SUPERNUS PHARMACEUTICALS INC
Form S-1/A
March 16, 2012

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As filed with the Securities and Exchange Commission on March 15, 2012

Registration No. 333-171375

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 4
to

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

1550 East Gude Drive
Rockville, MD 20850
(301) 838-2500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Jack A. Khattar
President and Chief Executive Officer
1550 East Gude Drive
Rockville, MD 20850
(301) 838-2500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Paul M. Kinsella	**Gregory S. Patrick**	**Mitchell S. Bloom**
Ropes & Gray LLP	**Supernus Pharmaceuticals, Inc.**	**Edward A. King**
Prudential Tower	**Vice President, Chief Financial Officer**	**Goodwin Procter LLP**
800 Boylston Street	**1550 East Gude Drive**	**Exchange Place**
Boston, MA 02199-3600	**Rockville, MD 20850**	**Boston, MA 02109**
Telephone: (617) 951-7921	**Telephone: (301) 838-2500**	**Telephone: (617) 570-1000**
Facsimile: (617) 235-0822	**Facsimile: (301) 424-1364**	**Facsimile: (617) 523-1231**

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

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

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

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

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

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

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

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 MARCH 15, 2012

PRELIMINARY PROSPECTUS

Shares

Supernus Pharmaceuticals, Inc.

Common Stock
$ per share

This is the initial public offering of our common stock. We are selling shares of our common stock. We currently expect the initial public offering price to be between $ and $ per share of common stock.

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

We have applied to list our common stock on the Nasdaq Global Market under the symbol "SUPN."

Investing in our common stock involves risks. See "Risk Factors" on page 9.

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

	Per Share	Total
Public Offering Price	$	$
Underwriting 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.

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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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. 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.

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

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[(1)] 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.[2] Achieving reliable seizure control for patients, and avoiding the serious health and life dangers that can be associated with sudden unexpected, or breakthrough, seizures depends on patients being compliant and diligent in taking their medications. We believe there are a number of benefits associated with extended release products in epilepsy that create a significant market opportunity for us, including:

(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.[3]

(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.[4]

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

Managed care plans have not limited the success of extended release products.[5]

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

Extended release products generally have performed well in the market.[6]

(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. 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 treating epilepsy, is associated with many side effects that tend to limit its use. The side effects

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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. 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.[7] An estimated 60% to 80% of children with ADHD continue to meet the criteria for ADHD into adolescence, and as many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, conduct disorder, anxiety disorder and depression.[8] In addition, approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.[9]

(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.

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

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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 treprostinil 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.

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.

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

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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.

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	shares
Common stock to be outstanding after this offering	shares
Over-allotment option	We have granted the underwriters an option for a period of up to 30 days to purchase up to 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 will be approximately $ million, or approximately $ million if the underwriters exercise their over-allotment option in full. We expect to use the net proceeds from this offering to fund our clinical trials and for other general corporate purposes.
Risk factors	You should read the "Risk Factors" section of this prospectus beginning on page 9 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Global Market symbol	SUPN

The number of shares of our common stock to be outstanding after this offering is based on 55,649,302 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 49,000,000 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:

- 2,392,470 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2011, with exercise prices ranging from $0.10 to $1.76 per share and a weighted average exercise price of $0.69 per share (of which options to acquire 1,050,284 shares of common stock were vested as of December 31, 2011);
- 1,958,228 additional shares of common stock reserved for future grants under our 2005 Stock Plan as of December 31, 2011;
- shares of common stock reserved for future issuance under our 2012 Equity Incentive Plan;
- shares of common stock reserved for future issuance under our 2012 Employee Stock Purchase Plan;
- 375,000 shares of common stock issuable upon the exercise of preferred stock warrants outstanding as of December 31, 2011 at an exercise price of $1.00 per share, which will convert into common stock warrants upon the closing of this offering; and
- 200,000 shares of common stock issuable upon the exercise of preferred stock warrants outstanding as of December 31, 2011 with an exercise price of $1.50 per share, which will convert into common stock warrants upon the closing of this offering.

