

SUPERNUS PHARMACEUTICALS INC  
Form S-1/A  
February 08, 2011

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As filed with the Securities and Exchange Commission on February 8, 2011

Registration No. 333-171375

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 1  
to

### FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

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

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

As soon as practicable after this Registration Statement becomes effective.

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

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

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

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

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

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

(Do not check if a  
smaller reporting company)

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

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

**SUBJECT TO COMPLETION, DATED FEBRUARY 8, 2011**

**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.  
\_\_\_\_\_

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

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2011 through the book-entry facilities of The Depository Trust Company.  
\_\_\_\_\_

**Citi**

**Barclays Capital**

**Cowen and Company**

**Stifel Nicolaus Weisel**

, 2011.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. 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 subsidiaries.*

**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. 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 filed a new drug application, or NDA, in January 2011, and Epliga (extended release oxcarbazepine), which is in Phase III clinical trials. Our ADHD product candidates include SPN-810 (molindone hydrochloride), a novel treatment for impulsive aggression in patients with ADHD, and SPN-812, a novel non-stimulant treatment for ADHD. Both of these programs are in Phase II. In addition to these four lead product candidates, we have several additional product candidates in various stages of development, including SPN-809, for which we filed an investigational NDA in 2008 and which would represent a novel mechanism of action for the U.S. antidepressant market. We believe our broad and diversified portfolio of product candidates provides us with multiple opportunities to achieve our goal of becoming a leading specialty pharmaceutical company focused on CNS diseases.

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

<b>Product</b>	<b>Indication</b>	<b>Status</b>
<b>SPN-538</b>	Epilepsy	NDA filed
<b>Epliga</b>	Epilepsy	Phase III
<b>SPN-810</b>	Impulsive Aggression in ADHD	Phase II
<b>SPN-812</b>	ADHD	Phase II
<b>SPN-809</b>	Depression	IND filed

***Our Late-Stage Neurology Portfolio***

Epilepsy is a chronic neurological disorder characterized by recurrent convulsive seizures resulting from hyperactivity in the brain cells. It is estimated to affect 50 million people worldwide<sup>(1)</sup> and

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

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

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(2)

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

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

(3)

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

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

(4)

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

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

(5)

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

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

(6)

IMS Health data.

*SPN-538 (extended release topiramate)*

Our most advanced product candidate, SPN-538, is a novel oral once-daily extended release topiramate product for the treatment of epilepsy. Topiramate is marketed by Johnson & Johnson under the brand name Topamax and is available in a generic form. Topiramate is currently available only in immediate release form and is indicated for monotherapy and adjunctive therapy of epilepsy and for the treatment of migraine. It works by enhancing the inhibitory effect of the GABA (Gamma-Aminobutyric Acid) neurotransmitter that regulates neuronal excitability throughout the nervous system, blocking the excitatory effect of the glutamate neurotransmitter, blocking the sodium channel and inhibiting the carbonic anhydrase enzyme. The side effects associated with taking topiramate, which have tended to limit its use, include, among others, dizziness, fatigue, somnolence and slowing of certain cognitive functions.

SPN-538 is designed to improve patient compliance and to have a better tolerability profile compared to the current immediate release products that are taken multiple times per day. SPN-538's pharmacokinetic profile delivers lower peak plasma concentrations and lower input rate over an extended time period, resulting in smoother and more consistent blood levels of topiramate during the day compared to immediate release Topamax. We have completed ten clinical trials in support of our NDA, which we filed in January 2011. We are pursuing a regulatory strategy under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which would allow us to rely in our filing on the existing data and knowledge the U.S. Food and Drug Administration, or FDA, has from the NDA of Topamax.

*Epliga (extended release oxcarbazepine)*

Our second late-stage product candidate, Epliga, is a novel oral once-daily extended release formulation of oxcarbazepine and is currently in Phase III trials. 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





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that tend to limit its use. The side effects associated with taking oxcarbazepine include, among others, dizziness, double vision, somnolence, nausea and vomiting.

With a novel pharmacokinetic profile that delivers lower peak plasma concentrations, a slower rate of input, smoother and more consistent blood levels compared to immediate release products such as Trileptal, we believe Epliga has the potential of improving the tolerability of oxcarbazepine by reducing the side effects experienced by patients. We have completed eight clinical trials to support filing the NDA in the second half of 2011. We are pursuing a Section 505(b)(2) regulatory strategy, which would allow us to rely in our filing on the existing data and knowledge the FDA has from the NDA of Trileptal.

***Our Psychiatry Portfolio***

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States.<sup>(7)</sup> An estimated 60% to 80% of children with ADHD continue to meet the criteria for ADHD into adolescence, and as many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, conduct disorder, anxiety disorder and depression.<sup>(8)</sup> In addition, approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.<sup>(9)</sup>

(7)

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

(8)

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

(9)

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

*SPN-810 (molindone hydrochloride)*

We are developing SPN-810, which is currently in Phase II, as a novel treatment for impulsive aggression in patients with ADHD. If approved by the FDA, SPN-810 could be the first product available to address this serious, unmet medical need. SPN-810 is based on molindone hydrochloride, which was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. Molindone hydrochloride is unusual among anti-psychotics in that it is not 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, as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. We initiated a proof-of-concept Phase IIa trial in mid-2010, and expect the results of this trial in the first

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quarter of 2011. The trial is a randomized, double-blind, placebo-controlled trial in approximately 50 adults with a current diagnosis of ADHD, with approximately 25 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 long 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 currently in Phase III trials for pulmonary arterial hypertension.

***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 Epliga.* We are currently focused on attaining regulatory approval for, and bringing our two late-stage epilepsy product candidates, SPN-538 and Epliga, to market. As SPN-538 and Epliga progress towards U.S. regulatory approval, we intend to build our own targeted, specialty sales force to promote, if approved, SPN-538 and Epliga 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, we are currently preparing to initiate a Phase IIB trial of SPN-810.

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

*Establish strategic partnerships to accelerate and maximize the potential of our product candidates worldwide.* We intend to continue to seek strategic collaborations with other pharmaceutical companies to commercialize our product candidates outside the United States. We believe that we are an attractive collaborator for pharmaceutical companies due to our broad portfolio of proprietary technologies and our product development track record.

*Leverage our management team's expertise to develop and commercialize our broad portfolio of product candidates.* We intend to leverage the expertise of our executive management team in

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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, Epliga 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 Epliga, 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®," "Epliga®," "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.

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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 55,371,061 shares of common stock outstanding as of September 30, 2010 after giving effect to the conversion of 49,000,000 shares of our preferred stock outstanding as of September 30, 2010 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:

1,729,458 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010, with exercise prices ranging from \$0.10 to \$1.76 per share and a weighted average exercise price of \$0.48 per share (of which options to acquire 940,324 shares of common stock were vested as of September 30, 2010);

411,765 shares of common stock remaining to vest under a restricted stock award; and

2,487,716 additional shares of common stock reserved for future grants under our 2005 Stock Plan as of September 30, 2010.

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;

assumes our planned -for- reverse stock split of our common stock to be effected in connection with this offering;

gives effect to 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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We have derived our statement of operations data for the years ended December 31, 2007, 2008 and 2009 from our audited consolidated financial statements included in this prospectus. We have derived our balance sheet data as of September 30, 2010 and statement of operations data for each of the nine months ended September 30, 2009 and 2010 from our unaudited consolidated financial statements included in this prospectus. The unaudited consolidated financial statement data include, in our opinion, all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of our consolidated financial position and consolidated results of operations for these periods.

Our historical results are not necessarily indicative of future operating results, and the results for the first nine months of 2010 are not necessarily indicative of results expected for the full year or for any other period. You should read this summary consolidated financial data in conjunction with the sections entitled "Risk Factors," "Capitalization," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, all included elsewhere in this prospectus.

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
	(unaudited)				
	(in thousands of dollars, except share and per share data)				
Consolidated Statement of Operations Data:					
Revenues					
Development and milestone revenues	\$ 1,405	\$ 2,697	\$ 1,550	\$ 1,181	\$ 97
Royalty revenues	2,828	6,192	44,963	41,884	8,635
Total revenues	4,233	8,889	46,513	43,065	8,732
Costs and expenses					
Research and development	19,269	30,463	29,260	21,804	26,080
General and administrative	4,011	4,287	4,649	3,503	3,388
Total costs and expenses	23,280	34,750	33,909	25,307	29,468
Income (loss) from operations	(19,047)	(25,861)	12,604	17,758	(20,736)
Other income (expense):					
Interest income	1,773	1,057	514	101	623
Interest expense		(8,678)	(12,658)	(9,210)	(9,831)
Other					54
Total other income (expense)	1,773	(7,621)	(12,144)	(9,109)	(9,154)
Net income (loss)	\$ (17,274)	\$ (33,482)	\$ 460	\$ 8,649	\$ (29,890)
Cumulative dividends on Series A convertible preferred stock					
	\$ (3,430)	\$ (3,430)	\$ (3,430)	\$ (2,573)	\$ (2,573)
Net income (loss) attributable to common stockholders	\$ (20,704)	\$ (36,912)	\$ (2,970)	\$ 6,076	\$ (32,463)
Net income (loss) per common share					
Basic	\$ (4.21)	\$ (6.61)	\$ (0.53)	\$ 1.08	\$ (5.12)
Diluted	\$ (4.21)	\$ (6.61)	\$ 0.01	\$ 0.15	\$ (5.12)

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Weighted average number of  
common shares

Basic	4,921,376	5,587,467	5,653,506	5,610,047	6,345,420
Diluted	4,921,376	5,587,467	56,324,761	56,282,411	6,345,420

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

\$ 460 \$ (29,890)

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

56,324,761 55,345,420

Pro forma net income (loss) per  
share basic and diluted(1)

\$ 0.01 \$ (0.54)

(1)

Pro forma net 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 net 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 2 to our audited 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 number of the per share amounts.

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As of September 30, 2010

Actual	Pro Forma	Pro Forma as
	(unaudited)	Adjusted

(in thousands of dollars)

**Consolidated Balance Sheet Data:**

Unrestricted cash and cash equivalents, and marketable securities	\$ 45,822	\$ 45,822	\$
Restricted cash and cash equivalents, and marketable securities	1,680	1,680	
Working capital	33,835	33,835	
Total assets	57,502	57,502	
Accumulated deficit	(85,210)	(85,210)	
Total stockholders' deficit	(35,917)	(35,917)	

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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 Epliga, 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 Epliga. Neither SPN-538 nor Epliga 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 U.S. Food and Drug Administration, or 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, Epliga 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 Epliga, 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, Epliga 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 a new drug application, or NDA, from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. We cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any.

With respect to our two most advanced product candidates, SPN-538 (extended release topiramate) and Epliga (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 would allow us to rely in our filings 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 has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

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

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, Epliga 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;

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, Epliga 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.

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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 Epliga 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 problems, somnolence, double vision, gingival enlargement, nausea, weight gain, and fatigue. The use of SPN-538 and Epliga 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;

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

the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;

sales of approved 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 Epliga, 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 Epliga 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 Laboratories, or Upsher-Smith, is currently conducting a Phase III clinical trial for USL255 (extended release topiramate). 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 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 Epliga's entry into the U.S. market. Such a delay would limit the potential success of Epliga 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 Epliga.

***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

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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 approval to conduct a trial at a prospective site;

challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;

severe or unexpected drug-related side effects experienced by patients in a clinical trial; and

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.

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 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



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protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards 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 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. Of these, 15 are currently in late-stage (Phase II or later) clinical trials. 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 Epliga. 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;

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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 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, Epliga or any other of our product candidates will be approved. If the commercial launch of SPN-538 or Epliga 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

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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 others. To that end, we seek patent protection in the United States and internationally for our product candidates. Our policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad (including Europe, Canada and certain other countries when appropriate) relating to proprietary technologies that are important to the development of our business.

The strength of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we were the first to conceive inventions covered by our patents and pending patent applications or that we were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property or that such patents will not be challenged, narrowed, invalidated or circumvented.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. Any failure to adequately prevent disclosure of our trade secrets and other proprietary information could have a material adverse impact on our business.

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

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell their approved products and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our collaborators' approved products and our product candidates may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware, that may be infringed by our collaborators' approved products or our product candidates including SPN-538 and Epliga, 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.

We may be exposed to, or threatened with, future litigation by third parties alleging that our collaborators' approved products and product candidates infringe their intellectual property rights. If one of our collaborators' approved products and 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.

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. For example, we are involved in the following matters related to Paragraph IV Certification Notice Letters that we have received in connection with our collaborators' products. In connection with an ANDA, a Paragraph IV Certification Notice Letter notifies the FDA that one or more patents listed in the FDA's Approved Drug Product List (Orange Book) is alleged 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 the U.S. Patent Number 7,410,978 issued to us is invalid, unenforceable and/or will not be infringed by the respective company's manufacture, use or sale of the product described in its ANDA submission. Our patent covers extended-release formulations containing trospium chloride and expires on February 1, 2025, and is licensed to Endo Pharmaceuticals Solutions Inc. Each of the ANDA filers subsequently amended their respective notice letters to include other U.S. patents related to Sanctura XR trospium chloride (specifically, U.S. Patent Nos. 7,759,359; 7,763,635; 7,781,448; and 7,781,449). We intend to support Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. in their efforts to contest this matters.

*Oracea Litigation.* We are involved in a patent infringement action filed in response to a Paragraph IV Certification Notice Letter that we received in November 2010 regarding an ANDA, submitted to the FDA by Lupin Limited, 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 filer, Lupin, alleged in the original notice letter 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 its ANDA submission. In addition, we have received in October 2010, a complaint for Declaratory Judgment from Mylan alleging invalidity of the 7,749,532 patent. 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 also received a Paragraph IV Certification Notice Letter in January 2011 regarding an ANDA submitted to the FDA by Sandoz Inc., requesting approval to market and sell generic versions of Oracea doxycycline. In its notice letter, Sandoz Inc. alleged 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 its ANDA submission. We intend to support Galderma Laboratories, L.P. in its efforts to contest these matters.

*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 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.; and Impax Laboratories, Inc. The ANDA filers allege that our U.S. Patent Numbers 6,287,599

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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.

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;

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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.

***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;



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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.***

As we do not currently own or operate manufacturing facilities for the production of any of our product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently depend on third-party contract manufacturers for the supply of the active pharmaceutical ingredients for our product candidates, including drug substance for our preclinical research and clinical trials. For SPN-538 and Epliga, 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. 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

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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 Epliga, 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 currently being evaluated by United Therapeutics in Phase III trials for PAH. If United Therapeutics receives approval to market and sell this product candidate, we are entitled to receive single digit gross royalties based on worldwide net sales. We are also entitled to receive milestones and royalties for use of this formulation in other indications. If we materially breach any of our obligations under the license agreement, however, we could lose the potential to receive any future royalty payments thereunder, which could be financially significant to us.

In addition, 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;

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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 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 Epliga, 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. 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.

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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 Epliga, 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.

***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

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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 Epliga, 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 Epliga, less attractive to patients and prescribing physicians. We also may be required to sell our product candidates at a discount, which would adversely affect our ability to realize an appropriate return on our investment in our product candidates or compete on price.

We expect that private insurers and managed care organizations will consider the efficacy, cost effectiveness and safety of our product candidates, including SPN-538 and Epliga, 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.

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In addition, many managed care organizations negotiate the price of products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. If our 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;

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.***

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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

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completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products.

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

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

exposure to unknown liabilities;

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

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

higher than expected acquisition and integration costs;

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

increased amortization expenses;

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

inability to motivate key employees of any acquired businesses.

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

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

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. 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.





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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 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.

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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 Mr. Khattar. Although no member of our management team has informed us to date that he or she intends to resign or retire, if we lose any members of our management team in the future, we may not be able to find suitable replacements in a timely fashion, if at all, which may serve to impede the achievement of our research, development and commercialization objectives. 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

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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, 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.

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***Our business involves the use of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

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

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

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

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

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

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

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

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***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 arrangements, and non-recourse debt that is secured by our royalty rights related to sales of Oracea under our agreement with Galderma and our royalty rights related to sales of Sanctura XR under our agreement with Allergan. We have incurred significant operating losses since our inception in 2005. We incurred net losses of approximately \$17.3 million and \$33.5 million in the years ended December 31, 2007 and 2008, respectively, and approximately \$29.9 million in the nine months ended September 30, 2010. We incurred net income of approximately \$0.5 million in the year ended December 31, 2009. As of September 30, 2010, we had an accumulated deficit of approximately \$85.2 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 Epliga from inception to September 30, 2010 are approximately \$18.2 million and \$35.4 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.

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. 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.

***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, anticipated future product revenues and any additional borrowings available under our \$25.0 million secured credit facility, will be sufficient to

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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. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

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

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

the rate of progress and cost of our trials and other product development programs for our product candidates;

the costs and timing of in-licensing additional product candidates or acquiring other complementary companies;

the timing of any regulatory approvals of our product candidates;

the costs of establishing sales, marketing and distribution capabilities; and

the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

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

Our ability to become profitable depends upon our ability to generate revenues from sales of our product candidates. To date, we have not generated any revenues from 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 royalty, on product sales of Oracea, Sanctura XR and Intuniv licensed products. In April 2008, we raised approximately \$63.3 million in net proceeds through a private placement to institutional investors of \$75.0 million aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due April 15, 2024 by our subsidiary, TCD Royalty Sub LLC, or Royalty Sub. As part of the transaction, we transferred to Royalty Sub our payment rights and other license rights related to two products that utilize our proprietary technologies: Oracea, which is marketed by Galderma as a treatment for rosacea; and Sanctura XR, which is marketed by Allergan as a treatment for overactive bladder. The non-recourse notes are secured by these payment and other license rights, as well as by the pledge of all our outstanding equity interest in Royalty Sub. While the non-recourse notes are outstanding, all royalty and milestone payments due from net sales of Oracea and Sanctura XR go to the payment of interest, and when available, to the principal on such non-recourse notes. Accordingly, unless and until the non-recourse notes are fully paid, future royalties and milestone payments due from net sales of Oracea and Sanctura XR will not be available to fund our operations. In May 2009, we received a one-time payment of approximately \$36.9 million from Shire plc as consideration for a royalty-free, fully paid-up license to Shire plc for

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Intuniv. Accordingly, we will not receive any future royalties payments from Shire plc with respect to the net sales of Intuniv.

Our ability to generate product revenues is dependent on our ability to receive regulatory approval of our product candidates, including SPN-538 and Epliga, 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 Epliga; and

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

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

***Our quarterly operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. Prior to commercializing any of our product candidates, we expect that any revenues we generate will fluctuate from quarter to quarter as a result of the timing and amount of development and milestones and royalty revenues received under our collaboration license agreements, as our revenues from these arrangements are principally based on the achievement of clinical and commercial milestones outside of our control. To date, we have monetized the future royalties due to us from our existing license agreements for Oracea, Sanctura XR and Intuniv.

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.

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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.

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. Although we have not identified any material weaknesses in our internal controls over financial reporting to date, 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.

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***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.***

Section 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, 2009, we had approximately \$54.1 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of approximately \$3.1 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, and promissory notes issued in favor of each lender, providing for term loans of up to an aggregate of \$25.0 million. On January 26, 2011, we drew down our first \$15.0 million of term loans under our new secured credit facility. All obligations under our new 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;

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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.

As of the date of this prospectus, our new secured credit facility permits additional borrowings of up to \$10.0 million under the same terms and conditions of our current term loans on or before April 30, 2011, provided that we are not in default under the terms of the loan and security agreement or other loan documents. To the extent additional debt is added to our current debt levels, the risks described above would increase.

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

Since our inception in 2005, we have generated no revenue from product sales and have incurred significant operating losses. As of September 30, 2010, we had an accumulated deficit of \$85.2 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 \$25.0 million secured credit facility. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations would be significantly limited, and we may be required to delay, significantly curtail or eliminate one or more of our programs.

Failure to satisfy our current and future debt obligations under our new 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 new 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 new 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 subsidiaries to, among other things:

dispose of certain assets;

change our lines of business;

engage in mergers or consolidations;

incur additional indebtedness;

create liens on assets, including our intellectual property;

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

engage in certain transactions with affiliates.



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Our new secured credit facility also includes certain customary representations and warranties and affirmative covenants. Our failure to comply with the restrictions contained in our new secured credit facility, if not cured by us or waived by our lenders, could result in an event of default. All obligations under our new 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 new secured credit facility, our lenders could take various actions, including the acceleration of all amounts due under our new 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.

