup> and 2 million people in the United States.<sup>(5)</sup> According to IMS Health, U.S. sales of AEDs were approximately \$4.0 billion in 2010. The annual cost of epilepsy to the healthcare system is estimated to be \$12.5 billion.<sup>(6)</sup>

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(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.

(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 Scandinavica*).

Epileptic seizures can cause a person to experience severe muscle jerking, to lose consciousness and fall, or to suffer from distorted vision, all potentially leading to physical injuries or hospitalization. Until reliable seizure control has been achieved, patients are forced to adjust their lifestyles to avoid activities that a seizure can significantly disrupt or render life threatening. A breakthrough seizure is a sudden, unexpected seizure experienced by a patient who previously had achieved reliable seizure control. Even when no physical injury occurs, breakthrough seizures often result in significant social, legal and developmental consequences for patients such as loss of driver's license, loss of employment, disruption of school attendance, academic underachievement, and disruption of social networks. In addition, a single breakthrough seizure can lead to permanent loss or reduction in overall seizure control. Data suggest that a significant proportion of patients who experience a breakthrough seizure have a lower chance of achieving reliable seizure control.<sup>(7)</sup> 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.<sup>(8)</sup>

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### ***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 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.<sup>(9)</sup> 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 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.<sup>(10)</sup> 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.<sup>(11)</sup>

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

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

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

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

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

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fluctuations of blood levels of the active drug during the day, with peak concentrations when the drug is released and potentially sub-therapeutic concentrations thereafter. At least one study has shown that complaints of side effects typically occur when blood levels exceed certain concentrations, particularly at high doses, and the risk of breakthrough seizures can occur when blood levels are below certain minimum effective levels, as indicated in the chart below.

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

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

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

Patients today are most typically switched from branded drugs to generics, or from one generic drug to another, mainly to reduce cost. In most states, unless a physician explicitly writes "dispense as written" or "no substitution," pharmacists can switch a patient to a lower-cost generic drug without the consent of either the patient or the physician. Epilepsy patients are particularly vulnerable to changes in their drugs. 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.<sup>(12)</sup>

(12)

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

A number of epilepsy advocacy groups such as the Epilepsy Foundation, 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 (NICE), Sweden's Medical Products Agency (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





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increase in breakthrough seizures resulting from switching from branded drugs to generics.<sup>(13)</sup> 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.

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(13)

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

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

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

***Benefits of Extended Release Products in the Epilepsy Market***

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

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

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

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

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

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

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

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**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 launches of extended release products Keppra XR and Lamictal XR have enjoyed acceptance rates by managed care plans that are similar to those of the corresponding immediate release products. Most managed care plans also acknowledge the position of several patient advocacy groups and the American Academy of Neurology regarding the risks of generic substitution of AEDs, including potential for breakthrough seizures. Although switching to a low-cost generic AED may initially offer some cost savings, we believe they also recognize that the risk and cost of one breakthrough seizure outweighs the potential savings from generics. For example, the healthcare costs associated with the treatment of patients who experience breakthrough seizures, which may run in excess of \$26,000 per patient on an annual basis, is significantly greater than any cost savings per patient that may be achieved through switching to a low-cost generic AED. According to a 2009 survey, the total healthcare costs for patients using branded topiramate products were approximately 20% lower than for patients using multiple generic topiramate products.<sup>(14)</sup>

(14)

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



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***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 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 launch. We believe that the modest conversion of the corresponding molecule prescriptions of the recent launches of Keppra XR and Lamictal XR was due to limited promotional support behind both products resulting from the launch by the same companies shortly thereafter of other AEDs competing for the same promotional resources.

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

Source: IMS Health

**Our Late-Stage Neurology Portfolio**

We are developing a promising epilepsy product portfolio consisting of SPN-538 and SPN-804 that utilize our proprietary technologies, Microtrol and Solutrol, 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 with the molecules' pharmacokinetic profiles. Our differentiated approach to product development and the strength of our technologies have allowed us to develop SPN-538 with what we believe to be a unique pharmacokinetic profile and to develop a once-daily formulation of oxcarbazepine with SPN-804 where others have failed.

SPN-538 and SPN-804 are novel extended release formulations of two well known and approved AEDs, topiramate and oxcarbazepine, 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

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concentrations of topiramate and oxcarbazepine, our product candidates 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 SPN-538 and SPN-804 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 accepted our NDA for SPN-538 for filing in November 2011 and our NDA for SPN-804 for filing in February 2012. The PDUFA date for SPN-538 is in July 2012. The PDUFA date for SPN-804 is in October 2012. The development and regulatory strategy for both products follows a Section 505(b)(2) pathway, which allows us to rely upon FDA's previous findings of safety and efficacy for two known and approved products, Topamax and Trileptal. Therefore, our NDAs are not required to have the same amount of safety or efficacy data as would be required in the case of an NCE, and each NDA could contain different types of clinical trials and clinical data.