Unless otherwise indicated, all information in this prospectus:

- assumes the issuance and sale of shares of our common stock in the offering at the initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus;
- assumes our planned -for- reverse stock split of our common stock to be effected in connection with this offering;

assumes the automatic conversion of all outstanding shares of our preferred stock into 49,000,000 shares of common stock upon the closing of this offering; and

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

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SUMMARY FINANCIAL DATA

We have derived the consolidated statements of operations data for the years ended December 31, 2009, 2010 and 2011 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)

Net income (loss) attributable to common stockholders	$ (2,970)	$ (41,893)	$ 50,385
Income (loss) per common share			
Basic			
Continuing operations	$ 0.12	$ (6.70)	$ (4.15)
Discontinued operations	(0.65)	0.10	12.00
Net income (loss)	(0.53)	(6.60)	7.85
Diluted			
Continuing operations	$ 0.08	$ (6.70)	$ (4.15)
Discontinued operations	(0.07)	0.10	12.00
Net income (loss)	0.01	(6.60)	7.85
Weighted average number of common shares			
Basic	5,653,506	6,351,883	6,421,312
Diluted	56,324,761	6,351,883	6,421,312

Net income (loss) used to compute pro forma net income (loss) per common share basic and diluted (unaudited)(1)	
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)(1)	55,421,312
Pro forma net income (loss) per share basic and diluted(1)	
Continuing operations	$ (0.42)
Discontinued operations	$ 1.39
Net income	$ 0.97

(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 49,000,000 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 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 49,000,000 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 shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	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	$
Restricted cash and cash equivalents, and marketable securities	245	245	
Working capital	30,629	30,629	
Total assets	53,730	53,730	
Secured notes payable, including current portion	29,486	29,486	
Series A convertible preferred stock	49		
Accumulated deficit	(39,971)	(39,971)	
Total stockholders' equity	9,443	9,443	

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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, some of which will be committed prior to any confirmation that SPN-538, SPN-804 or any other of our product candidates will be approved. 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 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.

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

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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). We intend to support Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. in their efforts to contest this matter.

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.

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 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 plc. 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.; 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 plc. We intend to support Shire plc in its efforts to contest this matter.

Unless a court determines that our patents are invalid or unenforceable, we do not expect an adverse decision in any of the foregoing matters will have a material adverse effect on our business as we have monetized the future revenues associated with each of Sanctura XR, Oracea and Intuniv. However, in any infringement proceeding including the foregoing, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not issuing.

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

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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 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.

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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.

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

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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.

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. 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

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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 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

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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.

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

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

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

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

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

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

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

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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.

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;

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impairment of our business reputation and exposure to adverse publicity;

withdrawal of bioequivalence and/or clinical trial participants;

initiation of investigations by regulators;

costs of related litigation;

distraction of management's attention from our primary business;

substantial monetary awards to patients or other claimants;

loss of revenues; and

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

Our product liability insurance coverage for our clinical trials is limited to $5 million per occurrence, and $10 million in the aggregate, and covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. 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.

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;

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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 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

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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 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

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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.

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,

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

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

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

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 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

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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. In addition, the inclusion of a going concern statement by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

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

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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.

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.

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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;
- 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 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. 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.

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As a public company, we expect to become subject to Section 404 of the Sarbanes-Oxley Act relating to internal controls over financial reporting. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. 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.

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

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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, 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

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licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations would be significantly limited, and we may be required to delay, significantly curtail or eliminate one or more of our programs.

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

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

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

dispose of certain assets;

change our lines of business;

engage in mergers or consolidations;

incur additional indebtedness;

create liens on assets, including our intellectual property;

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

engage in certain transactions with affiliates.

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

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

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

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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 founders, directors, executives, employees 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, the current holders of our Series A convertible preferred stock will, in the aggregate, beneficially own % of our outstanding common stock (or approximately % if the underwriters exercise their over-allotment option in full). 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. Participation in this offering by existing holders of our Series A convertible preferred stock will further concentrate voting rights and may negatively impact liquidity for shares 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, our chief executive officer, our president or a majority of our board of directors. As a result, a

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holder, or holders, controlling a majority of our capital stock would not be able to call a special meeting.