***Royalties under our agreement with Endo Pharmaceuticals and Galderma may not be sufficient for our subsidiary to meet its payment obligations under the non-recourse notes.***

While Royalty Sub will be entitled to receive the royalties related to the sales of Sanctura XR under our agreement with Endo Pharmaceuticals as successor-in-interest to Indevus Pharmaceuticals, Inc. and its marketing partner, Allergan, Inc., and the royalties related to the sales of Oracea under our agreement with Galderma Pharma S.A., as successor-in-interest to CollaGenex Pharmaceuticals, Inc., such royalties may not be sufficient for it to meet its payment obligations under the non-recourse notes issued by Royalty Sub. As a result, Royalty Sub will be dependent on Allergan's and Galderma's respective sales and marketing efforts to receive royalties in sufficient amounts to meet its payment obligations. Any royalty modifications could result in Royalty Sub receiving significantly reduced or no royalties under the license agreements with Endo Pharmaceuticals and Galderma Pharma S.A., which would delay repayment of the non-recourse notes.

***In certain circumstances we could be required to pay damages if we fail to perform our obligations in connection with the non-recourse notes issued by Royalty Sub and we may lose the potential to receive future royalty payments after the non-recourse notes are repaid in full.***

In April 2008, Royalty Sub issued \$75.0 million in aggregate principal amount of non-recourse notes to institutional investors, which are secured principally by royalty payments from future sales of Sanctura XR and Oracea, and by a pledge by us of all the outstanding equity interest in Royalty Sub. If the royalty payments from Sanctura XR and Oracea are insufficient to repay the non-recourse notes or if an event of default occurs under the indenture governing the non-recourse notes, in certain circumstances, the royalty payments and our equity interest in Royalty Sub may be foreclosed upon and we would lose the potential to receive any future royalty payments, which could be financially significant after the non-recourse notes are repaid in full.

In addition, if we fail to perform our obligations under the purchase and sale agreement with Royalty Sub we may be required to indemnify Royalty Sub for damages arising due to such failure. For example, pursuant to this agreement, 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 the royalty stream from such patents may terminate. In such a scenario, we may be called upon to pay damages to Royalty Sub due to the loss of patent licensing revenue that Royalty Sub would have received from the sale of Sanctura XR and Oracea.

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

***The concentration of our capital stock ownership with our 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 preferred stock will, in the

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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 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 super majority (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





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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, investors will, as of September 30, 2010:

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.

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

As of September 30, 2010, we had options to purchase 1,729,458 shares of common stock outstanding, with exercise prices ranging from \$0.10 to \$1.76 per share and a weighted average exercise price of \$0.48 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 September 30, 2010, we had no outstanding warrants to purchase shares of Series A convertible preferred stock. In connection with our new secured credit facility, the lenders received from us ten-year warrants to purchase an aggregate of 375,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. In connection with any drawdown of additional term loans under our new secured credit facility, we would be required to issue to the lenders additional warrants to purchase up to 250,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. Upon completion of this offering, each warrant will be exercisable for

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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 of \$1.00. 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 and planned Phase III clinical trials for Epliga;

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 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

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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 September 30, 2010 and after giving effect to the conversion of \_\_\_\_\_ shares of our preferred stock outstanding as of September 30, 2010 into \_\_\_\_\_ 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 September 30, 2010, we had outstanding options to purchase 1,729,458 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 that we may issue under our 2005 Stock Plan. Effective upon the closing of this offering, an aggregate of \_\_\_\_\_ shares of our common stock will be reserved for future issuance under this plan. Once we register these shares, which we plan to do shortly after the closing of this offering, they can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock. See "Shares Eligible for Future Sale" for a more detailed description of sales that may occur in the future.

***We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock.***

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

***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 we will receive net proceeds from the sale of shares of our common stock in this offering of approximately \$ , based upon an assumed initial public offering price of \$ per share, the mid-point of the price range set forth on the cover of this preliminary prospectus, and after deducting underwriting discounts and commissions and 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 to us from this offering by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this preliminary prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to fund our clinical trials, to fund operations, and to provide working capital. We intend to use the net proceeds of this offering for general corporate purposes including to fund the development and commercialization of SPN-538 and Epliga, as well as development of our other product candidates, general and administrative expenses, working capital, prosecution and maintenance of our intellectual property and the potential investment in or acquisition of technologies or products that complement our business. We have no current agreements or commitments with respect to such investment or acquisition.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds from this offering. The amounts and timing of our actual expenditures may vary significantly from our expectations depending upon numerous factors, including the progress of our research, development and commercialization efforts, the progress of our clinical trials, and our operating costs and capital expenditures. Accordingly, we will retain the discretion to allocate the net proceeds of this offering among the identified uses described above, and we reserve the right to change the allocation of the net proceeds among the uses described above as a result of contingencies such as the progress and results of our clinical trials and our research and development activities, the results of our commercialization efforts, competitive developments and our manufacturing requirements.

Pending use of proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

**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 subsidiaries and us to pay dividends or make distributions, including restrictions under the terms of the agreements governing our indebtedness. For additional information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations." Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.



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# CAPITALIZATION

The following table sets forth our cash and capitalization as of September 30, 2010:

on an actual basis;

on a pro forma basis, reflecting the conversion of all of our 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 September 30, 2010				
	Actual	Pro Forma	Pro Forma		
		(unaudited)	as Adjusted(1)		
	(in thousands of dollars, except share data)				
<b>Balance Sheet Data:</b>					
Unrestricted cash and cash equivalents and marketable securities	\$	45,822	\$	45,822	\$
Restricted cash and cash equivalents and marketable securities		1,680		1,680	
Non-recourse Notes	\$	75,000	\$	75,000	\$
Redeemable Series A convertible preferred stock, \$0.001 par value 49,000,000 shares authorized, issued and outstanding, actual; none, pro forma and pro forma as adjusted		49			
Stockholders' deficit:					
Common stock, \$0.001 par value 62,000,000 shares authorized, 6,371,061 shares issued and outstanding, actual;		6		55	
Additional paid-in capital		49,238		49,238	
Accumulated deficit		(85,210)		(85,210)	
Total stockholders' deficit		(35,917)		(35,917)	
Total capitalization	\$	39,083	\$	39,083	\$

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(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 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 additional paid-in capital, total stockholders' equity and total capitalization by approximately \$            million, assuming that the assumed initial public offering price remains the same.

The table above does not include:

1,729,458 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010 at a weighted average exercise price of \$0.48 per share;

411,765 shares of common stock remaining to vest under a restricted stock award;

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2,487,716 additional shares of common stock reserved for future issuance under our 2005 Stock Plan;

375,000 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price \$1.00 per share;  
and

our \$25.0 million secured credit facility.

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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 \_\_\_\_\_, 2010 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 September 30, 2010.

Our pro forma net tangible book value per share as of \_\_\_\_\_, 2010 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 \_\_\_\_\_ into \_\_\_\_\_ 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 \_\_\_\_\_, 2010 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 <sup>(1)</sup>	\$
Net tangible book value per share as of _____, 2010	\$
Pro forma increase in net tangible book value per share attributable to conversion of preferred stock outstanding at _____, 2010	
Pro forma net tangible book value per share of common stock as of _____, 2010	\$
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 September 30, 2010, 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
	Number	Percent	Amount	Percent	Price Per
	(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 or 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 6,371,061 shares of our common stock outstanding as of September 30, 2010 after giving effect to the conversion of 49,000,000 shares of our preferred stock outstanding as of September 30, 2010 into 49,000,000 shares of our common stock at the closing of this offering and exclude:

shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010 with exercise prices ranging from \$0.10 to \$1.76 per share and a weighted average exercise price of \$0.48 per share (of which options to acquire 940,324 shares of common stock were vested as of September 30, 2010); and

shares of our common stock available for future grants under our 2005 Stock Plan as of September 30, 2010.

If all of our outstanding options as of September 30, 2010 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, 2009 and for the fiscal years ended December 31, 2007, 2008 and 2009 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The consolidated financial data for the fiscal year ended December 31, 2006 are derived from our audited consolidated financial statements not included in this prospectus. The consolidated financial data for the nine month periods ended September 30, 2009 and 2010, is derived from our unaudited consolidated financial statements which are presented elsewhere in this prospectus, but has been prepared on the same basis as the audited consolidated financial statements and the notes thereto, which include, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the information for the unaudited interim periods. The operating results for the nine month period ended September 30, 2010 may not be indicative of the operating results for the full year.*

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	Year Ended December 31,				Nine Months Ended September 30,	
	2006	2007	2008	2009	2009	2010
	(unaudited)					
	(in thousands of dollars, except share and per share data)					
Consolidated Statement of Operations Data:						
Revenue:						
Development and milestone revenue	\$ 5,616	\$ 1,405	\$ 2,697	\$ 1,550	\$ 1,181	\$ 97
Royalty revenue	652	2,828	6,192	44,963	41,884	8,635
Total revenues	6,268	4,233	8,889	46,513	43,065	8,732
Operating Expenses:						
Research and development	8,958	19,269	30,463	29,260	21,804	26,080
General and administrative	3,945	4,011	4,287	4,649	3,503	3,388
Total operating expenses	12,903	23,280	34,750	33,909	25,307	29,468
Income (loss) from operations	(6,635)	(19,047)	(25,861)	12,604	17,758	(20,736)
Other income (expense):						
Interest income	1,712	1,773	1,057	514	101	623
Interest expense			(8,678)	(12,658)	(9,210)	(9,831)
Other	40					54
Total other income (expense)	1,752	1,773	(7,621)	(12,144)	(9,109)	(9,154)
Net income (loss)	\$ (4,883)	\$ (17,274)	\$ (33,482)	\$ 460	\$ 8,649	\$ (29,890)
Cumulative dividends on Series A convertible preferred stock						
	(3,316)	(3,430)	(3,430)	(3,430)	(2,573)	(2,573)
Net income (loss) attributable to common stockholders	\$ (8,253)	\$ (20,704)	\$ (36,912)	\$ (2,970)	\$ 6,076	\$ (32,463)
Basic net income (loss) per share						
	\$ (2.39)	\$ (4.21)	\$ (6.61)	\$ (0.53)	\$ 1.08	\$ (5.12)
Diluted net income (loss) per share						
	\$ (2.39)	\$ (4.21)	\$ (6.61)	\$ 0.01	\$ 0.15	\$ (5.12)
Weighted average number of common shares:						
Basic	3,455,762	4,921,376	5,587,467	5,653,506	5,610,047	6,345,420

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Diluted	3,455,762	4,921,376	5,587,467	56,324,761	56,282,411	6,345,420
Net income (loss) used to compute pro forma net income (loss) per common share basic and diluted (unaudited)(1)				\$ 460	\$	(29,890)
Weighted-average number of shares used in calculating pro forma net income (loss) per share basic and diluted (unaudited):(1)				56,324,761		55,345,420
Pro forma net income (loss) per share basic and diluted (unaudited)(1)				\$ 0.01	\$	(0.54)

(1)

Pro forma net 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 net 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 2 to our audited 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 number of the per share amounts.



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	Year Ended December 31,				As of
	2006	2007	2008	2009	September 30,
					2010
					(unaudited)
(in thousands of dollars)					
<b>Consolidated Balance Sheet Data:</b>					
Unrestricted cash and cash equivalents and marketable securities	\$ 40,655	\$ 25,592	\$ 60,380	\$ 66,524	\$ 45,822
Restricted cash and cash equivalents and marketable securities	256	281	6,281	2,076	1,680
Working capital	39,746	22,674	61,183	62,847	33,835
Total assets	46,426	31,907	77,134	79,899	57,502
Long-term debt			75,000	75,000	75,000
Series A convertible preferred stock	49	49	49	49	49
Accumulated deficit	(5,027)	(22,301)	(55,782)	(55,321)	(85,210)
Total stockholders' equity (deficit)	43,830	26,635	(6,747)	(6,155)	(35,917)
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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 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. Our two epilepsy product candidates are SPN-538 (extended release topiramate), for which we have filed a new drug application, or NDA, in January 2011, and Epliga (extended release oxcarbazepine), which is in Phase III clinical trials. Our ADHD product candidates include SPN-810 (molindone hydrochloride), a novel treatment for impulsive aggression in patients with ADHD, and SPN-812, a novel non-stimulant treatment for ADHD. Both of these programs are in Phase II. In addition to these four lead product candidates, we have several additional product candidates in various stages of development. We intend to market our product candidates in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists. We believe our broad and diversified portfolio of product candidates provides us with multiple opportunities to achieve our goal of becoming a leading specialty pharmaceutical company focused on CNS diseases.

We use our proprietary technologies to enhance the therapeutic benefits of approved anti-epileptic drugs, or AEDs through advanced extended release formulations. Our most advanced product candidates, SPN-538 and Epliga, are novel oral once-daily extended release formulations of topiramate and oxcarbazepine, respectively, for the treatment of epilepsy. Immediate release formulations of topiramate and oxcarbazepine, are available in generic form and are marketed under the brand names of Topamax and Trileptal, respectively. According to IMS Health, peak sales of Topamax and Trileptal represented an estimated 25.8% and 8.1% of the total seizure disorder market in 2008 and 2006, respectively. We are pursuing a Section 505(b)(2) regulatory strategy for SPN-538 and Epliga, which would allow us to rely on the existing data from the NDAs of Topamax and Trileptal, respectively. The once-per-day dosing of each of SPN-538 and Epliga is designed to improve patient compliance and to have a better tolerability profile compared to the current immediate release AEDs that are taken multiple times per day to maintain therapeutic drug concentrations over the dosing interval. We believe there is a significant unmet need for extended release products, such as SPN-538 and Epliga, for the treatment of epilepsy. Extended release products have been shown to improve compliance, increase seizure control,<sup>(1)</sup> reduce side effects and improve tolerability as compared to immediate release products.<sup>(2)</sup>

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(1)

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

(2)

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

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We are also developing treatments for new indications in diseases such as ADHD and its coexisting disorders. We are developing SPN-810, which is currently in Phase II, as a novel treatment for impulsive aggression in patients with ADHD. If approved by the U.S. Food and Drug Administration, or FDA, SPN-810 could be the first product available to address this serious, unmet medical need. SPN-810 is based on molindone hydrochloride, which was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. In addition, SPN-812, which is currently in Phase II, is being developed as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. In addition, because the active ingredient of SPN-812 has demonstrated efficacy as an antidepressant in Europe, this product candidate may provide increased benefit to an estimated 40% of ADHD patients who suffer from depression.<sup>(3)</sup> In addition to these four lead product candidates, we have a number of other product candidates in various stages of development such as SPN-809, which would represent a novel mechanism of action for the U.S. antidepressant market.

(3)

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

Historically, our revenues have been generated through research and development agreements, which included fees for development services provided to customers and payments for achievement of specified development, regulatory and sales milestones, as well as royalties on product sales of licensed products, Oracea, Sanctura XR, and Intuniv. Since our inception in 2005, we have generated \$0 in revenue from product sales and have incurred significant operating losses. As of September 30, 2010, we had an accumulated deficit of \$85.2 million. We expect to continue to incur net losses and negative cash flow from operating activities for the foreseeable future as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of SPN-538 and Epliga, as well as our other product candidates.

## **History of our Company**

We have a long track record of developing novel products by applying proprietary technologies to known drugs to improve existing therapies and to enable the treatment of new indications. We have a broad portfolio of drug development technologies consisting of six platforms that include the following: Microtrol (multiparticulate delivery platform), Solutrol (matrix delivery platform) and EnSoTrol (osmotic delivery system). Our proprietary technologies have been used in the following approved products: Carbatrol (carbamazepine), Adderall XR (mixed amphetamine salts), and Intuniv (guanfacine), marketed by Shire; Equetro (carbamazepine), marketed by Validus Pharmaceuticals Inc.; Sanctura XR (trospium chloride), marketed by Allergan; and Oracea (doxycycline), marketed by Galderma. Throughout our 20 year history, we have continued our commitment to innovation with a focus for the past five years on developing our own product candidates in neurology and psychiatry.

We have historically raised capital through private equity and the monetization of certain future royalty streams under our existing licenses for Oracea, Sanctura XR and Intuniv. In connection with the commencement of our operations, in December 2005 and February 2006, we raised approximately \$45.0 million through the sale of 45 million shares of Series A convertible preferred stock. We raised approximately \$63.3 million in net proceeds in April 2008 through the monetization of future royalty payment rights and other license rights for both Oracea and Sanctura XR. In that deal, we transferred the license rights to both Oracea and Sanctura XR to TCD Royalty Sub LLC, our wholly-owned subsidiary ("Royalty Sub"), which issued \$75.0 million in non-recourse notes in a private placement to institutional investors. All milestone and royalty revenues due from net sales of Oracea and Sanctura XR are required to be used to satisfy the payment of principal and interest on the non-recourse notes. The non-recourse notes are non-recourse to us and are secured by our Royalty Sub's assets, which include the royalty payment rights and other rights related to net sales of Oracea and Sanctura XR. In

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addition, we entered into an agreement with an affiliate of Shire plc in May 2009, whereby the Shire affiliate paid us a one-time, lump-sum payment of approximately \$36.9 million as consideration for a royalty-free, fully paid-up license for Intuniv.

We also have a license agreement with United Therapeutics Corporation, or United Therapeutics, to use one of our proprietary technologies for an oral formulation of treprostinil for the treatment of pulmonary arterial hypertension, or PAH, as well as for other indications. This oral formulation is currently being evaluated by United Therapeutics in Phase III trials for PAH. Remaining milestone payments to us could total up to approximately \$6.8 million, which includes milestone payments of up to approximately \$2.8 million for the satisfaction of development milestones relating to the product candidate for the treatment of PAH. If United Therapeutics receives approval to market and sell this product candidate, we are entitled to receive single digit royalties based on worldwide net sales. We are also entitled to receive milestones and royalties for use of this formulation in other indications.

In January 2011, we entered into a secured credit facility pursuant to a loan and security agreement among Oxford Finance Corporation, as collateral agent and lender, and Compass Horizon Funding Company LLC, as lender, and promissory notes issued in favor of each lender, providing for term loans of up to an aggregate of \$25.0 million. On January 26, 2011, we drew down our first \$15.0 million of term loans under our new secured credit facility. The term loans bear interest at a fixed rate per annum of 11.0% and will mature in 42-months from the date of each term loan, subject to a three-month extension under certain circumstances. We intend to use the proceeds of the term loans under our new secured credit facility for working capital and general corporate purposes. In addition, we have the right to obtain additional term loans of up to \$10.0 million under the same terms and conditions of our current term loans under our new secured credit facility on or before April 30, 2011, provided that we are not in default under the terms of the loan and security agreement or other loan documents.

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

## **Financial Overview**

### ***Revenue***

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

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

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

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
	(unaudited)				
	(in thousands of dollars)				
Development and milestone revenues					
Oracea & Sanctura XR	\$ 400	\$ 1,500	\$ 500	\$ 500	\$
Other collaboration arrangements	1,005	1,197	1,050	681	97
Total development and milestone revenues	1,405	2,697	1,550	1,181	97
Royalty revenues:					
Oracea & Sanctura XR	2,828	6,192	8,088	5,009	8,635
Intuniv			36,875	36,875	
Total royalty revenues	2,828	6,192	44,963	41,884	8,635
Total revenues	\$ 4,233	\$ 8,889	\$ 46,513	\$ 43,065	\$ 8,732

From and after April 15, 2008, all development and milestone revenues and royalty revenues due from net sales of Oracea and Sanctura XR are required to be used to satisfy the payment of principal and interest on the non-recourse notes of Royalty Sub. We also received in May 2009 a one-time payment of approximately \$36.9 million from Shire plc as consideration for a royalty-free, fully paid-up license to Shire plc for Intuniv and, as a result, we will not receive any future royalty payments with respect to the net sales of Intuniv.

If we obtain regulatory approval for SPN-538, Epliga or any of our other product candidates, we would expect to begin to generate revenues from product sales and, over time, we expect that our future revenues would begin to be principally derived from product sales as compared to development and milestone revenues and royalty revenues.

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

### Research and Development Expense

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

employee-related expenses, which include salaries and benefits;

expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;

the cost of acquiring and manufacturing clinical trial materials;

costs related to facilities, depreciation and other allocated expenses;

license fees for and milestone payments related to in-licensed products and technology;

stock-based compensation expense to employees and consultants; and

costs associated with non-clinical activities and regulatory approvals.