**SPN-538 (extended release topiramate)**

Our most advanced product candidate is SPN-538, a novel oral once-daily extended release topiramate product for the treatment of epilepsy. We initially submitted the NDA for this product candidate in January 2011 and resubmitted it in September 2011 to address refusal-to-file questions raised by the FDA, relating to chemistry and manufacturing controls issues. We addressed these questions to the FDA's satisfaction and, consequently, the FDA issued an acceptance of the NDA for filing in November 2011. We have conducted fourteen clinical trials in support of the development of SPN-538 and one additional clinical trial is ongoing. SPN-538 delivers topiramate, one of the most effective AEDs, which 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.<sup>(15)</sup> With approximately 9.6 million total topiramate prescriptions in 2010 and trending at 10.1 million prescriptions in 2011, topiramate continues to represent a significant portion of prescriptions with approximately 9.7% 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 SPN-538 as an alternative therapy to immediate release topiramate with an improved once-per-day profile.

(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.

SPN-538 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. SPN-538'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.

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SPN-538 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 equivalent Topamax twice-a-day immediate release doses for two weeks and then converted to an equivalent once daily dose of SPN-538 for two more weeks. The study successfully met its primary objective of showing that SPN-538 is bioequivalent to Topamax immediate release in epilepsy patients. For example, the ratio of dose-normalized (200 mg) geometric least-square means SPN-538 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). SPN-538 was also well tolerated and the majority of the patients (85.5%) converted from Topamax immediate release to SPN-538 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 (SPN-538) help you to be more compliant in taking your medication?**

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***SPN-538 Development Program***

We have conducted fourteen clinical trials in support of the development of SPN-538 and one additional clinical trial is ongoing. The NDA for SPN-538 was accepted by the FDA in November 2011 and the PDUFA date is in July 2012. We are pursuing a Section 505(b)(2) regulatory strategy, which allows us to rely in our filing on the FDA's findings of safety and effectiveness of Topamax. The various clinical trials conducted on SPN-538 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 SPN-538 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 regulatory approval, we believe that SPN-538 will be the first once-daily topiramate product approved for the monotherapy and adjunct therapy of epilepsy. We believe that SPN-538 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. Upon the launch of SPN-538, we plan to build a small specialty sales force primarily targeting neurologists to promote the use of SPN-538 in epilepsy in the United States. This physician group is responsible for a substantial portion of the prescriptions for the treatment of epilepsy and, accordingly, provides an attractive, focused market opportunity for us.

**SPN-804 (extended release oxcarbazepine)**

Our second late-stage product candidate, SPN-804, formerly referred to as Epliga, is a novel oral once-daily extended release formulation of oxcarbazepine, for which we submitted an NDA in December 2011 that was accepted for filing by the FDA in February 2012. To date, we have conducted nine clinical trials, including bioequivalence trials and a Phase III trial, and we are conducting two clinical trials to support the development of SPN-804.

SPN-804 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.<sup>(16)</sup> With approximately 3.4 million total oxcarbazepine prescriptions in 2010 and trending at 3.5 million prescriptions in 2011, oxcarbazepine represents a portion of prescriptions with approximately 3.4% 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. SPN-804 has been designed to reduce side effects, resulting in improved patient compliance and tolerability.

(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.

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 SPN-804 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



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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, SPN-804's once-per-day dosing is designed to improve patient compliance compared to the current immediate release products that are taken multiple times per day.

***SPN-804 Development Program***

We have conducted nine clinical trials, including bioequivalence trials and a Phase III trial, and we are conducting two ongoing clinical trials to support the development of SPN-804. We submitted the NDA for SPN-804 that was accepted for filing by the FDA in February 2012. The PDUFA date for SPN-804 is in October 2012. We submitted an IND for SPN-804 in 2007. We are pursuing a Section 505(b)(2) regulatory strategy, which allows us to rely in our filing on the existing data and knowledge the FDA has from the NDA of Trileptal. The various clinical trials conducted on SPN-804 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 has produced clinical supplies to conduct our Phase III trial.

In our pilot clinical trial in 32 healthy subjects, which took place in Canada, SPN-804 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 SPN-804 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 SPN-804 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 SPN-804. There were 190 total adverse events reported for Trileptal, while SPN-804 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 SPN-804. More specifically, Trileptal demonstrated a 36.7% occurrence rate of dizziness as compared to SPN-804 which demonstrated a 0.0% occurrence rate in our trial. In other trials, SPN-804 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.

We have discussed our Phase III trial for SPN-804 with the FDA in the form of a Special Protocol Assessment, or SPA. The Phase III protocol assessed the safety and effectiveness of SPN-804 as an adjunctive therapy in patients with a diagnosis of simple partial seizures and complex partial seizures with or without secondarily generalized seizures as confirmed by the 1981 and 1989 International League Against Epilepsy Classifications. We met with the FDA in July 2008 regarding the Phase III protocol. We revised the clinical protocol to address the FDA's comments and submitted a protocol amendment to the FDA in October 2008. We have not had any further discussions with the FDA relating to trial design after we submitted the amended protocol and proceeded with our study design

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in the absence of further discussion or confirmation from the FDA. The FDA has substantial discretion in the drug approval process and could determine that the amended protocol is inadequate, requiring us to revise our trial design or co