A majority of the outstanding shares of common stock are required to amend our certificate of incorporation and a supermajority (75%) of the outstanding shares of common stock are required 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 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. 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 $ per share of common stock, based on the initial public offering price of $ per share of common stock; and

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

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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 2,392,470 shares of common stock outstanding, with exercise prices ranging from $0.10 to $1.76 per share and a weighted average exercise price of $0.69 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 be exercisable for one share of our common stock for each share of our Series A convertible preferred stock into which it was convertible at a price per share equal to the lesser of the initial public offering price, or $1.00 or $1.50, as applicable. 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;

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

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

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 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 49,000,000 shares of our common stock at the completion of this offering. Of these outstanding shares, shares are being sold in this offering and will be freely tradable immediately after this offering, except for shares purchased by affiliates, and the remaining shares may be sold upon expiration of lock-up agreements 180 days after the date of this offering. In addition, as of December 31, 2011, we had outstanding options to purchase 2,392,470 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, the 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 Plan, 2012 Equity Incentive Plan and 2012 Employee Stock Purchase Plan. Effective upon the closing of this offering, an aggregate of and 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

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do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We 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;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidates;
- our ability to increase our manufacturing capabilities for our product candidates;
- our projected markets and growth in markets;
- our product formulations and patient needs and potential funding sources;

our staffing needs;

our use of the proceeds from this offering; and

our plans for sales and marketing.

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

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

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of common stock that we are offering will be approximately $ million, or $ million if the underwriters exercise their over-allotment option in full. This projection is based upon an initial public offering price of $ per share, which is the midpoint of the range listed on the cover page of this prospectus, 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 $ per share would increase (decrease) the net proceeds from this offering by $ 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 $ 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 $ million for sales and marketing expenses in conjunction with the commercial launch of SPN-538 and SPN-804 in the marketplace, following approval by the FDA.
- Approximately $ million to fund the manufacture of validation batches for SPN-538 and SPN-804, and to pay mandated manufacturing site filing fees.
- Approximately $ 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 $ 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 $ million to repay a portion 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.

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. After application of approximately $ million of the net proceeds from this offering to repay a portion of our indebtedness under our term loans, we expect that approximately $ million will be outstanding under the term loans.

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

The costs and timing of drug development and commercialization and of regulatory approval, particularly conducting clinical studies, are highly uncertain, are subject to substantial risks and can often change. Accordingly, we may change the allocation of use of these proceeds as a

result of contingencies such as the progress of research, progress of clinical trials, ability to secure approval of our products from the FDA, uptake of our products in the marketplace and competitive responses.

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

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance operations. Additionally, our ability to pay dividends on our common stock is limited by restrictions on the ability of our subsidiary and us to pay dividends or make distributions, including restrictions under the terms of the agreements governing our indebtedness. For additional information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations." Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

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CAPITALIZATION

The following table sets forth our cash and capitalization as of 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 49,000,000 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 shares of common stock offered hereby at an assumed initial public offering price of $ per share, the mid-point of the price range reflected on the cover of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

	As of December 31, 2011		
	Actual	Pro Forma	Pro Forma as Adjusted(1)
	(unaudited)		
	(in thousands of dollars, except share and per share data)		
Balance Sheet Data:			
Unrestricted cash and cash equivalents and marketable securities	$ 48,544	$ 48,544	$
Restricted cash and cash equivalents and marketable securities	245	245	
Debt outstanding	$ 29,486	$ 29,486	$
Stockholders' equity:			
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		
Common stock, $0.001 par value 62,625,000 shares authorized, 6,649,302 shares issued and outstanding, actual; 55,649,302 shares issued and outstanding, pro forma and shares issued and outstanding, pro forma as adjusted	7	56	
Additional paid-in capital	49,357	49,357	
	1	1	

Accumulated other comprehensive income (loss)			
Accumulated deficit	(39,971)	(39,971)	
Total stockholders' equity	9,443	9,443	
Total capitalization	$ 38,929	$ 38,929	$

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the price range reflected on the cover page of this prospectus, would increase (decrease) each of additional unrestricted cash, additional paid-in capital, total stockholders' equity and total capitalization by approximately $ 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 $ million, assuming that the assumed initial public offering price remains the same.