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

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

The majority of our external costs relate to later-stage product candidates, as costs associated with later-stage clinical trials are, in most cases, more significant than those incurred in earlier stages of our pipeline. For example, the external costs related to our Epliga program have been higher than our other programs in recent years because Epliga is undergoing a Phase III clinical trial that began in late 2008.

We track external development expenses and direct personnel expense on a program-by-program basis. Costs related to facilities, depreciation, employee benefits and bonuses, stock-based compensation, research and development management and research and development support services and supplies are not charged to specific programs, because the number of clinical and preclinical product candidates or development projects tends to vary from period to period and internal resources are utilized across and benefit multiple programs over any given period of time. The following table is a summary of our research and development expenses for the years ended December 31, 2007, 2008 and 2009, and the nine months ended September 30, 2009 and 2010.

	Year Ended December 31,			Nine Months Ended September 30,		From Inception to September 30,
	2007	2008	2009	2009	2010	2010
	(unaudited)					
	(in thousands of dollars)					
SPN-538	\$ 1,044	\$ 4,098	\$ 6,464	\$ 5,013	\$ 5,923	\$ 18,232
Epliga	3,845	10,834	10,027	7,352	10,190	35,360
SPN-810	2,192	2,199	3,333	2,265	1,705	9,429
SPN-812 and SPN-809	2,392	2,923	680	370	1,684	7,721
Other research and development programs	2,796	1,822	426	312	538	7,564
Development expenses general	7,000	8,587	8,331	6,492	6,041	35,821
Total research and development expenses	\$ 19,269	\$ 30,463	\$ 29,261	\$ 21,804	\$ 26,081	\$ 114,127

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

The duration of clinical trials varies substantially according to the type, complexity and novelty of the product candidate;

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;

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Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;

The duration and cost of nonclinical studies and clinical trials may vary significantly over the life of a product candidate and are difficult to predict;

The costs, timing and outcome of regulatory review of a product candidate are uncertain; and

The emergence of competing technologies and products and other adverse market developments could impede our commercial efforts.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as ongoing assessments of such product candidate's commercial potential. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or money that we will be required to expend in the future on SPN-538, Epliga or other product candidates to complete current or future clinical stages prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, SPN-538, Epliga or any of our other product candidates will generate revenues and cash flows.

We expect our research and development costs to continue to be substantial for the foreseeable future and to increase with respect to our product candidates as we advance those product candidates through preclinical studies, clinical trials, manufacturing scale-up and other pre-approval activities. We may elect to expand existing collaborative relationships or to seek new partnerships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

***General and Administrative Expenses***

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

We expect that our general and administrative expenses in 2011 will be higher than in 2010 as a result of greater expenses relating to our operations as a public company, including increased payroll and increased consulting, legal and compliance, accounting, insurance and investor relations costs. Additionally, we plan to increase spending related to the build-out of our commercial infrastructure for the anticipated launch of both SPN-538 and Epliga in the United States in 2012. Upon approval of SPN-538, we would hire a small specialty sales force, initially consisting of a limited number of field sales representatives to support the launch of the product. We would then seek to expand our sales force in connection with an approval and commercial launch of Epliga. Having two epilepsy products that can be promoted to the same physician audience would allow us to leverage our commercial infrastructure with these prescribers.

***Other Income and Expense***

Other income and expense is comprised of interest income, gain on sales of equipment and interest expense. Interest income consists of interest earned on our cash and cash equivalents and marketable securities. The primary objective of our investment policy is capital preservation.



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Interest expense consists primarily of interest on the \$75.0 million non-recourse notes of Royalty Sub and the amortization of the related deferred financing costs. The non-recourse notes have a final stated maturity date of April 15, 2024. Until any portion of the principal on the non-recourse notes is paid down, the annual interest expense is \$12.0 million, or \$3.0 million per quarter. We will also begin paying interest on the \$15.0 million outstanding principal amount of our term loans after January 2011. As a result of the borrowings under our new secured credit facility, we expect that our future interest expense will increase over the levels incurred through September 30, 2010.

***Net Operating Losses and Tax Carryforwards***

As of December 31, 2009, we had approximately \$54.1 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of approximately \$3.1 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. The Tax Reform Act of 1986 provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes that could limit our ability to utilize these carryforwards. 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 may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

***Net Income and Loss***

We have incurred significant net losses since our inception in 2005, with the exception of 2009 when we generated net income of \$0.5 million principally because of the one-time payment of \$36.9 million that we received from Shire plc as consideration for a royalty-free, fully-paid-up license to Shire plc for Intuniv. We expect to continue to incur net losses for the foreseeable future as we continue to develop our product portfolio, seek regulatory approval, and, if such approval is obtained, commercialize SPN-538 and Epliga as well as our other product candidates.

Table of Contents**Results of Operations***Comparison of Nine Months Ended September 30, 2010 and Nine Months Ended September 30, 2009*

	<div> <div>Nine Months Ended</div> <div>September 30,</div> <div>2009</div> <div>2010</div> </div>		Increase/ (decrease)
	(unaudited)		
	(in thousands of dollars)		
Revenues:			
Development and milestone revenues	\$ 1,181	\$ 97	\$ (1,084)
Royalty revenues	41,884	8,635	(33,249)
Total revenues	43,065	8,732	
Operations Expenses:			
Research and development	21,804	26,080	4,276
General and administrative	3,503	3,388	(115)
Total operating expenses	25,307	29,468	
Income (loss) from operations	17,758	(20,736)	
Interest income	101	623	522
Interest expense	(9,210)	(9,831)	621
Net income (loss)	\$ 8,649	\$ (29,890)	

**Revenues.** Our revenues were \$8.7 million for the nine months ended September 30, 2010 compared to \$43.1 million for the same period in 2009, representing a decrease of \$34.3 million or approximately 80%. This decrease was principally attributable to the one-time, lump-sum payment of approximately \$36.9 million that we received in May 2009 from Shire plc as consideration for a royalty-free, fully paid-up license to Shire plc for Intuniv. We also generated lower development and milestone revenues for the nine months ended September 30, 2010 period as compared to same period in 2009 due to our focus on the development of our own product candidates as opposed to developing product candidates for third parties.

**Research and Development.** Our research and development expenses were \$26.1 million for the nine months ended September 30, 2010 compared to \$21.8 million for the same period in 2009, representing an increase of \$4.3 million or approximately 20%. The \$4.3 million increase in research and development expense is primarily attributable to an increase in clinical trial costs of approximately \$3.2 million, the largest portion of which was due to the continuing costs for our Phase III clinical trial for Epliga and higher manufacturing costs of approximately \$0.8 million principally associated with pre-validation work done at our commercial manufacturers for both SPN-538 and Epliga.

**General and Administrative.** Our general and administrative expenses were \$3.4 million for the nine months ended September 30, 2010 compared to \$3.5 million for the same period in 2009, representing a decrease of \$0.1 million or approximately 3%. The \$0.1 million decrease in general and administrative expense is primarily the result of lower patent and outside consulting fees incurred during the nine months ended September 30, 2010.

**Interest and Other Income.** Interest income was \$0.6 million for the nine months ended September 30, 2010 compared to \$0.1 million for the same period in 2009, representing an increase of \$0.5 million. The \$0.5 million increase is primarily because we invested a larger portion of our cash in marketable securities during the nine months ended September 30, 2010, which yielded higher returns than in the prior period. For the nine months ended September 30, 2010, we also had a one-time net gain of approximately \$54,000 on the sale of certain laboratory equipment.

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**Interest Expense.** Interest expense was \$9.8 million for the nine months ended September 30, 2010 compared to \$9.2 million for the same period in 2009, representing an increase of \$0.6 million or approximately 7%. Interest expense is comprised primarily of interest payable on the non-recourse notes of Royalty Sub at \$3.0 million per quarter, or approximately \$9.0 million for both nine month periods reported here, together with amortization of the related deferred financing costs related to the non-recourse notes. The \$0.6 million increase in interest expense in the nine months ended September 30, 2010 is largely because of amortization expense associated with marketable securities purchased at a premium.

**Net Income (Loss).** Net loss was \$29.9 million for the nine months ended September 30, 2010 compared to net income of \$8.6 million for the same period in 2009, representing a decrease of \$38.6 million. The \$38.6 million decrease is principally a result of the higher royalty revenues recognized in the nine months ended September 30, 2009, including in connection with our sale to Shire plc of a fully paid-up license for Intuniv and also due to the higher research and development costs incurred for the same period in 2010.

**Comparison of Year Ended December 31, 2009 and Year Ended December 31, 2008**

	Year Ended December 31,		Increase/ (decrease)
	2008	2009	
(in thousands of dollars)			
Revenues:			
Development and milestone revenues	\$ 2,697	\$ 1,550	\$ (1,147)
Royalty revenues	6,192	44,963	38,771
Total revenues	8,889	46,513	
Operations Expenses:			
Research and development	30,463	29,260	(1,203)
General and administrative	4,287	4,649	362
Total operating expenses	34,750	33,909	
Income (loss) from operations	(25,861)	12,604	
Interest income	1,057	514	(543)
Interest expense	(8,678)	(12,658)	3,980
Net income (loss)	\$ (33,482)	\$ 460	

**Revenues.** Our revenues were \$46.5 million for the year ended December 31, 2009 compared to \$8.9 million for the same period in 2008, representing an increase of \$37.6 million. This increase was principally due to the one-time, lump-sum payment from Shire plc of approximately \$36.9 million as consideration for a royalty-free, fully paid-up license for Intuniv. We also received increased royalty revenues of approximately \$1.9 million from Oracea and Sanctura XR. These gains were offset by a decrease in development and milestone revenues of approximately \$1.1 million as we continue to increase our focus on the development of our own product candidates, as opposed to earning revenues from developing collaborators' product candidates.

**Research and Development.** Our research and development expenses were \$29.3 million for the year ended December 31, 2009 compared to \$30.5 million for the same period in 2008, representing a decrease of \$1.2 million or approximately 4%. The decrease was primarily attributable to an approximately \$0.9 million decrease in salaries, benefits and laboratory supplies associated with a reduction in the average number of research and development employees from 69 for the year ended December 31, 2008 as compared to 56 for the year ended December 31, 2009 as part of our business strategy to improve our operating efficiencies and reduce our operating costs.

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**General and Administrative.** Our general and administrative expenses were \$4.7 million for the year ended December 31, 2009 compared to \$4.3 million for the same period in 2008, representing an increase of \$0.4 million or approximately 8%. This increase in general and administrative expense was primarily a result of increases in consulting expenses associated with market research and partnering opportunities as well as higher patent and legal costs.

**Interest Income.** Interest income was \$0.5 million for the year ended December 31, 2009 compared to \$1.1 million for the same period in 2008, representing a decrease of \$0.5 million or approximately 51%. Although average cash balances were higher for the year ended December 31, 2009, the decrease in interest income was principally a result of lower prevailing interest rates during the period.

**Interest Expense.** Interest expense was \$12.7 million for the year ended December 31, 2009 compared to \$8.7 million for the same period in 2008, representing an increase of \$4.0 million or approximately 46%. The increase in interest expense was primarily due to interest payments on the non-recourse notes of Royalty Sub, together with amortization of related deferred financing costs, for the year ended December 31, 2009 compared with the eight and one-half months that the non-recourse notes were outstanding in 2008.

**Net Income (Loss).** Net income was \$0.5 million for the year ended December 31, 2009 compared to a net loss of \$33.5 million for the same period in 2008, representing a decrease of \$34.0 million. The \$34.0 million change between the net loss of \$33.5 million for the year ended December 31, 2008 and the net income of \$0.5 million for the same period in 2009 is primarily due to higher royalty revenues recognized in the year ended December 31, 2009, offset by the higher interest expense related to the non-recourse notes in 2009 because the non-recourse notes were outstanding for the full year.

**Comparison of Year Ended December 31, 2008 and Year Ended December 31, 2007**

	Year Ended December 31,		Increase/ (decrease)
	2007	2008	
	(in thousands of dollars)		
Revenues:			
Development and milestone revenues	\$ 1,405	\$ 2,697	\$ 1,292
Royalty revenues	2,828	6,192	3,364
Total revenues	4,233	8,889	
Operations Expenses:			
Research and development	19,269	30,463	11,194
General and administrative	4,011	4,287	276
Total operating expenses	23,280	34,750	
Income (loss) from operations	(19,047)	(25,861)	
Interest income	1,773	1,057	(716)
Interest expense		(8,678)	8,678
Net income (loss)	\$ (17,274)	\$ (33,482)	

**Revenues.** Our revenues were \$8.9 million for the year ended December 31, 2008 compared to \$4.2 million for the same period in 2007, representing an increase of \$4.7 million. The increase in revenues relates primarily to an increase in royalties received from Oracea and the receipt of royalty revenues related to the product launch of Sanctura XR in the second half of 2008. The increase in development and milestone revenues was due to a \$1.3 million milestone payment related to the FDA approval of Sanctura XR that we received.

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**Research and Development.** Our research and development expenses were \$30.5 million for the year ended December 31, 2008 compared to \$19.3 million for the same period in 2007, representing an increase of \$11.2 million or approximately 58%. The increase in research and development expense is primarily attributable to an increase in clinical trial expenses of approximately \$9.4 million, principally due to outside costs associated with the Phase III clinical trial for Epliga that began in second half of 2008, as well as an increase in compensation costs of approximately \$1.7 million, primarily related to an increase in clinical and regulatory personnel hired to run and support the Phase III program for Epliga.

**General and Administrative.** Our general and administrative expenses were \$4.3 million for the year ended December 31, 2008 compared to \$4.0 million for the same period in 2007, representing an increase of \$0.3 million or approximately 7%. The increase in general and administrative expense was primarily a result of an increase in salaries and benefits costs of \$0.2 million due to an increase in personnel to support our expanded clinical operations.

**Interest Income.** Interest income was \$1.1 million for the year ended December 31, 2008 compared to \$1.8 million for the same period in 2007, representing a decrease of \$0.7 million or approximately 40%. The decrease in interest income for the year ended December 31, 2008 was principally the result of significantly lower prevailing interest rates during the period, notwithstanding higher average cash balances.

**Interest Expense.** Interest expense was \$8.7 million for the year ended December 31, 2008 compared to \$0 for the same period in 2007, representing an increase of \$8.7 million. The increase in interest expense was due to interest on the non-recourse notes of Royalty Sub, which were issued by it in April 2008, together with amortization of the related deferred financing costs.

**Net Income (Loss).** Net loss was \$33.5 million for the year ended December 31, 2008 compared to \$17.3 million for the same period in 2007, representing an increase of \$16.2 million or approximately 94%. This change was principally the result of the higher research and development expenses associated with initiating the Phase III program for Epliga, and the higher interest expense for the year ended December 31, 2008 associated with the issuance of the non-recourse notes of Royalty Sub. These expenses were slightly offset by higher royalty revenues from product sales of Oracea and Sanctura XR.

**Liquidity and Capital Resources**

In December 2005, we acquired substantially all of the assets of Shire Laboratories, Inc. from Shire plc in exchange for a cash payment of approximately \$0.8 million and the issuance of 4 million shares of our Series A convertible preferred stock at a value of \$1.00 per share. In connection with the commencement of our operations, in December 2005 and February 2006, we raised approximately \$45.0 million through the sale of 45 million shares of Series A convertible preferred stock. To date, we have not generated any revenues from the product sales. Since our inception in 2005, we have funded our operations largely through venture capital equity and other financings, such as the monetization of future royalties due to us from existing license agreements with Endo Pharmaceuticals Solutions Inc., Galderma Laboratories, L.P. and Shire plc pursuant to which we have received net proceeds of approximately \$100.2 million through September 30, 2010. As of September 30, 2010, we had unrestricted cash, cash equivalents and marketable securities of approximately \$45.8 million.

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***Financing History and Future Capital Requirements***

***Non-recourse Notes.*** In April 2008, we raised approximately \$63.3 million in net proceeds through a private placement to institutional investors of \$75.0 million aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due April 15, 2024 (the "Non-recourse Notes") by Royalty Sub. As part of the transaction, we transferred to Royalty Sub our payment rights and other license rights related to two products that utilize our proprietary technologies: Oracea, which is marketed by Galderma as a treatment for rosacea; and Sanctura XR, which is marketed by Allergan as a treatment for overactive bladder. The Non-recourse Notes are secured by these payment and other license rights, as well as by the pledge of all our outstanding equity interest in Royalty Sub. While the Non-recourse Notes are outstanding, all royalty and milestone payments due from net sales of Oracea and Sanctura XR go to the payment of interest, and when available, to the principal on such Non-recourse Notes. Accordingly, unless and until the Non-recourse Notes are fully paid, future royalties and milestone payments due from net sales of Oracea and Sanctura XR will not be available to fund our operations. Annual interest expense related to the Non-recourse Notes is \$12.0 million.

Royalty Sub began making quarterly debt service payments on the Non-recourse Notes on July 15, 2008. Applicable royalties received by Royalty Sub on net sales of Oracea and Sanctura XR for any quarter that exceed the interest payments and expenses due for that quarter are applied to the repayment of principal on the Non-recourse Notes. Any portion of the principal amount of the Non-recourse Notes not repaid on or before the legal final maturity date of April 15, 2024, will be payable on that date. As of September 30, 2010, no principal payments have been made. Upon payment of the Non-recourse Notes in full, any residual rights to the royalty payments will revert to us. In addition, the Non-recourse Notes may be redeemed at our option on any quarterly payment date, subject to the payment of a redemption premium if repaid on or before April 15, 2012. After April 15, 2012, the Non-recourse Notes may be redeemed without premium.

In connection with the Non-recourse Note transaction, an \$8.0 million interest reserve was established to fund potential interest shortfalls or, if none, for repayment of principal due under the Non-recourse Notes. These funds came out of the debt proceeds and are restricted. Deferred financing costs of approximately \$4.4 million were paid by Royalty Sub to complete the transaction. These costs were funded from the debt proceeds and will be amortized to interest expense over 16.2 years, which is the expected term of Non-recourse Notes.

In the first quarter of 2010, the \$8.0 million interest reserve was exhausted. As of September 30, 2010, the Royalty Sub had approximately \$1.4 million available for the quarterly interest payment of \$3.0 million due on October 15, 2010. As of December 1, 2010, the Royalty Sub paid the interest shortfall of \$1.6 million and had \$0.8 million available for future interest payments. Under the terms of the Non-recourse Notes, the Royalty Sub is not in default for payment of interest unless it fails to make payment in full on the interest payment by the next succeeding payment date. To date, the Royalty Sub has been able to make payment in full of all interest payments before the next succeeding payment date. In the event of a default for failure to pay interest timely, the noteholders do not have recourse to us as the Non-recourse Notes are non-recourse beyond Royalty Sub and non-convertible into any other of our securities, and have not been guaranteed by us. However, we have pledged all of our equity interests in Royalty Sub to secure the Non-recourse Notes and, upon an event of default, the noteholders could elect to exercise their rights to acquire those equity interests in the Royalty Sub.

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

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***United Therapeutics License***

We have a license agreement with United Therapeutics to use one of our proprietary technologies for an oral formulation of Remodulin for the treatment of PAH, and potentially for additional indications. This oral formulation of treprostinil diethanolamine, or treprostinil, is currently being evaluated by United Therapeutics in Phase III trials for PAH. Through September 30, 2010, we have received approximately \$750,000 in pre-commercial milestone payments under the agreement. Remaining milestone payments to us could total up to approximately \$2.8 million based on satisfaction of development milestones of oral treprostinil and up to approximately \$4.0 million for the development of each additional product that combines a form of oral treprostinil that utilizes our technologies with another drug compound. If United Therapeutics receives approval to market and sell oral treprostinil for additional indications and/or any additional combination products that utilizes our technologies, we will receive royalties in the single digits based on net sales worldwide. Any revenues received under this license will fluctuate as a result of the timing and amount of milestone and other payments received under this license, and the amount and timing of payments that we receive upon the sale of covered products, to the extent any are successfully commercialized by United Therapeutics or its sublicensees. Our license agreement with United Therapeutics will expire, on a country-by-country and product-by-product basis, 12.5 years from the first commercial sale of each product in such country. United Therapeutics may terminate, at its option, the agreement for a technical, strategic or market-related cause after giving us a reasonable opportunity to cure. We may terminate the agreement if, after having launched a product in a country, United Therapeutics or its sublicensee discontinues the sale of such product for a prolonged period of time for reasons unrelated to force majeure, regulatory or safety issues. In addition, either party may terminate the agreement for the material, uncured breach by the other party and in certain events of bankruptcy or insolvency of the other party.