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The table above does not include:

- 2,392,470 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2011 at a weighted average exercise price of $0.69 per share;
- 1,958,228 additional shares of common stock reserved for future issuance under our 2005 Stock Plan;
- shares of common stock reserved for future issuance under our 2012 Equity Incentive Plan;
- shares of common stock reserved for future issuance under our 2012 Employee Stock Purchase Plan;
- 375,000 shares of common stock issuable upon the exercise of preferred stock warrants outstanding with an exercise price $1.00 per share, which will convert into common stock warrants upon the closing of this offering; and
- 200,000 shares of common stock issuable upon the exercise of preferred stock warrants outstanding as of December, 31, 2011 with an exercise price of $1.50 per share, which will convert into common stock warrants upon the closing of this offering.

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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 $, or $ per share of common stock. Net tangible book value per share is equal to our total tangible assets 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 $ 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 49,000,000 shares of our common stock, upon the closing of this offering.

After giving effect to the sale of the shares of common stock we are offering based on an assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover of this prospectus, less 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 $, or $ per share. This represents an immediate increase in pro forma net tangible book value of $ per share and an immediate dilution of $ 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[(1)]	$
Net tangible book value per share as of December 31, 2011	$
Pro forma increase in net tangible book value per share attributable to conversion of preferred stock outstanding at December 31, 2011	
Pro forma net tangible book value per share of common stock as of December 31, 2011	$
Increase per share attributable to the offering	
Pro forma as adjusted net tangible book value per share of common stock after this offering	
Pro forma dilution per share to new investors	$

(1) The mid-point of the price range set forth on the cover of this prospectus.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after giving effect to this offering by $ per share and would increase (decrease) the dilution in pro forma net tangible book value per share to investors in this offering by $ 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 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 $ per share, representing an increase to existing holders of $ per share, and there will be an immediate dilution of $ 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		%	$	%	$
New Investors					
Total		%	$	%	

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 % 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 % 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 55,649,302 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 49,000,000 shares of our common stock at the closing of this offering and exclude:

- 2,392,470 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2011 with exercise prices ranging from $0.10 to $1.76 per share and a weighted average exercise price of $0.69 per share (of which options to acquire 1,050,284 shares of common stock were vested as of December 31, 2011);
- 1,958,228 shares of our common stock available for future grants under our 2005 Stock Plan as of December 31, 2011;
- shares of common stock reserved for future issuance under our 2012 Equity Incentive Plan;
- shares of common stock reserved for future issuance under our 2012 Employee Stock Purchase Plan;
- 375,000 shares of common stock issuable upon the exercise of preferred stock warrants outstanding as of December 31, 2011 at an exercise price of $1.00 per share, which will convert into common stock warrants upon the closing of this offering; and
- 200,000 shares of common stock issuable upon the exercise of preferred stock warrants outstanding as of December, 31, 2011 at an exercise price of $1.50 per share, which will convert into common stock warrants upon the closing of this offering.

If all of our outstanding options as of December 31, 2011 were exercised, the pro forma as adjusted net tangible book value per share after this offering would be $ per share, representing an increase to existing holders of $ per share, and there will be an immediate

dilution of $ 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 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.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth selected consolidated financial data that is qualified in its entirety by and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes thereto appearing elsewhere in this prospectus. The consolidated financial data as of December 31, 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

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	$ (4.21)	$ (5.93)	$ 0.12	$ (6.70)	$ (4.15)
Discontinued operations		(0.68)	(0.65)	0.10	12.00
Net income (loss)	(4.21)	(6.61)	(0.53)	(6.60)	7.85
Diluted					
Continuing obligations	$ (4.21)	$ (5.93)	$ 0.08	$ (6.70)	$ (4.15)
Discontinued obligations		(0.68)	(0.07)	0.10	12.00
Net income (loss)	(4.21)	(6.61)	0.01	(6.60)	7.85
Weighted average number of common shares:					
Basic	4,921,376	5,587,467	5,653,506	6,351,883	6,421,312
Diluted	4,921,376	5,587,467	56,324,761	6,351,883	6,421,312
Income (loss) used to compute pro forma income (loss) per common share basic and diluted (1)					
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 (1)					55,421,312
Pro forma net income (loss) per common share basic and diluted (1)					
Continuing operations					$ (0.42)
Discontinued operations					$ 1.39
Net income					$ 0.97

(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 49,000,000 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 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)				
Consolidated Balance Sheet Data:					
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 (1)	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	
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

(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. 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