***Secured Credit Facility***

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, and promissory notes issued in favor of each lender, providing for term loans of up to an aggregate of \$25.0 million. In connection with our first drawdown of \$15.0 million under our new secured credit facility on January 26, 2011, the lenders received from us ten-year warrants to purchase an aggregate of 375,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. Upon completion of this offering, each warrant 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 of \$1.00. We intend to use the proceeds of the term loans under our new secured credit facility for working capital and general corporate purposes. The term loans bear interest at a fixed rate per annum of 11.0% and will mature in 42-months from the date of each term loan, subject to a three-month extension under certain circumstances. In February 2011, we will make the first of twelve monthly interest-only payments on the outstanding term loans. Thereafter, beginning in March 2012, which is the amortization date for our outstanding term loans, we will make principal and interest payments to fully amortize the balance over the term of the loans, except that the date of such amortization is subject to a three-month extension under certain circumstances. In addition, we have the right to obtain additional term loans of up to \$10.0 million under the same terms and conditions of our current term loans under our new secured credit facility on or before April 30, 2011, provided that we are not in default under the terms of the loan and security agreement or other loan documents. In connection with any drawdown of additional term loans, we would be required to issue additional warrants to purchase up to 250,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share.

We may voluntarily prepay all, but not less than all, outstanding term loans under our new secured credit facility at any time, subject to the payment of a premium. With respect to any prepayment, the

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premium is 5.0% if such prepayment is made before the amortization date, 2.0% if such prepayment is made during the 15-month period after the amortization date and 1.0% if such prepayment is made thereafter. Upon the maturity of any outstanding term loans or the acceleration or prepayment thereof, we will also be required to make a final payment equal to 2.5% of the aggregate principal amount of the term loans borrowed under our new secured credit facility.

All obligations under our new secured credit facility are secured by substantially all of our existing property and assets (excluding our intellectual property) and by a pledge of the capital stock of, subject to certain exceptions, our U.K. subsidiary and any future subsidiary. Our new secured credit facility includes negative covenants that, subject to certain exceptions, limit our ability and the ability of our subsidiaries to, among other things, dispose of certain assets, change our lines of business, engage in mergers or consolidations, incur additional indebtedness, create liens on assets (including our intellectual property), pay dividends and make distributions on or repurchase our capital stock or engage in certain transactions with affiliates. Our new secured credit facility also includes certain customary representations and warranties, affirmative covenants and events of default, which, among other things, include payment defaults, covenant defaults, a material adverse change in our business, certain events of bankruptcy, cross-defaults to certain indebtedness, material judgments, breach of representations and warranties and the revocation, rescission, suspension or other adverse modification of a governmental approval. Upon the occurrence of an event of default, the lenders under our new secured credit facility will be entitled to take various actions, including the acceleration of all amounts due under our new secured credit facility and all actions permitted to be taken by a secured creditor.

We incurred debt financing costs of approximately \$ , which included the payment of an upfront fee and the reimbursement of certain of the lenders' related expenses. We expect that the issuance of the warrants and the payment of the upfront fee will be recognized as a discount on the loan issuance. We also expect that the legal and related expenses that we incurred will be recorded as deferred financing costs in our consolidated balance sheet, which, together with the estimated fair value of the warrants, the upfront fee, the final payment, and the fixed interest rate of the term loans, will be amortized to interest expense over the term of the loans using the effective interest rate.

***Funding Requirements***

As of September 30, 2010, we had unrestricted cash, cash equivalents and marketable securities of \$45.8 million, and \$1.4 million in restricted cash and cash equivalents reserved for interest payments by the Royalty Sub. 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, anticipated future product revenues and any additional borrowings under our new secured credit facility, will be sufficient to fund our operations for at least the next months. However, successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure, which we do not expect in the near term, if at all. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

We expect to continue to incur substantial additional operating losses for at least the foreseeable future as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of SPN-538, Epliga and our other product candidates. If we obtain marketing approval for SPN-538 or Epliga, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company following the closing of this offering.



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

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

The timing and outcome of Phase III data for Epliga, along with the timing of our submission to the FDA, and the outcome of the FDA's review, of the NDA for Epliga;

The extent to which the FDA may require us to perform additional clinical trials for SPN-538 or Epliga;

The timing and success of this offering;

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

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

The scope, progress, results and costs of development for our other product candidates;

The cost, timing and outcome of regulatory review of our other product candidates;

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

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

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

We may need to obtain additional capital through equity offerings, debt financing and/or payments under new or existing licensing and research and development collaboration agreements. We expect that our progress in the development of our product candidates may provide sufficient value inflection milestones, based on which we will be able to seek additional funding. The type, timing, and terms of financing, if required, will depend upon our cash needs, the availability of financing sources and the prevailing conditions in the financial markets. There can be no assurance that such financing will be available to us at any given time or available on favorable terms, if at all. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition. In addition, additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
	(unaudited)				
	(in thousands of dollars)				
Net cash provided by (used in):					
Operating activities	\$ (13,980)	\$ (29,652)	\$ 2,634	\$ 11,994	\$ (20,840)
Investing activities	14,854	15,481	(28,385)	(19,618)	14,278
Financing activities	5	64,462	4,280	2,546	412
Net increase (decrease) in cash and cash equivalents	\$ 879	\$ 50,291	\$ (21,471)	\$ (5,078)	\$ (6,150)

***Operating Activities***

Net cash used in operating activities for the nine months ended September 30, 2010 compared to net cash provided by operations for the same period in 2009 decreased by \$32.8 million. This decrease in cash was primarily the result of a \$38.5 million increase in the difference between the net loss for the nine months ended September 30, 2010 compared to the net income for the same period in 2009. This difference was principally driven by the recognition of royalty revenues in 2009 of approximately \$36.9 million related to a license agreement with Shire plc for Intuniv. In addition, we incurred higher research and development costs of approximately \$4.3 million for the nine months ended September 30, 2010 compared to the same period in 2009 to support our clinical programs relating to SPN-538 and Epliga. This decrease in cash flow from operating activities was offset by an increase of \$5.6 million between the two periods related to net changes in working capital. The largest portion of the increase in working capital related to a \$5.8 million increase in account payables and accrued expenses, principally relating to the increased clinical trial and pre-validation manufacturing expenses for SPN-538 and Epliga incurred during the 2010 period.

Net cash provided by operating activities for the year ended December 31, 2009 compared to net cash used in operations for the same period in 2008 increased by \$32.3 million. This increase was primarily the result of a \$33.8 million increase in the difference between the net income for the year ended December 31, 2009 compared to the net loss for the same period in 2008. This difference between the net income in 2009 relative to the net loss in 2008 was principally related to the recognition in 2009 of \$38.8 million of additional royalty revenues, including approximately \$36.9 million in royalty revenues related to the license agreement with Shire plc for Intuniv and higher year-over-year royalty revenues of approximately \$1.9 million attributable to Sanctura XR and Oracea. The higher royalty revenues in 2009 were offset by, among other things, higher interest expense in 2009 of approximately \$4.0 million related to interest payments on the non-recourse notes of Royalty Sub, together with amortization of related deferred financing costs for the full twelve months of 2009, as compared with the eight and one-half months that the Non-recourse Notes were outstanding in 2008. This was further offset by a \$1.7 million decrease in working capital, principally due to the increase in interest payable of approximately \$2.5 million due under the Non-recourse Notes in 2008.

Net cash used in operations for the year ended December 31, 2008 compared to the same period in 2007 increased by \$15.7 million. This increase was primarily the result of a \$16.2 million increase in the net loss for the year ended December 31, 2008 compared to the same period in 2007. The increase in the net loss was a result of approximately \$11.0 million in higher research and development expenses, primarily attributable to an increase in clinical trial expenses to support our Phase III clinical trial for Epliga that began in the second half of 2008, and an increase in interest expense of

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approximately \$8.7 million due to interest on the Non-recourse Notes of Royalty Sub, which were issued by it in April 2008. These uses of cash in operations were offset by, among other things, a \$0.4 million increase in non-cash items, such as depreciation, stock-based compensation expense and amortization of deferred financing expenses associated with the Non-recourse Notes of Royalty Sub.

We expect cash used in operating activities to increase for the year ending December 31, 2010 as compared to same period in 2009 due to the anticipated increase in our operating losses associated with the clinical trials, particularly the Phase III trials for Epliga, costs associated with the preparation of the NDA for SPN-538, which we filed in January 2011, and the expected acceleration of our development programs.

***Investing Activities***

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

The increase of \$33.9 million in net cash provided by investing activities for the nine months ended September 30, 2010 compared to the same period in 2009 was primarily the result of a \$37.8 million increase in the cash received from the sales and maturities of marketable securities, offset by a \$4.1 million increase in the cash used to purchase marketable securities. This increase in cash provided by financing activities was augmented by a \$0.2 million decrease in cash used for the purchase of property and equipment for the nine months ended September 30, 2010 compared to the same period in 2009.

Net cash used in investing activities for the year ended December 31, 2009 compared to net cash provided by investing activities for the same period in 2008 decreased by \$43.9 million. This decrease was primarily a result of a \$76.5 million decrease in cash received from the sales and maturities of marketable securities and a \$33.2 million increase in the cash used for the purchase of marketable securities, together with a \$0.6 million increase in purchases of property and equipment primarily related to the leasehold improvements for our facility and the purchase of laboratory equipment.

Net cash used in investing activities increased by \$0.6 million for the year ended December 31, 2008 compared to the same period in 2007. This increase in cash used for investing activities was primarily a result of a \$40.8 million increase in the cash received from the sales and maturities of marketable securities and a \$0.9 million decrease in purchases of property and equipment, offset by \$41.1 million decrease in purchases of marketable securities.

***Financing Activities***

Net cash provided by financing activities decreased by \$2.1 million for the nine months ended September 30, 2010 compared to the same period in 2009. This decrease was primarily due to the drawdown in full by January 2010 of the remaining balance in the interest reserve account that was established to fund potential shortfalls in interest payments for the Non-recourse Notes.

Net cash provided by financing activities decreased by \$60.2 million for the year ended December 31, 2009 compared to the same period in 2008 and increased by \$64.5 million for the year ended December 31, 2008 compared to the same period in 2007. The increase for the year ended December 31, 2008 and the decrease for the year ended December 31, 2009 were primarily due to the issuance of the \$75 million in Non-recourse Notes in April 2008, offset by issuance costs of \$4.4 million, and the establishment of, and subsequent interest payments from, the interest reserve

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account required by the indenture governing the Non-recourse Notes and the deferred financing costs associated with the Non-recourse Notes.

### Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2010 (except as noted below):

Contractual Obligations	Less than 1 Year	1 3 Years	3 5 Years	Greater than 5 Years	Total
(in thousands of dollars)					
Non-recourse Notes <sup>(1)</sup>	\$	\$	\$	\$ 75,000	\$ 75,000
Interest on Non-recourse Notes <sup>(1)</sup>	12,000	24,000	24,000	102,500	162,500
Operating leases <sup>(2)</sup>	983	1,610			2,593
Purchase obligations <sup>(3)</sup>	9,988	190			10,178
Total <sup>(4)</sup>	\$ 22,971	\$ 25,800	\$ 24,000	\$ 177,500	\$ 250,271

- (1) Annual interest expense is \$12.0 million, based on a principal amount outstanding of \$75.0 million as of September 30, 2010. For purposes of this table, we have assumed that the repayment of principal will not be repaid before the legal final maturity date of April 15, 2024. The Non-recourse Notes and related interest payments are non-recourse beyond Royalty Sub and non-convertible into any other of our securities.
- (2) Our commitments for operating leases relate to our lease of office and laboratory space as of September 30, 2010.
- (3) Relates primarily to agreements and purchase orders with contractors for the conduct of clinical trials and other research and development and marketing activities.
- (4) This table does not include (a) any milestone payments which may become payable to third parties under license agreements as the timing and likelihood of such payments are not known, (b) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known and (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

In November 2010, we amended the lease for our principal office and laboratory space. Under terms of the amended lease, we extended the term for an additional five years to April 2018, obtained six months' rent abatement beginning in November 2010, with no future rent increase until November 2013 and thereafter only 2% annual rent increase per year, as well as additional funds and reimbursements for certain tenant improvements.

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, and promissory notes issued in favor of each lender, providing for term loans of up to an aggregate of \$25.0 million. On January 26, 2011, we drew down our first \$15.0 million of term loans under our new secured credit facility. The term loans bear interest at a fixed rate per annum of 11.0% and will mature in 42-months from the date of each term loan, subject to a three-month extension under certain circumstances. We intend to use the proceeds of the term loans under our new secured credit facility for working capital and general corporate purposes. In addition, we have the right to obtain additional term loans of up to \$10.0 million under the same terms and conditions of our current term loans under our new secured credit facility on or before April 30, 2011, provided that we are not in default under the terms of the loan and security agreement or other loan documents.

We have obtained exclusive licenses from third parties for proprietary rights to support the product candidates in our psychiatry portfolio. Under license agreements with Afecta, we have an exclusive



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

**Off-Balance Sheet Arrangements**

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

**Critical Accounting Policies and Estimates**

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

While a summary of significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing at the end of this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

***Revenue Recognition***

Our revenues have been generated through research and development agreements, which included fees for development services provided to customers, payments for achievement of specified development, regulatory and sales milestones and royalties on product sales of licensed products. For multiple element arrangements, we evaluate the components of each arrangement as separate elements based on certain criteria. Accordingly, revenues from collaboration agreements are recognized based on the performance requirements of the agreements. We recognize revenues when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collection is reasonably assured.

Our development revenues have been earned under contracts which were less than one year in duration. Development contracts generally take the form of fee-for-service arrangements based on an annual contractual full time equivalent billing rate. In cases where performance spanned multiple accounting periods, we recognized revenue as services were performed, measured on a proportional-performance basis. We used output measures, specifically labor hours, to measure performance as they reflect our pattern of performance over the contractual term. Milestone payments are recognized as

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revenues when the collaborative partner acknowledges completion of the milestone and substantive effort was necessary to achieve the milestone.

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

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

***Accrued Expenses***

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

fees paid to contract research organizations, or CROs, in connection with clinical trials;

fees paid to investigative sites in connection with clinical trials;

fees paid to contract manufacturers in connection with the production of clinical trial materials; and

professional service fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical

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trial milestones. In accruing the related service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not anticipate the future settlement of existing accruals to differ materially from our estimates.

***Stock-Based Compensation***

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

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

	Years Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
	(unaudited)				
	(in thousands of dollars)				
Research and development	\$ 9	\$ 28	\$ 28	\$ 21	\$ 32
General and administrative	65	71	83	62	92
Total	\$ 74	\$ 99	\$ 111	\$ 83	\$ 124

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

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the input of subjective assumptions, including stock price volatility, assumed dividend yield, the expected life of stock options and a risk-free interest rate. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies, or guideline peer group, for which the historical information is available. We will continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants. The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future. We determine the average expected life of stock options according to the "simplified method" as described in Staff Accounting Bulletin 110, which is the mid-point between the vesting date and the end of the contractual term. We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2009 and 2010 are set forth in our consolidated financial statements appearing at the end of this prospectus.

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



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There is a high degree of subjectivity involved when using option-pricing models to estimate stock-based compensation. There currently is no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the estimated fair value of employee stock-based awards is determined using an option-pricing model, that value may not be indicative of the fair value observed in a market transaction between a willing buyer and willing seller. If factors change and we employ different assumptions when valuing our options, the compensation expense that we record in the future may differ significantly from what we have historically reported.

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

our stage of development and business strategy;

our financial condition, operating results and book value;

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

our projected operating results;

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

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

important developments relating to the results of our clinical trials;

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

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

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

The holders of our Series A convertible preferred stock are entitled to a liquidation preference. The aggregate amount of liquidation preferences, excluding any dividends, has increased from \$6.8 million as of December 31, 2007 to \$16.2 million as of September 30, 2010. In the event of liquidation, dissolution or winding up of our company, the liquidation preference for each Series A convertible preferred share equals the original purchase price of \$1.00 per share, plus accumulated unpaid dividends.



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The following table represents stock option grant information from January 1, 2009 through the date of this prospectus, including the estimated fair value of the option grant as determined by the Black-Scholes option-pricing model.

Grant Date	Number of Options	Exercise Price	Estimated Fair Value	Intrinsic Value
January 19, 2009	225,000	\$ 0.40	\$ 0.23	\$
December 15, 2009 <sup>(1)</sup>	257,200	\$ 1.76 <sup>(1)</sup>	\$ 1.03	\$
February 10, 2010	52,500	\$ 0.84	\$ 0.49	\$
April 16, 2010	32,750	\$ 0.84	\$ 0.49	\$
July 20, 2010	38,500	\$ 0.84	\$ 0.48	\$
October 15, 2010	15,000	\$ 0.64	\$ 0.37	\$
November 2, 2010	880,000	\$ 0.64	\$ 0.41	\$
November 16, 2010	35,000	\$ 0.64	\$ 0.41	\$
<b>Total</b>	<b>1,535,950</b>			

(1) On November 2, 2010, 255,000 of these options were repriced from \$1.76 to \$0.64 per share.

The intrinsic value of all outstanding vested and unvested options as of September 30, 2010 based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and the exercise price of the outstanding options are as follows:

	Number of Options	Intrinsic Value
Unvested	789,134	\$
Vested	940,324	\$

Our board of directors has made only one grant of non-vested stock. This grant was made in December 2005 for 3,500,000 shares of common stock. The estimated fair value of those shares as of the date of grant was \$0.10 per share.

On November 2, 2010, our board of directors repriced 255,000 of the options granted on December 15, 2009 from a per share exercise price of \$1.76 to \$0.64. In addition, our board approved the modification of the performance vesting requirements related to 157,697 employee stock options and 411,765 shares of non-vested stock awarded to our chief executive officer. The vesting of these share-based awards were contingent upon the filing of our first NDA on or before December 22, 2010, and our board extended the deadline for the achievement of this performance condition to March 31, 2011. As a result of these actions, there is no immediate charge related to the repriced and modified options, and we will recognize additional stock based compensation of approximately \$50,000 over the remaining vesting periods for these options.

All contemporaneous valuations were prepared consistent with the AICPA Practice Aid. At each valuation date, we considered the use of market, income and asset valuation approaches. We lacked relevant financial metrics to utilize the market approach and the asset approach was not utilized because the majority of our assets are intangible, accordingly we used an income approach for each valuation. The income approach values a business based upon the future benefits that will accrue to it with the value of the future economic benefits discounted back to a present value at some appropriate discount rate. Implicit in the market price of all publicly traded securities is a consensus forecast of earnings and financial condition. The consensus forecast results from the information made available to the investing public by us and from the numerous forecasts prepared by financial analysts. We have replicated this approach through the preparation of an operating forecast and the use of discounted cash flow analysis. The discount rate reflects all the risk of ownership and the associated risks of

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

***Stock Option Grants on January 19, 2009***

Our board of directors granted stock options on January 19, 2009, with each having an exercise price of \$0.40 per share. In addition to considering the objective and subjective factors listed above, our board of directors considered the valuation as of December 31, 2007 provided by management in determining the fair value of our common stock on January 19, 2009. We considered this valuation relevant in our determination of the estimated fair value of the common stock primarily because the deterioration of the overall financial markets in the second half of 2008 overshadowed progress on our clinical pipeline and the financing from the Non-recourse Notes. Our board of directors considered that in the face of the credit and liquidity crisis and the resulting uncertainties, the prospects for a liquidity event in the foreseeable future were significantly lower.

In the December 31, 2007 valuation, we used the income approach, specifically a discounted cash flow analysis, to estimate our company's equity value. The first step in that process was to calculate the present value of our discrete net cash flows for the periods projected. Next, the present value of our terminal net cash flow was calculated. The sum of these two present values, utilizing a cost of capital discount rate of 21.2%, determined the total market value capitalization on a minority basis to approximate \$59.5 million. We added free cash (cash remaining after all investments and commitments that could potentially be available for debt service or shareholders dividends without impairing operations) in the amount of \$25.9 million to estimate the market value of the total equity on a minority interest basis to approximate \$85.4 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using the option-pricing method. A discount of 25.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at December 31, 2007 of \$0.40 per share. Our board determined this valuation analysis to be reasonable and, on the basis of the factors described above, that the estimated fair value of our common stock on January 19, 2009 was \$0.40 per share.

***Stock Option Grants on December 15, 2009***

Our board of directors granted stock options on December 15, 2009, with each having an exercise price of \$1.76 per share. In addition to considering the objective and subjective factors listed above, our board of directors considered the valuation as of July 16, 2009 provided by management in determining the fair value of our common stock on December 15, 2009. We utilized the income approach, specifically a discounted cash flow analysis, to estimate the equity value of our company. In addition, to the a non-risk adjusted forecast we also considered a risk-adjusted forecast using various probabilities to reflect the risks of achieving commercialization based on the products clinical stage of development. We utilized non-risk adjusted and risk adjusted costs of capital of 25.0% and 18.9%, respectively. These

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discount rates were applied to our discrete net cash flows to determine the present value. This present value was combined with the present value of our terminal cash flow to determine the total market value of capitalization for us on a minority interest basis of approximately \$122.9 million. We added free cash in the amount of \$80.6 million to estimate the market value of the total equity, on a minority interest basis, of to be approximately \$203.5 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using option-pricing method. A discount of 30.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at July 16, 2009 of \$1.76 per share. Based on the foregoing, we concluded the fair value of our common stock as of December 15, 2009 was \$1.76 per share. No significant changes had come to our attention between July 16, 2009 and the December 15, 2009 grant date to warrant a revaluation of the stock. We therefore concluded there was no basis for a change in the fair value during such period.

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

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

Our board of directors granted stock options on February 10, April 16 and July 20, 2010, with each having an exercise price of \$0.84 per share. In addition to considering the objective and subjective factors listed above, our board of directors considered the valuation as of December 31, 2009 provided by management in determining the fair value of our common stock on each of February 10, April 16 and July 20, 2010. We utilized the income approach, specifically a discounted cash flow analysis, to estimate the equity value of our company. We considered a non-risk adjusted forecast and risk-adjusted forecast using various probabilities to reflect the risks of achieving commercialization based on our products clinical stage of development. We utilized non-risk adjusted and risk adjusted costs of capital of 25.0% and 15.7%, respectively. These discount rates were applied to our discrete net cash flows to determine the present value. This present value was combined with the present value of our terminal cash flow to determine the total market value of capitalization for us, on a minority interest basis, of approximately \$53.0 million. We added free cash in the amount of \$66.7 million to estimate the market value of the total equity on a minority interest basis to be approximately \$119.7 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using option-pricing method. A discount of 30.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at December 31, 2007 of \$0.84 per share. Based on the foregoing, we concluded the fair value of our common stock as of February 10, 2010 was \$0.84 per share. We further determined the fair value of the common stock as of April 16 and July 20, 2010 to be \$0.84 per share. No significant changes had come to our attention between December 31, 2009 and each of the foregoing grants date to warrant a revaluation of the stock. We therefore concluded there was no basis for a change in the fair value during such period.

The decrease in the estimated fair value of the common stock as compared to the July 16, 2009 valuation principally relates to information regarding the announcement in December 2009 by a competitor of the initiation of a Phase III clinical trial for a once-a-day, extended-release topiramate product to treat epilepsy that could compete head-to-head with SPN-538, and, if approved before SPN-538, would have three years of market exclusivity.

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

Our board of directors granted stock options on October 15, November 2 and November 16, 2010, with each having an exercise price of \$0.64 per share. In addition to considering the objective and

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subjective factors listed above, our board of directors considered the valuation as of October 1, 2010 provided by management in determining the fair value of our common stock on each of October 15, November 2 and November 16, 2010. We utilized the income approach, specifically a discounted cash flow analysis, to estimate the equity value of our company. We utilized a non-risk adjusted forecast and a risk-adjusted forecast using various probabilities to reflect the risks of achieving commercialization based on our product candidates' clinical stage of development. We utilized non-risk adjusted and risk adjusted costs of capital of 22.0% and 14.2%, respectively. These discount rates were applied to our discrete net cash flows to determine the present value. This present value was combined with the present value of our terminal cash flow to determine our total market value of capitalization on a minority interest basis of approximately \$64.4 million. We added free cash in the amount of \$45.8 million to estimate the market value of the total equity on a minority interest basis to be approximately \$110.2 million. This estimated value was allocated between the Series A convertible preferred stock and common stock using option-pricing method. A discount of 20.0% was applied to account for the lack of marketability of our common stock. This analysis yielded an estimated fair value of our common stock at October 1, 2010 of \$0.64 per share. Based on the foregoing, we concluded the fair value of our common stock as of October 15, November 2 and November 16, 2010 was \$0.64 per share. No significant changes had come to our attention between October 1, 2010 and each of the foregoing grants date to warrant a revaluation of the stock. We therefore concluded there was no basis for a change in the fair value during such period.

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

### ***Lender Warrants***

In connection with our new secured credit facility, the lenders received from us ten-year warrants to purchase an aggregate of 375,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. We determined the fair value of these warrants to be \$ , under the Black-Scholes valuation model using the following assumptions: risk-free interest rate of %; dividend yield of 0.0%; expected volatility of %; and a contractual term of years. We expect that the value of the warrants will be recorded as a discount to the note payable, and will be amortized to interest expense over the expected term of the loans.

### **Recent Accounting Pronouncements**

In August 2009, the FASB issued ASU No. 2009-05, *Fair Value Measurements and Disclosures (Topic 820) Measuring Liabilities at Fair Value* ("ASU 2009-05"). ASU 2009-05 provides guidance in measuring the fair value of a liability when a quoted price in an active market does not exist for an identical liability or when a liability is subject to restrictions on its transfer. ASU 2009-15 was effective for us beginning with the quarter ended December 31, 2009. The adoption of ASU 2009-05 had no impact on the fair value measurements of our liabilities.

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (Topic 605) Multiple-Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force* ("ASU 2009-13"). ASU 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available, third-party evidence, if VSOE is unavailable, and estimated selling prices if neither VSOE or third-party evidence is available. In addition, ASU 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. ASU 2009-13 will be effective prospectively for multiple-deliverable revenue arrangements entered into, or materially modified, in

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fiscal years beginning on or after June 15, 2010. Presently, we are assessing what impact, if any, the adoption of ASU 2009-13 may have on our consolidated financial statements.

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements* ("ASU No. 2010-06"). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances, and settlements be disclosed on gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities; and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 becomes effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances, and settlements of Level 3 assets and liabilities which will be effective for fiscal years beginning after December 15, 2010. We are currently assessing what impact, if any, ASU No. 2010-06 will have on our fair value disclosures; however, we do not expect the adoption of the guidance provided in this codification update to have any material impact on our consolidated financial statements.

In February 2010, the FASB issued amended guidance on subsequent events. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and we adopted these new requirements upon issuance of this guidance.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition Milestone Method* (ASU 2010-017). ASU 2010-017 provides guidance in applying the milestone method of revenue recognition to research or development arrangements. This guidance concludes that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance is effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this accounting standard is not expected to impact our financial position or results of operations.

**Quantitative and Qualitative Disclosure About Market Risk**

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2010, we had unrestricted cash, cash equivalents and marketable securities of \$45.8 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments. We do not have any foreign currency or other derivative financial instruments.

We contract with contract research organizations and investigational sites globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements, primarily with respect to Euro denominated currencies. We do not hedge our foreign currency exchange rate risk. A hypothetical 10% appreciation in Euro exchange rates against the U.S. dollar from prevailing market rates would have decreased our net income by approximately \$139,000 for the year ended December 31, 2009. Conversely, a hypothetical 10% depreciation in Euro exchange rates against the U.S. dollar from prevailing market rates would have increased our net income by approximately \$139,000 for the year ended December 31, 2009.

We do not believe that inflation and changing prices over the years ended December 31, 2008 and 2009 and the nine months ended September 30, 2010 had a significant impact on our results of operations.

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**BUSINESS**

**Overview**

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system, or CNS, diseases. Our extensive expertise in product development has been built over the past 20 years: initially as a stand alone development organization, then as a U.S. subsidiary of Shire plc and, upon our acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals. We are developing several product candidates in neurology and psychiatry to address large market opportunities in epilepsy and attention deficit hyperactivity disorder, or ADHD. Our two epilepsy product candidates are SPN-538 (extended release topiramate), for which we filed a new drug application, or NDA, in January 2011, and Epliga (extended release oxcarbazepine), which is in Phase III clinical trials. Our ADHD product candidates include SPN-810 (molindone hydrochloride), a novel treatment for impulsive aggression in patients with ADHD and SPN-812, a novel non-stimulant treatment of ADHD. Both of these programs are in Phase II. In addition to these four lead product candidates, we have several additional product candidates in various stages of development. We intend to market our product candidates in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists. We believe our diversified and broad portfolio of product candidates provides us with multiple opportunities to achieve our goal of becoming a leading specialty pharmaceutical company focused on CNS diseases.

We use our proprietary technologies to enhance the therapeutic benefits of approved anti-epileptic drugs, or AEDs through advanced extended release formulations. Our most advanced product candidates, SPN-538 and Epliga, are novel oral once-daily extended release formulations of topiramate and oxcarbazepine, respectively; for the treatment of epilepsy. Immediate release formulations of topiramate and oxcarbazepine, are available in generic form and are marketed by Johnson & Johnson and Novartis under the brand names of Topamax and Trileptal, respectively. According to IMS Health, peak sales of Topamax and Trileptal represented an estimated 25.8% and 8.1% of the total seizure disorder market in 2008 and 2006, respectively. We are pursuing a Section 505(b)(2) regulatory strategy for SPN-538 and Epliga, which would allow us to rely on the existing data from the NDAs of Topamax and Trileptal, respectively. The once-per-day dosing of each of SPN-538 and Epliga is designed to improve patient compliance and to provide a better tolerability profile compared to the current immediate release AEDs that are taken multiple times per day to maintain therapeutic drug concentrations over the dosing interval. We believe there is a significant unmet need for extended release products, such as SPN-538 and Epliga, for the treatment of epilepsy. Extended release products have been shown to improve compliance, increase seizure control, reduce side effects and improve tolerability as compared to immediate release products, which can lead to fewer side effects, better tolerability,<sup>(1)</sup> increased seizure control and greater patient compliance.<sup>(2)</sup>

(1)

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

(2)

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



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We are also developing treatments for new indications in diseases such as ADHD and its coexisting disorders. We are developing SPN-810, which is currently in Phase II, as a novel treatment for impulsive aggression in patients with ADHD. If approved by the U.S. Food and Drug Administration, or FDA, SPN-810 could be the first product available to address this serious, unmet medical need. SPN-810 is based on molindone hydrochloride, which was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. In addition, SPN-812, which is currently in Phase II, is being developed as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. In addition, because the active ingredient of SPN-812 has demonstrated efficacy as an antidepressant in Europe, this product candidate may provide increased benefit to an estimated 40% of ADHD patients who suffer from depression.<sup>(3)</sup>

(3)

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

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

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

Product	Indication	Status
SPN-538	Epilepsy	NDA filed
Epliga	Epilepsy	Phase III
SPN-810	Impulsive Aggression in ADHD	Phase II
SPN-812	ADHD	Phase II
SPN-809	Depression	IND filed

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

**Our Strategy**

Our goal is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry. Key elements of our strategy to achieve this goal are to:

*Build in-house sales and marketing capabilities, focused on specialty markets in the United States, to promote SPN-538 and Epliga. We are currently focused on attaining regulatory approval for, and bringing our two late-stage epilepsy products, SPN-538 and Epliga, to market. As SPN-538 and Epliga progress towards U.S. regulatory approval, we intend to build our own targeted, specialty*

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sales force to promote, if approved, SPN-538 and Epliga in the United States. We intend to direct our marketing efforts to high potential prescribers of both products.

*Continue to advance our product candidates in our psychiatry portfolio, including SPN-810 and SPN-812.* As part of our longer term strategy, we intend to further develop our product candidates in our psychiatry portfolio to enable further diversification of our pipeline and future growth. For example, we are currently preparing to initiate a Phase IIb trial for SPN-810.

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

*Establish strategic partnerships to accelerate and maximize the potential of our product candidates worldwide.* We intend to continue to seek strategic collaborations with other pharmaceutical companies to commercialize our product candidates outside the United States. We believe that we are an attractive collaborator for pharmaceutical companies due to our broad portfolio of proprietary technologies and our product development track record.

*Leverage our management team's expertise to develop and commercialize our broad portfolio of product candidates.* We intend to leverage the expertise of our executive management team in developing and commercializing innovative therapeutic products. We plan to continue to evaluate and develop additional CNS product candidates that we believe have significant commercial potential through our internal research and development efforts or, if appropriate, external collaborations.

## Epilepsy

### *Overview*

Epilepsy is a complex neurological disorder characterized by spontaneous recurrence of unprovoked seizures, which are sudden surges of electrical activity in the brain that impair a person's mental or physical abilities. Epilepsy, which is typically diagnosed by a neurologist, is estimated to affect 50 million people worldwide<sup>(4)</sup> and 2 million people in the United States.<sup>(5)</sup> According to IMS Health, U.S. sales of AEDs were approximately \$5.3 billion in 2009. The annual cost of epilepsy is estimated to be \$12.5 billion.<sup>(6)</sup>

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

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

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

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

(7)

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

(8)

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

***Current Treatment Options***

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

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

(9)

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

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***Dynamics of the Epilepsy Market***

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

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

Compliance with drug treatment regimens is critically important to achieving effective therapy for patients with epilepsy where the consequences of non-compliance can be life threatening. Patient non-compliance with AED therapy is a serious issue and remains one of the most common causes of breakthrough seizures. Not only is taking all prescribed doses critical for epileptic patients, but the timing of when patients take their prescribed doses is also important. Typically, non-compliance is caused by frequent or multiple dosing, serious side effects, or a lack of tolerability. A 2002 survey undertaken by neurologists in the United States found that, at least once per month, 71% of patients with epilepsy forgot to take their AED, and it was evident that the chances of a patient missing a dose increased with the number of tablets prescribed.<sup>(10)</sup> Of patients that missed a dose, 45% reported a breakthrough seizure. Patients taking a larger number of tablets/capsules further increased their odds of having a breakthrough seizure after a missed dose by 43%. In addition, other studies have shown reduced rates in breakthrough seizures as a result of improved compliance with AED treatment regimens.

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(10)

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

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

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

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

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

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

Patients today are most typically switched from branded drugs to generics, or from one generic drug to another, mainly to reduce cost. In most states, unless a physician explicitly writes "dispense as written" or "no substitution," pharmacists can switch a patient to a lower-cost generic drug without the consent of either the patient or the physician. Epilepsy patients are particularly vulnerable to changes in their drugs. Slight variations in the blood concentrations of these drugs could lead to the occurrence of breakthrough seizures. Accordingly, despite existing regulatory criteria to ensure the bioequivalence of generic drugs, the "switch-back" rates of AEDs (that is, the frequency of an individual being returned to his or her previous branded product under a physician's guidance) is much higher than for many other drug products. For example, the rates of patients switching back from generics to branded drugs because of adverse events were found to be 20.8% to 44.1% for AEDs compared to 7.7% to 9.1% for non-AEDs.<sup>(11)</sup>

(11)

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

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

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

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

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

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

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

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

When extended release formulations are used appropriately, drug levels remain within the patient's therapeutic zone, thereby reducing patient exposure to fluctuating drug levels, which may exacerbate side effects or induce breakthrough seizures. Because extended release formulations can reduce peak concentrations, it may also be possible to adjust doses upward to a more efficacious level without exacerbating side effects associated with peak concentrations. Extended release formulations can also reduce the frequency and the extent of the troughs, or lower concentrations of the drug in the blood, thereby avoiding concentrations below the minimum effective concentrations that can increase the risk of breakthrough seizures.

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

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

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

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

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

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

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

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

Given the serious nature of epilepsy and the key dynamics in the epilepsy market, we believe managed care plans acknowledge the important benefits of extended release AED products and, therefore, have not limited the success of such products even when lower cost generic immediate release products are available. For example, according to industry data, the recent launches of extended release products Keppra XR and Lamictal XL have enjoyed acceptance rates by managed care plans that are similar to those of the corresponding immediate release products. Most managed care plans also acknowledge the position of several patient advocacy groups and the American Academy of Neurology regarding the risks of generic substitution of AEDs, including potential for breakthrough seizures. Although switching to a low-cost generic AED may initially offer some cost savings, we believe they also recognize that the risk and cost of one breakthrough seizure outweighs the potential savings from generics. For example, the healthcare costs associated with the treatment of patients who experience breakthrough seizures, which may run in excess of \$26,000 per patient on an annual basis, is significantly greater than any cost savings per patient that may be achieved through switching to a low-cost generic AED. According to a 2009 survey, the total healthcare costs for patients using branded topiramate products were approximately 20% lower than for patients using multiple generic topiramate products.<sup>(12)</sup>

(12)

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





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***Extended Release Products Perform Well in the Market***

Extended release products have performed well in the epilepsy market, even in the face of immediate release generic products. Moreover, IMS Health prescription data for seizure disorder drugs from 1994 to 2005 shows that extended release products perform better than NCEs during the first five years of their launch. Currently, there are five extended release AEDs on the market (Tegretol XR, Carbatrol, Depakote ER, Lamictal XL, Keppra XR), and each of these products has gained significant market penetration as measured by the total prescriptions written for each specific molecule. For example, as reflected in the chart below, Depakote ER gained almost 40% of all divalproex prescriptions, including immediate release versions of Depakote and generic divalproex, in its fifth year after launch.

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

Source: IMS Health

**Our Late-Stage Neurology Portfolio**

We are developing a promising epilepsy product portfolio consisting of SPN-538 and Epliga that utilize our proprietary technologies, Microtrol and Solutrol, respectively, each of which has been proven and validated through use in products that are currently on the market. Among them is Carbatrol, an AED that has been shown to reduce side effects compared to immediate release carbamazepine products. We believe that our 20 years of history and portfolio of technologies have enabled us to develop highly-customized product candidates that overcome challenges with the molecules' pharmacokinetic profiles. Our differentiated approach to product development and the strength of our technologies have allowed us to develop SPN-538 with what we believe to be a unique pharmacokinetic profile and to develop a once-daily formulation of oxcarbazepine with Epliga where others have failed.

SPN-538 and Epliga are novel extended release formulations of two well known and approved AEDs, topiramate and oxcarbazepine, respectively. Both product candidates are designed to offer epilepsy patients effective therapy, reduced side effects and improved compliance with once-per-day dosing. We believe that by delivering more consistent and steady maintenance of blood level



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concentrations of topiramate and oxcarbazepine, our product candidates can reduce adverse side effects and improve tolerability of the drugs, which can improve compliance and enable patients to benefit from better seizure control and fewer breakthrough seizures as compared to similar immediate release products. Given that SPN-538 and Epliga are based on different drug compounds and different mechanisms of action, they would target different market segments and patient populations within the epilepsy market.

We filed the NDA for SPN-538 in January 2011 and currently expect to file the NDA for Epliga in the second half of 2011. The development and regulatory strategy for both products follows a Section 505(b)(2) pathway, which allows us to rely upon FDA's previous findings of safety and efficacy for two known and approved products, Topamax and Trileptal. Therefore, our NDAs are not required to have the same amount of safety or efficacy data as would be required in the case of an NCE, and each NDA could contain different types of clinical trials and clinical data.

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

Our most advanced product candidate is SPN-538, a novel oral once-daily extended release topiramate product for the treatment of epilepsy. We filed the NDA for this product candidate in January 2011. We have completed ten clinical trials in support of our NDA. SPN-538 delivers topiramate, one of the most effective AEDs, which is marketed by Johnson & Johnson under the brand name Topamax and is also available in a generic form. Topiramate is currently available only in immediate release form and is indicated for monotherapy and adjunctive therapy of epilepsy and for the treatment of migraine. Topamax reached peak worldwide sales of \$2.7 billion in 2008, before generic products entered the U.S. market in March 2009.<sup>(13)</sup> With approximately 9.1 million total topiramate prescriptions in 2009, topiramate continues to represent a significant portion of prescriptions with approximately 8.7% of total prescriptions, according to data from IMS Health. Topiramate is believed to work in epilepsy through various mechanisms. It enhances the inhibitory effect of the GABA (Gamma-Aminobutyric Acid) neurotransmitter that regulates neuronal excitability throughout the nervous system, blocks the excitatory effect of the glutamate neurotransmitter, blocks the sodium channel and inhibits the carbonic anhydrase enzyme. The side effects associated with taking topiramate, which have tended to limit its use, include, among others, dizziness, fatigue, somnolence and slowing of certain cognitive functions. We believe that this creates an opportunity for us to offer patients SPN-538 as an alternative therapy to immediate release topiramate with an improved once-per-day profile.

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(13)

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

SPN-538 is designed to improve patient compliance and to have a better tolerability profile compared to the current immediate release products that are taken multiple times per day. SPN-538's pharmacokinetic profile delivers lower peak plasma concentrations and lower input rate over an extended time period resulting in smoother and more consistent blood levels of topiramate during the day compared to immediate release Topamax. We believe such a profile avoids blood level fluctuations that are typically associated with many of the side effects or breakthrough seizures that patients can suffer when taking immediate release products. These side effects can lead patients to skipping doses, and such non-compliance, which could place them at higher risk for breakthrough seizures.

***SPN-538 Development Program***

We have completed ten clinical trials, including bioequivalence trials, in support of our NDA for SPN-538, which we filed in January 2011. We are pursuing a Section 505(b)(2) regulatory strategy, which would allow us to rely in our filing on the existing data and knowledge the FDA has from the NDA of Topamax. The various clinical trials conducted on SPN-538 were designed to select the best extended release once-per-day formulation that delivers equivalent levels of topiramate compared to

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the immediate release twice-per-day Topamax product, as well as to test the robustness and consistency of our technology in delivering the once-per-day formulation across a full range of product strengths. We also have scaled up production of the product candidate at our commercial contract manufacturing facility and have conducted studies that confirm that the commercial scale product is bio-equivalent to the clinical product that was initially developed at our research laboratories.

***Commercialization Strategy***

If we are successful in obtaining regulatory approval, we believe that SPN-538 will be the first once-daily topiramate product approved for the monotherapy and adjunct therapy of epilepsy. We believe that SPN-538 could, over time, capture a significant share of the topiramate prescriptions, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market over the past 15 years. Upon the launch of SPN-538, we plan to build a small specialty sales force primarily targeting neurologists to promote the use of SPN-538 in epilepsy in the United States. This physician group is responsible for a substantial portion of the prescriptions for the treatment of epilepsy and, accordingly, provides an attractive, focused market opportunity for us.

**Epliga (extended release oxcarbazepine)**

Our second late-stage product candidate, Epliga, is a novel oral once-daily extended release formulation of oxcarbazepine and is currently in a Phase III clinical trial for the treatment of epilepsy. We currently anticipate having data from the Phase III trial available early in 2011, and expect to file an NDA in the second half of 2011. To date, we have conducted eight clinical trials to support the filing of an NDA.

Epliga delivers oxcarbazepine, another effective AED, which is marketed by Novartis under the brand name Trileptal and is available in a generic form. Trileptal was initially developed and approved in the United States in 2000. Trileptal is indicated for monotherapy and adjunctive therapy of epilepsy. It reached peak worldwide sales of \$721 million in 2006, before generic products entered the U.S. market in October 2007.<sup>(14)</sup> With approximately 3.3 million total oxcarbazepine prescriptions in 2009, oxcarbazepine represents a portion of prescription of prescriptions with approximately 3.2% of total prescriptions, according to data from IMS Health. Oxcarbazepine is an active voltage-dependent sodium channel blocker that, despite its effectiveness in treating epilepsy, is associated with many side effects that tend to limit its use. The side effects associated with taking oxcarbazepine include, among others, dizziness, double vision, somnolence, nausea and vomiting. Epliga has been designed to reduce side effects, resulting in improved patient compliance and tolerability.

(14)

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

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

***Epliga Development Program***

We have completed eight clinical trials, including bioequivalence trials, to support filing the NDA in the second half of 2011. We are pursuing a Section 505(b)(2) regulatory strategy, which would allow us to rely in our filing on the existing data and knowledge the FDA has from the NDA of Trileptal. The various clinical trials conducted on Epliga were designed to select the best extended release

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once-per-day formulation that delivers equivalent levels of oxcarbazepine compared to immediate release twice-per-day Trileptal, as well as to test the robustness and consistency of our technology in delivering the once-per-day formulation across a full range of product strengths. We also have scaled up our production of the product candidate at our commercial contract manufacturing facility, which has produced clinical supplies to conduct our Phase III trial.

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

In this trial, the adverse events in the trial were observed in 30 healthy subjects using a total daily dose of 1200 mg of each of Trileptal and Epliga. There were 190 total adverse events reported for Trileptal, while Epliga generated a total of only 120 adverse events, a reduction of 37%. Of these, a total of 197 adverse events were considered by the principal investigator to be possibly drug related: 131 for Trileptal and 66 for Epliga. More specifically, Trileptal demonstrated a 36.7% occurrence rate of dizziness as compared to Epliga which demonstrated a 0.0% occurrence rate in our trial. In other trials, Epliga demonstrated higher occurrence rates of dizziness. The results from these trials and the pilot clinical trial are preliminary and based on small populations, and may not be predictive of the results in the pivotal Phase III trial.

In the pivotal Phase III trial for Trileptal, refractory patients had increasing reductions in seizures as dose levels increased, including 50% median reduction in seizures at the highest dose of 2400 mg. Of those subjects at 2400 mg, 22% of the subjects were seizure free at the highest dose of 2400 mg. However, Trileptal is not without a host of side effects at the highest doses, which result in many subjects discontinuing treatment. Accordingly, while 22% of subjects were seizure-free during the pivotal trial for Trileptal at the highest dose of 2400 mg, approximately three-quarters of subjects at the highest dose discontinued their participation in the trial, largely because of the adverse events associated with the drug.

We have discussed our Phase III trial for Epliga with the FDA in the form of a Special Protocol Assessment, or SPA. The Phase III protocol will assess the safety and effectiveness of Epliga as an adjunctive therapy in patients with a diagnosis of simple partial seizures and complex partial seizures with or without secondarily generalized seizures as confirmed by the 1981 and 1989 International League Against Epilepsy Classifications. We met with the FDA in July 2008 regarding the Phase III protocol. We revised the clinical protocol to address the FDA's comments and submitted a protocol amendment to the FDA in October 2008. We have not had any further discussions with the FDA relating to trial design after we submitted the amended protocol. Epilepsy can be broadly characterized into partial and generalized seizures. Partial seizures occur in a specific location of the brain, affecting the physical or mental activity controlled by that particular area of the brain, whereas generalized seizures occur throughout both hemispheres of the brain at once. Partial seizures may be further subdivided into both simple and complex seizures. This refers to the effect of such a seizure on consciousness; simple seizures cause no interruption to consciousness (although they may cause sensory distortions or other sensations), whereas complex seizures interrupt consciousness to varying degrees.

The Phase III trial is a multi-center, multiple-dose, randomized (1:1:1 ratio), double-blind, placebo-controlled, three-arm, parallel group trial in male and female subjects (18 to 65 years of age, inclusive) with refractory partial epilepsy on at least one and up to three concomitant AEDs. Enrollment in the trial has been completed with a total of 369 patients enrolled across 95 sites and 8 different countries

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in North America and Europe. Patients will be randomized to one of three treatment groups and will take Epliga (1200 mg/day or 2400 mg/day) or placebo.

The primary objective of the trial is to evaluate the efficacy of Epliga as an adjunctive therapy in the treatment of seizures of partial origin in adults with refractory epilepsy on at least one and up to three other AEDs. The secondary objectives are:

To assess the safety and tolerability of adjunctive Epliga in the treatment of seizures of partial origin in subjects with refractory epilepsy on at least one and up to three other AEDs;

To assess the effect of Epliga on the subject's global impression of change in his/her epilepsy status;

To assess the effect of Epliga on quality of life as assessed by the Quality of Life in Epilepsy Inventory-31, which is a measurement tool of the overall impact of an AED on a patient; and

To assess secondarily generalized seizures for each treatment group.

We expect top-line data from this trial to be available in the first quarter of 2011 and, based on such data, to file the NDA in the second half of 2011.

***Commercialization Strategy***

If we are successful in obtaining regulatory approval, we expect Epliga to be the only once-daily oxcarbazepine product indicated for the treatment of epilepsy and to compete against the existing immediate release oxcarbazepine products on the market. We believe that Epliga could, over time, capture a significant share of the oxcarbazepine prescription market, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market over the past 15 years. To support the commercial launch of Epliga, we plan to further expand our U.S. specialty sales force in epilepsy to promote both SPN-538 and Epliga.

**ADHD**

***Overview***

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States.<sup>(15)</sup> An estimated 60% to 80% of children with ADHD continue to meet criteria for ADHD into adolescence.<sup>(16)</sup> In 2008, the U.S. market for ADHD prescription drugs was more than \$4 billion, according to data from IMS Health.

Diagnosis of ADHD requires a comprehensive clinical evaluation based on identifying patients who exhibit the core symptoms of inattention, hyperactivity, and impulsivity. Generally, behavior is sufficiently severe and persistent to cause functional impairment. Although many children may be inattentive, hyperactive or impulsive, the level of severity and degree of functional impairment, as well as considerations of what may be behind the underlying symptoms, determine which children meet the diagnosis and are treated for ADHD. It is estimated that the annual societal cost of illness for ADHD is more than \$36 billion.<sup>(17)</sup>

(15)

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

(16)

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

(17)

## Edgar Filing: SUPERNUS PHARMACEUTICALS INC - Form S-1/A

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



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***Current Treatment Options***

Since Ritalin was introduced, stimulant therapies have grown to become the most common form of treatment for ADHD. Studies indicate that approximately 80% of ADHD patients respond to stimulants.<sup>(18)</sup> A key difference between older and newer oral stimulants is the duration of action. Most of the older stimulants, representing approximately 35% of total oral stimulant prescriptions based on IMS Health data, are immediate release products that last approximately four hours, requiring multiple administrations throughout the day. In contrast, most of the recently launched products, representing approximately 65% of total oral stimulant prescriptions based on IMS Health data, are extended release formulations that last up to twelve hours or more.

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(18)

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

While stimulant treatments calm and improve the concentration of ADHD patients, these drugs have been shown to have various side effects including loss of appetite, insomnia and, to a lesser degree, cardiovascular effects. Stimulant treatments are controlled substances and can be associated with social stigma and the potential for abuse. Approximately 30% of patients with ADHD are non-responsive to or non-tolerant of treatment with stimulants.<sup>(19)</sup> Non-stimulants offer physicians an alternative ADHD therapy, including for patients who have coexisting conditions, such as conduct disorder, major depressive disorder, or bipolar disorder, that are contraindicated for stimulant use based on the risk for stimulant abuse.

(19)

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

***Coexisting Conditions***

Studies show that as many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, conduct disorder, anxiety disorder and depression.<sup>(20)</sup> In addition, it has been estimated that approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.<sup>(21)</sup> Untreated, these serious conduct problems can place patients at risk of persistent aggressive and anti-social behavior, such as knowingly destroying property, physically attacking people and bullying. These patients also face an increased risk of suicidal behavior, and are at high risk of entering the juvenile justice system and developing substance abuse problems later in adulthood.

(20)

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

(21)

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*.

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

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***Current Treatments for Impulsive Aggression in Patients with ADHD***

Currently, there are no approved medications for treating impulsive aggression in patients with ADHD. The current treatment options for impulsive aggression in patients with ADHD include psychosocial interventions, such as school- or family-based behavioral therapies, which are usually not wholly effective. In the large, multisite Multimodal Treatment Study of Children with ADHD,<sup>(22)</sup> a seminal clinical trial designed by experts from key stakeholder communities such as the National Institute of Mental Health, researchers observed that after 14 months of either ADHD medication-only or a regimen that combined ADHD medication with behavioral interventions, 44% of those children with ADHD (or 26% of the total sample size in the trial) who exhibited initial aggression still had what can be described as impulsive aggression at the end of the trial, demonstrating that psychosocial interventions may not work for a large percentage of children with ADHD who exhibit aggressive behaviors.

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(22)

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

In response, doctors have also tried to address this group with off-label use of prescription medicines, such as mood stabilizers, stimulants and anti-psychotic drugs. Results have varied, but anti-psychotic drugs appear to have the best therapeutic potential. Unfortunately, many of these agents are associated with adverse effects including obesity, lipid abnormalities, and diabetes, which is of particular concern when treating pediatric populations.

**Our Psychiatry Portfolio**

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

**SPN-810 (molindone hydrochloride)**

We are developing SPN-810, which is currently in Phase II, as a novel treatment for impulsive aggression in patients with ADHD. If approved by the FDA, SPN-810 could be the first product available to address this serious, unmet medical need.

We are studying SPN-810, which contains molindone hydrochloride, as a treatment of impulsive aggression in patients with ADHD. Molindone hydrochloride was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. Molindone hydrochloride is unusual among anti-psychotics in that it is not associated with weight gain. In addition, we believe the lower doses tested for the proposed indication of impulsive aggression should be more easily tolerated than the higher doses approved to treat schizophrenia. SPN-810's low potential to cause weight gain leads us to believe that SPN-810 could be an attractive candidate among the anti-psychotic drugs for the effective treatment of impulsive aggression in patients with ADHD. Although initially we are developing SPN-810 as a treatment of impulsive aggression, if we are successful in demonstrating the effectiveness of SPN-810 for the treatment of impulsive aggression in patients with ADHD, we may then look to develop the product candidate for the treatment of other patient populations that have impulsive aggression, such as autism and bipolar disorder.

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***SPN-810 Development Program***

We have completed four clinical trials for SPN-810, including a Phase IIa trial in which we tested the safety and tolerability of SPN-810, immediate release molindone hydrochloride, in patients with ADHD who suffer from serious persistent conduct problems. This open-label, dose-ranging trial randomized 78 children, 6-12 years of age, into one of four treatment groups, which were given four different doses of immediate release molindone hydrochloride, between 10 mg and 40 mg per day, depending on weight, three times a day over a six-week treatment period, after 2-5 weeks of titration. SPN-810 was well tolerated in the trial, with no clinically meaningful changes in standard hematology, clinical chemistry values, vital signs or electrocardiogram (ECG) results.

Besides safety and tolerability assessments, the primary outcome measure was the change in the Nisonger Child Behavior Rating Form-Typical Intelligence Quotient (NCBRF-TIQ) conduct problem subscale scores from baseline to endpoint in the intent-to-treat (ITT) population. NCBRF-TIQ is a known instrument that has been used for assessing child and adolescent behavior. Scores improved after baseline in all treatment groups. By visit 12, after 6 weeks of treatment, the mean reduction from baseline for each treatment group was 7.0, 8.7, 8.2 and 14.3, in groups 1, 2, 3, and 4, respectively, representing decreases of 34%, 34%, 32% and 55%, respectively. In addition, the difference between group 1 and group 4 was statistically significant ( $p \leq 0.041$ ) at all time points except visit 2 and the greatest improvement in scores on the NCBRF-TIQ conduct problem subscale was seen in group 4, which was the highest-dose group (14.8 mean reduction). The below chart summarizes the mean change in NCBRF-TIQ conduct problem subscale observed in our Phase IIa trial.

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

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

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

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

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

We expect to test SPN-810 in another Phase II trial in 2011. The design and protocol of the trial have not been finalized but we expect to conduct a multicenter, randomized, double-blind, placebo-controlled trial in pediatric subjects 6 to 12 years of age with impulsive aggression in ADHD. The primary objective will be to assess the effectiveness of SPN-810 in reducing impulsive aggression after at least three weeks of treatment. Secondary objectives are likely to include measurement of the effectiveness of SPN-810 on Clinical Global Impression and ADHD scales as well as evaluation of the safety and tolerability of the drug. In addition, we will be exploring the potential added advantages of an extended-release formulation, such as greater compliance and, therefore, effectiveness in school-age children and lower unwanted side effects or interpatient variability.

**SPN-812**

We are developing SPN-812, which is currently in Phase II, as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. The active ingredient in SPN-812 has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant. 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.

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

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different pharmacological profile. Due to its demonstrated efficacy as an antidepressant, SPN-812 may exhibit increased benefit in up to an estimated 40% of ADHD patients who also suffer from major depression.<sup>(23)</sup> We are developing an intellectual property position around the novel synthesis process for this product candidate, its novel use in ADHD and its novel delivery with extended release.

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(23)

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

***SPN-812 Development Program***

We initiated a proof-of-concept Phase IIa trial in mid-2010, and we expect to get the results of this trial in the first quarter of 2011. The trial is a randomized, double-blind, placebo-controlled trial in approximately 50 adults with a current diagnosis of ADHD (approximately 25 subjects per treatment group). The subjects in the active arm will be administered SPN-812 at a single dose level three times a day over five weeks, after a one-week titration phase. The primary endpoint is the safety of SPN-812 and the secondary endpoints include, among others, the efficacy of SPN-812 as measured by Total ADHD Symptom Score on the Conners' Adult ADHD Rating Scale, a commonly-used measurement for ADHD in adults, as rated by each of the investigators and the subjects, and the effectiveness of SPN-812 when compared to placebo as determined by changes in the Clinical Global Impressions Improvement score. Depending on the results of this Phase IIa trial, we expect to focus on potentially developing an extended release formulation and to commence a Phase IIb trial.

**SPN-809**

We are developing SPN-809 as a novel once-daily product candidate for the treatment of depression. SPN-809 is based on the same active ingredient as our SPN-812 product candidate. We currently have an open IND for SPN-809 as a treatment of depression, the indication for which the active ingredient in SPN-809 was approved and marketed in Europe for many years. Depression is a serious and common disease affecting approximately 121 million people worldwide.<sup>(24)</sup> Based on IMS Health data, the worldwide market for antidepressants is approximately \$12 billion.

(24)

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

SPN-809 is a norepinephrine reuptake inhibitor that represents an opportunity to offer a differentiated treatment option for patients suffering from depression in the United States. Initial market research suggests that psychiatrists would like to have such a once-daily option at their disposal to treat various patients. Because SPN-809 contains the same active ingredient as SPN-812, we expect that many of our activities related to the development of SPN-812 will also benefit the development of SPN-809.

**Other Product Candidates**

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

**Our Proprietary Technology Platforms**

We have a long track record of developing novel products by applying proprietary technologies to known drugs to improve existing therapies and enable the treatment of new indications. Our key proprietary technology platforms include: Microtrol, Solutrol and EnSoTrol. These technologies create customized product profiles designed to meet efficacy needs, more convenient and less frequent dosing, enhanced patient compliance, and improved tolerability in certain specific applications. Our broad portfolio of technologies and extensive expertise in this area, which have been built over the past 20 years, enable us to develop products that are technically difficult to formulate or by design are made

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harder to be copied by others. We have employed our technologies in the development of our legacy products, as well as our current product portfolio.

***Microtrol (multiparticulate delivery platform)***

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

Sanctura XR (trospium chloride), a treatment for overactive bladder;

Oracea (doxycycline), a treatment for inflammatory lesions of rosacea;

Carbatrol (carbamazepine), an anti-epilepsy treatment;

Equetro (carbamazepine), a treatment for bipolar disorder; and

Adderall XR (mixed amphetamine salts), a stimulant ADHD treatment.

We do not expect the above products to contribute to our future cash. Carbatrol, Equetro and Adderall XR are legacy products that were developed by us when we were formerly Shire Laboratories. In addition, in April 2008, we monetized the revenues underlying the future royalty streams relating to Sanctura XR and Oracea by transferring certain of our royalty payment rights and other license rights for such products to TCD Royalty Sub LLC, our wholly-owned subsidiary, in exchange for \$63 million. We primarily reinvested the proceeds from this transaction into our research and development activities.

***Solutrol (matrix delivery platform)***

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

***EnSoTrol (osmotic delivery system)***

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

In June 2006, we entered into a license agreement with United Therapeutics for the worldwide development and commercialization of an oral formulation of treprostinil, which utilizes EnSoTrol for the treatment of pulmonary arterial hypertension, or PAH, as well as for other indications. Under the terms of the license agreement, we have received pre-commercial milestone payments of \$750,000. Remaining milestone payments to us could total up to \$6.8 million, which includes pre-commercial milestone payments of up to approximately \$2.8 million for the satisfaction of development milestones relating to the treatment of PAH and up to \$4.0 million for the development of each additional product that combines a form of oral treprostinil that utilizes our technologies with another drug compound. If United Therapeutics receives approval to market and sell an oral formulation of treprostinil, we will be



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entitled to receive royalties in the single digits based on net sales worldwide. Our license agreement with United Therapeutics will expire, on a country-by-country and product-by-product basis, 12.5 years from the first commercial sale of each product in such country. United Therapeutics may terminate, at its option, the agreement for a technical, strategic or market-related cause after giving us a reasonable opportunity to cure. We may terminate the agreement if, after having launched a product in a country, United Therapeutics or its sublicensee discontinues the sale of such product for a prolonged period of time for reasons unrelated to force majeure, regulatory or safety issues. In addition, either party may terminate the agreement for the material, uncured breach by the other party and in certain events of bankruptcy or insolvency of the other party.

***Other Technologies***

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

**Sales and Marketing**

We are preparing the build-out of our commercial infrastructure to launch both SPN-538 and Epliga in the United States. Upon approval of SPN-538, we would hire a small specialty sales force, initially consisting of a limited number of field sales representatives to support the launch of the product. We would then seek to expand our sales force in connection with an approval and commercial launch of Epliga. Having two epilepsy products that can be promoted to the same physician audience would allow us to leverage our commercial infrastructure with these prescribers. Once we have obtained approval for any of our product candidates in our psychiatry portfolio, we anticipate adding additional sales force members who will be dedicated towards marketing our psychiatry products.

**Manufacturing**

We do not own or operate manufacturing facilities for the production of any of our product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently depend on third-party contract manufacturing organizations, or CMOs, for all of our required raw materials and drug substance for our preclinical research and clinical trials. We do not have any current contractual relationships for the commercial manufacture of any of our product candidates. For SPN-538 and Epliga, 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. We currently employ internal resources and as needed third-party consultants to manage our manufacturing contractors.

For our two most advanced product candidates, SPN-538 and Epliga, we are presently negotiating agreements with leading CMOs headquartered in North America for the manufacture of the final commercial products. These CMOs offer a comprehensive range of contract manufacturing and packaging services and have successfully handled the scale up of the two product candidates to a commercial production scale in preparation for the commercialization of both product candidates.



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**Competition**

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

*Epilepsy*

There are currently over 15 branded products, as well as their generic counterparts, on the U.S. market indicated to treat some form of epilepsy. Several NCEs are expected to enter the epilepsy market in the next few years. Based on IMS Health prescription data from 1994 to 2005 for NCE launches for seizure disorders, such NCEs, on average, experienced slow market penetration characterized by a 0.58 to 1.1 market share point gain on an annual basis. We believe this is because physicians are often reluctant to change a stable patient's existing therapy and risk a breakthrough seizure in their patients. If approved, SPN-538 (extended release topiramate) will compete with all immediate release topiramate products including Topamax and related generic products. We are aware that Upsher-Smith Laboratories announced the initiation of a Phase III clinical trial for an extended release topiramate product, which it has described as an internally developed program for the management of epilepsy in adults using its proprietary formulation technology. If this product candidate is approved by the FDA before SPN-538, then Upsher-Smith could obtain three years of marketing exclusivity, which would significantly delay our entry into the U.S. market. If approved, Epliga (extended release oxcarbazepine) will compete with all immediate release oxcarbazepine products including Trileptal and related generic products. We are not aware of any other company that is currently developing an extended release oxcarbazepine product in the United States. In addition, we believe that Epliga's once-daily formulation solves a drug delivery challenge specific to oxcarbazepine that must be overcome by all potential competitors. We are aware of companies who have modified-release oxcarbazepine products that are marketed outside of the United States but, to our knowledge, such products are not being pursued for the U.S. market. These modified-release oxcarbazepine products include Apydan, which is developed by Desitin Arzneimittel GmbH and requires twice-daily administration.

*ADHD*

Competition in the U.S. ADHD market has increased with the launch of several products in recent years, including the launch of generic versions of branded drugs, such as Adderall XR. Shire plc is one of the leaders in the U.S. ADHD market with three products: Adderall XR, an extended release stimulant treatment designed to provide once-daily dosing; Vyvanse, a stimulant prodrug product launched in 2007; and Intuniv, a non-stimulant treatment launched in November 2009. Other stimulant products for the treatment of ADHD in the U.S. market include the following once-daily formulations: Concerta; Metadate CD; Ritalin LA; Focalin XR; and Daytrana. Other non-stimulants are Strattera and Clonidine. We are also aware of clinical development efforts by several large pharmaceutical companies including Shire plc, GlaxoSmithKline plc, Eisai Inc., AstraZeneca plc and Abbott Laboratories to develop additional treatment options for ADHD.

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**Intellectual Property and Exclusivity**

*Overview*

We have been building and continue to build our intellectual property portfolio relating to our product candidates, including SPN-538 and Epliga. We seek patent protection, where appropriate, 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. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technologies and products we consider important to our business, defend our patents, preserve the confidentiality of our trade secrets and operate our business without infringing the patents and proprietary rights of third parties.

We have established and continue to build proprietary positions for Epliga, SPN-538, our pipeline product candidates and technologies in the United States and abroad.

*Patent Portfolio*

Our Epliga patent portfolio currently includes one issued U.S. Patent, two pending U.S. continuation patent applications, and certain pending foreign patent applications that relate to the issued U.S. patent or pending U.S. non-provisional patent applications. The issued U.S. patent will expire in 2027. We own the issued patent and all of the pending applications.

In addition to the patents and patent applications relating to Epliga, we currently have one pending U.S. non-provisional patent application, two pending U.S. continuation patent applications and certain pending foreign counterpart patent applications in Europe, Canada and other countries, which are directed to SPN-538. The U.S. patent applications, if issued, could expire in 2027. We own all of these pending applications.

Our patent portfolio also contains patent applications relating to our other pipeline products. We have a pending U.S. non-provisional patent application and a pending international patent application relating to our SPN-810 product candidate. Patents, if issued, from the applications could have terms expiring in 2029. With regard to our SPN-812 product candidate we have a pending U.S. non-provisional patent application and a pending international patent application. The U.S. patent application, if issued as a patent, would expire in 2029.

The U.S. patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the U.S. Patent and Trademark Office, or USPTO, and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. A provisional patent application is not examined for patentability, and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into a patent. The requirements for filing a provisional patent application are not as strict as those for filing a non-provisional patent application. Provisional applications are often used, among other things, to establish an early filing date for a subsequent non-provisional patent application. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by

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patent term adjustment, or PTA, which compensates a patentee for administrative delays by the USPTO in granting a patent. In view of a recent court decision, the USPTO is under greater scrutiny regarding its calculations where the USPTO erred in calculating the patent term adjustment for the patents in question denying the patentee a portion of the patent term to which it was entitled. Alternatively, a patent's term may be shortened if a patent is terminally disclaimed over another patent.

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

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, or PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA or other regulatory approval, we may be able to apply for PTEs on patents covering those products. Depending upon the timing, duration and specifics of FDA approval of Epliga, SPN-538 and our other product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration.

***Other Intellectual Property Rights***

We seek trademark protection in the United States and internationally where available and when appropriate. We have filed for trademark protection for several marks, which we use in connection with our pharmaceutical research and development collaborations as well as products. We are the owner of various U.S. federal trademark registrations (®) and registration applications (TM), including the following marks referred to in this prospectus pursuant to applicable U.S. intellectual property laws: "Supernus®," "Epliga®," "Microtrol®," "Solutrol®," "ProScreen®," "OptiScreen®," "ProPhile®" and the registered Supernus Pharmaceuticals logo.

From time to time, we may find it necessary or prudent to obtain licenses from third party intellectual property holders. Where licenses are readily available at reasonable cost, such licenses are considered a normal cost of doing business. In other instances, however, we may use the results of freedom-to-operate inquiries and internal analyses to guide our early-stage research away from areas where we are likely to encounter obstacles in the form of third party intellectual property. For example, where a third party holds relevant intellectual property and is a direct competitor, a license might not be available on commercially reasonable terms or available at all. We strive to identify potential third party intellectual property issues in the early stages of research of our research programs, in order to minimize the cost and disruption of resolving such issues.

To protect our competitive position, it may be necessary to enforce our patent rights through litigation against infringing third parties. Litigation to enforce our own patent rights is subject to uncertainties that cannot be quantified in advance. In the case of an adverse outcome in litigation, we could be prevented from commercializing a product or using certain aspects of our technology platforms as a result of patent infringement claims asserted against us. This could have a material adverse effect on our business. In addition, litigation involving our patents carries the risk that one or

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more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize products or use technologies that are similar to ours, and then compete directly with us, without payment to us. See "Risk Factors If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business."

***In-Licensing Arrangements***

*Afecta Pharmaceuticals, Inc.*

We have entered into two license agreements with Afecta Pharmaceuticals, Inc., or Afecta, pursuant to which we obtained an exclusive option to evaluate Afecta's CNS pipeline and to obtain exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. Under the terms of the license agreements, we have paid Afecta \$400,000 in license fees and milestone payments. If a product candidate is successfully developed and commercialized, we will be obligated to pay royalties to Afecta based on net sales worldwide in the low-single digits. Unless terminated by us or Afecta for material breach or bankruptcy, by Afecta for our discontinuation of development and commercialization activities, or by us for convenience, the license agreements will continue in full force and effect on a country-by-country basis until six months from the discontinuation of the commercial sale and collection of revenues for the Afecta product.

*Rune Healthcare Limited*

In June 2006, we entered into a purchase and sale agreement with Rune Healthcare Limited, or Rune, where we obtained the exclusive worldwide rights to a product concept from Rune for SPN-809. Under the terms of the agreement, we have paid Rune a £25,000 up-front fee. If we receive approval to market and sell any products based on the Rune product concept, we will be obligated to pay royalties to Rune based on net sales worldwide in the low-single digits. Unless terminated by us or Rune for material breach, by Rune for our discontinuation of development or commercialization activities relating to a product based on the Rune product concept, we will be obligated to pay royalties to Rune on a country-by-country basis until the earlier of (a) ten years from the date of first commercial sale of a product based on the Rune product concept or (b) the market entry in such country of any product utilizing the Rune product by any entity other than us, our affiliates or our licensees.

***Confidential Information and Inventions Assignment Agreements***

We require our employees, temporary employees and consultants to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions resulting from work performed for us or relating to our business and conceived or completed by the individual during employment or assignment, as applicable, shall be our exclusive property to the extent permitted by applicable law.

We seek to protect our product candidates and our technologies through a combination of patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure.

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**Government Regulation**

***Product Approval***

Government authorities in the United States at the federal, state and local level, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates, including SPN-538 and Epliga, must be approved by the FDA before they may legally be marketed in the United States.

***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;

submission to the FDA of an IND, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of an NDA for a new drug;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practices, or cGMP; and

FDA review and approval of the NDA.

The testing and approval process require substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve

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any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

*Phase I.* The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.

*Phase II.* Phase II trials involve investigations in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

*Phase III.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

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

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

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***U.S. Review and Approval Processes***

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

The submission of an NDA is subject to the payment of a substantial user fee; a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, which was reauthorized under the Food and Drug Administration Amendments Act of 2007, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

***Section 505(b)(2) New Drug Applications.*** To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its 505(b)(2) application with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve, as applicable, a Section 505(b)(2) NDA application until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

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If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five year exclusivity period and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

In the NDA submissions for our product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates.

***FDA Review of New Drug Applications.*** The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will



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issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

***Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the drug. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active pharmaceutical ingredient, or active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, the FDCA will not prevent the submission or approval of another full Section 505(b)(1) NDA, but such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. Further, a Section 505(b)(2) application may be submitted after four years if it contains a Paragraph IV certification. The FDCA also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages, routes of administration or strengths of an existing drug, or for a new use, if new

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clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product or Section 505(b)(2) product that did not incorporate the exclusivity-protected changes of the approved drug product. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to be attached to any existing exclusivity (e.g., three or five year exclusivity) or patent protection for a drug. This six month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial. The current pediatric exclusivity provision was reauthorized in September 2007.

***Post-Approval Requirements***

Any drugs for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously

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unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

***Third Party Payor Coverage and Reimbursement***

In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services, or CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payors.

The United States Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the associated reconciliation bill, which we refer to collectively as the Health

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Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

The cost of pharmaceuticals continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

***Other Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. These regulations include:

the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of

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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.

**Legal Proceedings**

From time to time and in the ordinary course of business, we are subject to various claims, charges and litigation. For example, we may be required to file infringement claims against third parties for the infringement of our patents. For additional information regarding the patent litigation matters in which we are involved, please see "Risk Factors We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful." Although the outcome of litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us, we do not believe the outcome of any such litigation, individually or in the aggregate, will have a material adverse effect on our financial condition, results of operations or cash flows.

**Employees**

As of September 30, 2010, we employed 70 full-time employees, of which 57 were engaged in research and development, clinical trials and quality assurance and 13 were engaged in administration, finance, marketing and business development. None of our employees are represented by a labor union.

**Facilities**

Our principal executive offices are located at 1550 East Gude Drive, Rockville, Maryland 20850, where we occupy approximately 44,500 square feet of laboratory and office space. Our lease term expires in April 30, 2018 with an option for a five year extension. We believe that our existing facilities are sufficient for our present and future operations, and we currently have no plans to lease additional space.

Table of Contents**MANAGEMENT****Executive Officers, Directors And Key Employees**

The following table sets forth the names and ages of our executive officers, directors and key employees as of the date of this prospectus.

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
Jack A. Khattar	49	President & Chief Executive Officer, Director
Russell P. Wilson	51	Vice President, Chief Financial Officer
Jones W. Bryan, Ph.D.	46	Vice President of Business Development
Padmanabh P. Bhatt, Ph.D.	53	Vice President of Pharmaceutical Sciences
Paolo Baroldi, M.D., Ph.D.	59	Senior Vice President of Clinical Development & Chief Medical Officer
Tami T. Martin, R.N., Esq.	55	Vice President of Regulatory Affairs
M. James Barrett, Ph.D.	68	Director and Chairman of the Board
Michael Bigham	53	Director
Frederick M. Hudson	65	Director
Charles W. Newhall, III	66	Director
William A. Nuerge	58	Director
Michael B. Sheffery, Ph.D.	60	Director
John M. Siebert, Ph.D.	70	Director

**Jack A. Khattar** is the founder of our company and has served as our President and Chief Executive Officer and Director since 2005. From 1999 to 2005, Mr. Khattar served in various positions during that time as a Board member, President and CEO of Shire Laboratories Inc., the drug delivery subsidiary of Shire plc. From 1999 to 2004, he also served as a member of Shire plc's Executive Committee. Prior to that, Mr. Khattar served as an Executive Officer and the Chairman of the Management Committee at CIMA, a drug delivery company that is currently a division of Cephalon. At CIMA, he was also responsible for business development, including the licensing of CIMA's technologies, corporate alliances and strategic planning. Prior to joining CIMA in 1995, Mr. Khattar held several marketing and business development positions at Merck & Co., Novartis, Playtex and Kodak in various locations, including the United States, Europe and the Middle East. Mr. Khattar earned his degrees in Marketing with a BBA from American University of Beirut and an MBA from the Wharton School of the University of Pennsylvania. He is currently a director of Rockville Economic Development Inc. Mr. Khattar's leadership, executive, managerial, business and pharmaceutical company experience, along with his more than 20 years of industry experience in the development and commercialization of pharmaceutical products and drug delivery technologies, qualify him to be a director.

**Russell P. Wilson** has served as our Vice President, Chief Financial Officer since 2009. From 2000 to 2008, Mr. Wilson served at Iomai Corporation, which was sold to Intercell AG in August 2008, in various positions. While at Iomai Corporation, Mr. Wilson was responsible at different times for finance, legal, business development, regulatory affairs and quality systems, and served as Senior Vice President (from May 2005 to 2008), Chief Financial Officer (from June 2002 to 2008), General Counsel (from March 2000 to 2008) and Secretary (from May 2000 to 2008), and Vice President, Business Development (from March 2000 to June 2002). Mr. Wilson earned his B.A. from Princeton University and holds a joint M.B.A./ J.D. degree from the University of Virginia.

**Jones W. Bryan, Ph.D.**, has served as our Vice President of Business Development since 2005. From 2000 to 2005, he served as Vice President Business Development for Shire Laboratories Inc. Prior to that, Dr. Bryan was Director of Business Development for Pharmaceuticals and Clinical Supply Manufacturing for AAI. He began his career with Schering Plough in Pharmaceuticals and Formulation

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Development. Dr. Bryan earned his B.S. degree in Zoology from Clemson University, Ph.D. degree in Pharmaceutics from the Medical University of South Carolina and Executive Management Certificate from the University of North Carolina Kenan-Flagler Business School. He is a member of the Licensing Executives Society and serves on Clemson University's Spiro Institute Entrepreneurship Advisory Board.

**Padmanabh P. Bhatt, Ph.D.**, has served as our Vice President of Pharmaceutical Sciences since 2005. From 2003 to 2005, Dr. Bhatt was Vice President of Advanced Drug Delivery at Shire Laboratories Inc. From 2001 to 2003, Dr. Bhatt served as Vice President of Research and Development and Chief Technology Officer at Point Biomedical Corporation. From 1996 to 2001, he served at ALZA Corporation (now a Johnson & Johnson company) in various positions from Product Development Manager to Director of Technical Development. Prior to that time, Dr. Bhatt has held positions as Research Specialist and Group Leader of Novel Drug Delivery at Dow Corning Corporation (from 1992 to 1996) and Senior Scientist at Hercon Laboratories (from 1989 to 1992). Dr. Bhatt earned his B.Pharm. and M.Pharm. degrees from the University of Bombay, India. He also holds M.S. and Ph.D. degrees in Pharmaceutical Chemistry from the University of Kansas.

**Paolo Baroldi, M.D., Ph.D.**, has served as our Senior Vice President of Clinical Development & Chief Medical Officer since 2009. From 2006 to 2009, he served as a Senior Vice President and Chief Medical Officer at Vanda. From 2003 to 2006, Dr. Baroldi served as Vice President-Corporate Drug Development and Chairman of the R&D Board at Chiesi Farmaceutici SpA, where he led a research and development organization of 350 people across 3 sites in the United States, Italy and France. From 1998 to 2002, Dr. Baroldi was the Global Head of Clinical Pharmacology at Novartis AG, responsible for a staff of 140 people across five different sites, including France, the United Kingdom, Japan and the United States. Dr. Baroldi holds degrees in Medicine and Surgery and a Ph.D. in Clinical Pharmacology from the University of Milan and an Executive MBA from Harvard University.

**Tami T. Martin, R.N., Esq.**, has served as our Vice President of Regulatory Affairs since 2008. She has previously held positions as Vice President of Regulatory Affairs at Shire Pharmaceuticals (6 years), and Manager to Sr. Director of Regulatory Affairs at Otsuka America Pharmaceuticals (7 years). Ms. Martin has also consulted privately for domestic and international clients as President and CEO of Pyramid Regulatory Consulting. Earlier in her career, Ms. Martin held legal positions at Hogan & Hartson as a member of the Food and Drug Practice Group, and with the Department of Health and Human Services as a staff attorney. Ms. Martin previously served as an instructor for the Johns Hopkins University Masters of Biotechnology and Regulatory Affairs Graduate Degree program, and teaches a portion of the United States Regulatory Module for TOPRA (The Organization for Professionals in Regulatory Affairs) leading to a MSc in Regulatory Affairs through the University of Wales. Ms. Martin earned her Bachelor of Science in Nursing from Albright College and a Juris Doctorate degree from Suffolk University. Ms. Martin is a member of the Pennsylvania Bar.

**M. James Barrett, Ph.D.**, has served as the Chairman of our Board since 2005. Since September 2001, Dr. Barrett has been a general partner of New Enterprise Associates, or NEA, which is a venture capital firm that focuses on the medical and life sciences and information technology industries. He is currently a member of the board of directors of each of the publicly-traded companies Amicus Therapeutics, Inc., Inhibitex, Inc. and Targacept, Inc., within the past five years, he served on the board of directors of each of the publicly-traded companies Iomai Corporation (acquired by Intercell AG), MedImmune, LLC (acquired by AstraZeneca), Pharmion Corporation (acquired by Celgene Corporation) and YM Biosciences, Inc. As a result of Dr. Barrett's tenure as a general partner of New Enterprise Associates, he has served on numerous boards of directors of both public and private companies in the healthcare sector and brings to the Board significant first-hand experience in shaping strategic direction as a pharmaceutical company matures from a private venture-backed company to a development-stage public company and then to a product revenue-generating company. Dr. Barrett's

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substantial experience with public and private companies in the healthcare sector and his venture capital, financial and business experience qualify him to serve as a director.

**Michael Bigham** has served as a member of our Board since 2006. Since 2002, Mr. Bigham has been a general partner of Abingworth, a leading international venture capital firm concentrating in life sciences. From December 2002 to March 2004, he served as Vice Chairman of Corixa Corporation, and was President and Chief Executive of Coulter Pharmaceuticals from July 1996 until it merged into Corixa in December 2000. Previously, he was an early employee at Gilead Sciences where he spent eight years serving in various capacities, including Executive Vice President of Operations and Chief Financial Officer. Before joining Gilead, Mr. Bigham was a partner at Hambrecht & Quist where he became Co-Head of Healthcare Investment Banking. He chairs the compensation committee of the board of directors of Avila Therapeutics, Inc. and the audit committee of the board of directors of Valeritas, Inc. He is also a director of Magellan, Inc. and Secure EDI Holdings, Inc. He has previously served as a director of Hydra Biosciences, Inc., PrimeraDx, Inc., Xenogen Corporation and SED, Inc. Prior to February 23, 2009, Mr. Bigham was also a non-executive director of Dynogen Pharmaceuticals Inc., a private clinical stage pharmaceutical company that, on that date, filed a voluntary petition for relief under Chapter 7 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts. Mr. Bigham earned his B.S. Degree with distinction from the University of Virginia and holds an MBA from Stanford University Graduate School of Business. Mr. Bigham is also a Certified Public Accountant. Mr. Bigham's significant operational and investment banking experience in life science companies qualify him to serve as a director.

**Frederick M. Hudson** has served as a member of our Board since 2010. Mr. Hudson retired as a partner in charge of the health care audit practice for the Washington Baltimore business unit of the accounting firm of KPMG, LLP on January 1, 2006 after a 37-year career with the firm. He is a graduate of Loyola University Maryland and currently serves in a board capacity with the Board of Financial Administration of the Catholic Archdiocese of Baltimore and the Board of Trustees of the Maryland Historical Society. He chairs the audit committees of each of the boards of directors of Paradigm Management Services LLC (a provider of catastrophic care services), Woodhaven Holding Corporation, d/b/a Remedi Senior Care (an institutional pharmacy service provider), GBMC Healthcare, Inc. and its affiliate, the Greater Baltimore Medical Center, and Vicor Technologies, Inc. He is also a director of Maxim Health Care Services, Inc. Mr. Hudson's extensive accounting and health care audit experience qualify him to serve as a director.

**Charles W. Newhall, III** has served as a member of our Board since 2005. In 1977, Mr. Newhall co-founded NEA, a venture capital firm that focuses on the medical and life sciences and information technology industries. To date, Mr. Newhall has served as a director of over 40 venture-backed companies. He also started several healthcare information technology companies like PatientKeeper, TargetRx and LifeMetrix. Some of his current board memberships include Vitae Pharmaceuticals, TargetRx, Sensors for Medicine and Science, and BrainCells Inc. In 1986, he founded the Mid-Atlantic Venture Capital Association, or MAVA, which now has over 80 venture capital firms that are members, and is one of the most active regional venture associations in the country. He is Chairman Emeritus of MAVA. Before NEA, Mr. Newhall was a Vice President of T. Rowe Price. He served in Vietnam commanding an independent platoon including an initial reconnaissance of Hamburger Hill. His decorations include the Silver Star and Bronze Star V (1st OLC). He earned an Honors Degree in English from the University of Pennsylvania and an MBA from Harvard Business School. Mr. Newhall's substantial experience with companies in the healthcare sector and his venture capital, financial and business experience qualify him to serve as a director.

**William A. Nuerge** has served as a member of our Board since 2006. Since 2007, Mr. Nuerge has been a managing partner of Fortress Pharms Advisors, LLC. From 2004 to 2007, Mr. Nuerge served as a director and President and CEO of Xanodyne Pharmaceuticals. From 1997 to 2004, he served as



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President and CEO of Shire US, Inc. Prior to that, Mr. Nuerge served as Chief Operating Officer of Richwood Pharmaceuticals Company, Inc., which subsequently merged with Shire plc in 1997. Mr. Nuerge earned his Bachelor of Science degree from Purdue University and his MBA from Wesleyan University. He has also previously served as a director of Cutanogen Corporation. Mr. Nuerge's significant operational and business experience with life science companies qualify him to serve as a director.

**Michael B. Sheffery, Ph.D.**, has served as a member of our Board since 2005. Dr. Sheffery is a founding General Partner of OrbiMed Advisors, LLC, a healthcare investment firm, and Co-Head of Private Equity at Orbimed. Dr. Sheffery was formerly Head of the Laboratory of Gene Structure and Expression at Memorial Sloan-Kettering Cancer Center. Dr. Sheffery joined Mehta and Isaly, an investment firm, in 1996 as a Senior Analyst covering the biotechnology industry. He earned both his Ph.D. in Molecular Biology and his B.A. in Biology from Princeton University. He is currently a Director of Affimed Therapeutics AG and Pieris AG. Dr. Sheffery's background and expertise in private equity and investment banking, combined with his scientific experience, qualify him to serve as a director.

**John M. Siebert, Ph.D.**, has served as a member of our board since 2011. Dr. Siebert has over 30 years experience in the pharmaceutical industry. Since 2009, Dr. Siebert has been Chairman and CEO of Compan Pharmaceuticals, LLC, a veterinary specialty pharmaceutical company. From 2004 to 2009, Dr. Siebert served as Chairman and CEO at CyDex Pharmaceuticals Inc., a specialty pharmaceutical company. From 1995 through 2003, Dr. Siebert served as President and CEO Of CIMA LABS, Inc., an innovative oral drug delivery company. Dr. Siebert started his career at Procter & Gamble. He currently chairs the audit committees of each of the boards of directors of Primus Pharmaceutical Company and Aradigm, Inc. Dr. Siebert's substantial operational and business experience with companies in the healthcare sector, combined with his scientific experience, qualify him to serve as a director.

#### **Composition of Our Board of Directors**

Our board of directors currently consists of seven members. All of our directors were elected pursuant to the board composition provisions of our stockholders voting agreement. Our nominating and corporate governance committee and board of directors may consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and corporate governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established records of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, and professional and personal experiences and expertise relevant to our growth strategy.

#### **Director Independence**

We have applied to have our common stock listed on the Nasdaq Global Market. Under Rules 5605 and 5615 of the Nasdaq Marketplace Rules, a majority of a listed company's board of directors must be comprised of independent directors within one year of listing. In addition, the Nasdaq Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under Rule 5605(a)(2) of the Nasdaq Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Upon the

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completion of this offering, we expect that the composition and functioning of our board of directors and each of our board committees will comply with all applicable rules and regulations of the Securities and Exchange Commission, or the SEC, and the Nasdaq Global Market. There are no family relationships among any of our directors or executive officers.

**Board Leadership Structure and Board's Role in Risk Oversight**

Our board of directors has elected to separate the roles of Chief Executive Officer and Chairman of the board. Mr. Khattar serves as President and Chief Executive Officer and Dr. Barrett serves as Chairman of the board. The Chief Executive Officer and Chairman work closely together to execute the strategic plan of the Company.

We believe the combination of Mr. Khattar as President and Chief Executive Officer and Dr. Barrett as Chairman is an effective leadership structure for Supernus. The division of duties allows our Chief Executive Officer to focus on our day-to-day business, while allowing our Chairman of the board to lead the board of directors in its fundamental role of providing advice to, and independent oversight of, management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our Chairman, particularly as the board of directors' oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors.

Management is responsible for the day-to-day management of risks that we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed. Our board of directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily through the full board of directors who has generally retained responsibility for general oversight of risks. Our board of directors satisfies this responsibility through reports directly from officers responsible for oversight of particular risks within our company as our board of directors believes that full and open communication between management and the board of directors is essential for effective risk management and oversight.

**Committees Of Our Board Of Directors**

Our board of directors has established a compensation committee, audit committee and governance committee. Our board of directors recently approved our audit committee charter, and we expect that the compensation committee and governance committee will also operate under charters approved by our board of directors, all of which will be effective upon the closing of this offering.

***Compensation Committee***

The current members of our compensation committee are \_\_\_\_\_, who is the chair of the committee, \_\_\_\_\_ and \_\_\_\_\_. We expect that upon completion of this offering, each of the members of our compensation committee will be independent under the applicable rules and regulations of the SEC, the Nasdaq Global Market and the Internal Revenue Service. Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. The compensation committee's responsibilities will include:

reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer and other executive officers;

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evaluating the performance of these officers in light of those goals and objectives;

setting the compensation of these officers based on such evaluations;

reviewing and approving the terms of any employment agreements with our chief executive officer and other executive officers;

administering the issuance of stock options and other awards under our stock plans; and

reviewing and evaluating, at least annually, the performance of the compensation committee and its members, including compliance of the compensation committee with its charter.

***Audit Committee***

The current members of our audit committee are \_\_\_\_\_, who is the chair of the committee \_\_\_\_\_ and \_\_\_\_\_. We expect that upon completion of this offering, all members of our audit committee will meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Global Market. Our board has determined that \_\_\_\_\_ is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of the Nasdaq Global Market. \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ are independent directors as defined under the applicable rules and regulations of the SEC and the Nasdaq Global Market. The audit committee will operate under a written charter that satisfies the applicable standards of the SEC and the Nasdaq Global Market. Our audit committee's responsibilities will include:

overseeing our corporate accounting and financial reporting process;

evaluating the independent auditors' qualifications, independence and performance;

determining the engagement of the independent auditors;

reviewing and approving the scope of the annual audit and the audit fee;

discussing with management and the independent auditors the results of the annual audit and the review of our quarterly financial statements;

approving the retention of the independent auditors to perform any proposed permissible non-audit services;

monitoring the rotation of partners of the independent auditors on our engagement team as required by law;

reviewing our critical accounting policies and estimates;

overseeing our internal audit function; and

annually reviewing the audit committee charter and the audit committee's performance.

***Governance Committee***

The current members of our governance committee are \_\_\_\_\_, who is the chair of the committee, \_\_\_\_\_ and \_\_\_\_\_. We expect that upon completion of this offering, each of the members of our governance committee will be independent under the applicable rules and regulations of the SEC and the Nasdaq Global Market. The governance committee's responsibilities will include:

making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board;

overseeing our corporate governance guidelines; and

reporting and making recommendations to our board concerning governance matters.

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***Other Committees***

Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

**Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting.

**Executive Compensation**

***Compensation Discussion and Analysis***

**Introduction.** *This section discusses our executive compensation policies and arrangements as they relate to our named executive officers who are listed in the compensation tables set forth below. The following discussion should be read together with the compensation tables and related disclosure set forth below.*

Our named executive officers, or NEOs, for the year ended December 31, 2009 are listed in the table below.

Name	Title
Jack A. Khattar	Chief Executive Officer, President
Russell P. Wilson	Vice President, Chief Financial Officer
Paolo Baroldi, M.D., Ph.D.	Senior Vice President, Chief Medical Officer
Padmanabh Bhatt, Ph.D.	Vice President, Pharmaceutical Sciences
Jones W. Bryan, Ph.D.	Vice President, Business Development

With respect to these NEOs, our board of directors determined initial compensation for these persons based primarily on negotiations between our board and our NEOs prior to their being hired and our board's past practices and experiences with companies such as ours.

We expect that following the completion of this offering, our Compensation Committee will undertake a substantial review of our existing compensation programs, objectives and philosophy and determine whether such programs, objectives, and philosophy are appropriate after we have become a public company. In addition, as we gain experience as a public company, we expect that the specific direction, emphasis and components of our executive compensation program will continue to evolve.

**Executive Compensation Objectives and Philosophy**

The key objectives of our executive compensation programs are (1) to attract, motivate, reward and retain superior executive officers with the skills necessary to successfully lead and manage our business; (2) to achieve accountability for performance by linking annual cash incentive compensation to the achievement of measurable performance objectives; and (3) to align the interests of our executive officers and our equity holders through short- and long-term incentive compensation programs. For our NEOs, these short- and long-term compensation are designed to accomplish these objectives by providing a significant correlation between our results of operations and total compensation.

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We expect to provide our NEOs with a significant portion of their compensation through cash incentive compensation contingent upon the achievement of operational and personal performance metrics, as well as through equity compensation. These two elements of executive compensation are aligned with the interests of our stockholders because the amount of compensation ultimately received will vary with our company's financial and operational performance. Equity compensation derives its value from our equity value, which in the future is likely to fluctuate based on our financial and operational performance.

We seek to apply a consistent philosophy to compensation for all executive officers. Our compensation philosophy is based on the following core principles.

***To Pay for Performance***

Individuals in leadership roles are compensated based on a combination of total company and individual performance factors. Total company performance is evaluated primarily on the degree to which pre-established operational objectives are met. Individual performance is evaluated based upon several individualized leadership factors, including:

individual contribution to attaining specific operational objectives;

building and developing individual skills and a strong leadership team; and

developing an effective infrastructure to support business development and growth.

***To Pay Competitively***

We are committed to providing a total compensation program designed to retain our highest performing employees and attract strong leaders to our company. We have established compensation levels that we believe are competitive based on our board's experience with pay practices and compensation levels for companies such as ours.

***To Pay Equitably***

We believe that it is important to apply generally consistent guidelines for all executive officer compensation programs. In order to deliver equitable pay levels, our board considers depth and scope of accountability, complexity of responsibility, qualifications and executive performance, both individually and collectively as a team.

In addition to short- and long-term compensation, we have found it important to provide certain of our executive officers with competitive post-employment compensation. Post-employment compensation consists primarily of severance pay and benefits continuation. We believe that these benefits are important considerations for our executive officer compensation package, as they afford a measure of financial security in the event of certain terminations of their employment and also enable us to secure their cooperation following termination. We have sought to ensure that each combined compensation package is competitive at the time the package is negotiated with the executive officer. We elect to provide post-employment compensation to our executive officers on a case-by-case basis as the employment market, the qualifications of potential employees and our hiring needs dictate.

**Compensation Committee Review of Compensation**

We expect that following this offering, our Compensation Committee will review compensation elements and amounts for NEOs on an annual basis and at the time of a promotion or other change in level of responsibilities, as well as when competitive circumstances or business needs may require. We may, but do not currently, use a third party consultant to assist us with determining compensation levels. We expect that each year our management will compile a report of benchmark data for

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executive positions for similar companies, including summaries of base salary, annual cash incentive plan opportunities and awards and long-term incentive award values. We have not yet determined the companies that we will benchmark our compensation packages against, but we expect that the Compensation Committee will determine this list after completion of this offering and that it will compare our pay practices and overall pay levels with other leading industry organizations and, where appropriate, with non-industry organizations when establishing our pay guidelines.

We expect that the CEO will provide compensation recommendations to the Compensation Committee for executives other than himself based on this data and the other considerations mentioned in this Compensation Discussion and Analysis. We expect that the Compensation Committee will recommend a compensation package that is consistent with our compensation philosophy, strategically positioned at the median of the peer group and competitive with other organizations similar to ours. The Compensation Committee will then discuss these recommendations with the CEO and will make a recommendation to the board, which the board will consider and approve, if appropriate.

We expect that the Compensation Committee will consider input from our CEO and CFO when setting performance objectives for our incentive plans. We also expect that the Compensation Committee will consider input from our CEO and CFO, regarding benchmarking and recommendations for base salary, annual incentive targets and other compensation awards. The Compensation Committee will likely give significant weight to our CEO's and CFO's judgment when assessing performance and determining appropriate compensation levels and incentive awards for our other NEOs.

**Elements of Compensation**

As discussed throughout this Compensation Discussion and Analysis, the compensation policies applicable to our NEOs are reflective of our pay-for-performance philosophy and encourage executive officers to enhance equity holder value over the long term.

The elements of our compensation program are:

base salary;

performance-based cash incentives;

equity incentives; and

certain additional employee benefits.

Base salary, performance-based cash incentives and long-term equity-based incentives are the most significant elements of our executive compensation program and, on an aggregate basis, they are intended to substantially satisfy our program's overall objectives. Historically, our board of directors has, and following the offering, the Compensation Committee will seek to, set each of these elements of compensation at the same time to enable it to simultaneously consider all of these elements collectively and their impact on compensation as a whole. Taking this comprehensive view of all compensation components allows us also to make compensation determinations that will reflect the principles of our compensation philosophy with respect to allocation of compensation among certain of these elements and total compensation. We strive to achieve an appropriate mix between the various elements of our compensation program to meet our compensation objectives and philosophy; however, we do not apply any rigid allocation formula in setting our executive compensation, and we may make adjustments to this approach for various positions after giving due consideration to prevailing circumstances, the individuals involved and their responsibilities and performance.

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***Base Salary***

We provide a base salary to our executive officers to compensate them for their services during the year and to provide them with a stable source of income. The base salaries for our NEOs in 2009 were established by our board of directors, based in large part on the recommendation of our management and our board's review of other factors, including:

the individual's performance, results, qualifications and tenure;

the responsibilities associated with the position;

pay mix (base salary, annual cash incentives, equity incentives and employee benefits);

prevailing market conditions; and

our financial position.

The annual base salaries in effect for each of our NEOs employed by us as of December 31, 2009 and December 31, 2010, are as follows.

Name	Base Salary (\$)	
	2009	2010
Jack A. Khattar	396,060	407,942
Russell P. Wilson (1)	260,000	265,172
Paolo Baroldi, M.D., Ph.D. (2)	285,000	293,292
Padmanabh Bhatt, Ph.D.	258,448	266,200
Jones W. Bryan, Ph.D.	204,410	210,542

(1) Mr. Wilson joined us as our Vice President, Chief Financial Officer on May 4, 2009, and, as a result, his raise in 2010 has been prorated.

(2) Dr. Baroldi joined us as our Senior Vice President, Chief Medical Officer on January 12, 2009, and, as a result, his raise in 2010 has been prorated.

In setting base salaries for 2009, our board considered the prevailing market conditions and our financial position, including our need to raise additional funds, and decided to increase the base salary of our then-current NEOs by only 2.0% over their 2008 base salaries. In early 2010, in connection with setting the 2010 base salaries for our NEOs, our board considered the prevailing market conditions and our financial position, including our need to raise additional funds, and decided to increase the base salary of each of our NEOs by 3.0% over their 2009 base salaries.

In the future, we expect that salaries for executive officers will be reviewed annually, as well as at the time of a promotion or other change in level of responsibilities, or when competitive circumstances or business needs may require. As noted above, we expect that following completion of the offering, our Compensation Committee will recommend a compensation package that is consistent with our compensation philosophy, strategically positioned at market median of our to-be-determined peer group.

***Performance-Based Cash Incentives***

We pay annual performance-based cash incentives or bonuses in order to align the compensation of our NEOs with our short-term operational and performance goals and to provide near-term rewards for our NEOs to meet these goals. From time to time, our board has exercised its discretion in determining cash incentive amounts and making individual awards, but generally our performance-based cash



incentives are made under our annual cash incentive plan. Our annual cash incentive plan for our CEO is based on the attainment by our company of objective operational goals and for all

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other NEOs is based on two components: the attainment by our company of non-financial operational goals and the achievement by each NEO of personal and often subjective performance goals. The final evaluation made by our board combines often subjective assessments of each of our company's operational goals and each NEO's personal goals and does not necessarily involve a mathematical analysis or pre-established weighting of each goal. Each of these components allows us to establish appropriately aggressive performance expectations and incentives that align business performance expectations to the prevailing market and economic conditions.

Currently, our board has determined that the target bonus for our CEO under our annual cash incentive plan is based 100% on the achievement of our company objectives. The annual performance bonuses for the other NEOs are currently based 60% on the achievement of company objectives and 40% on the achievement of individual performance objectives. Our board establishes our company objectives for each fiscal year prior to the end of the first quarter of the year and determines a separate weighting for each of our company objectives.

We do not disclose our company operational goals component of our annual cash incentive plan. We believe that such disclosure would result in serious competitive harm and be detrimental to our operating performance because the components of our performance goals for 2009 contain highly sensitive data, such as regulatory, strategic partnering and other non-financial operational goals. These goals are intended to be realistic and reasonable, but challenging, in order to drive performance by our NEOs.

The personal performance goals vary for each NEO whose bonus is based in part on personal performance goals and are based on specific priorities in the NEO's area of responsibility, which may include, among others, regulatory and operating performance measures, as well as more subjective goals such as achievement of operational goals or implementation of specific plans, publications or projects in each NEO's area of management. Each year, our CEO and each NEO jointly determine what the NEO's performance priorities will be for the year, and our CEO makes a recommendation to our Compensation Committee. Our Compensation Committee reviews these recommendations, may have further discussions with our CEO or the NEO and then makes a final determination as to the personal performance goals.

After our fiscal year 2009 ended, our board reviewed the company goals that were attained and were not attained and determined that the company performance component of our annual cash incentive plan was 100% achieved. This decision was primarily due to the continued progress of SPN-538 and Epliga in the clinic and the non-dilutive financing achieved through payment of \$36.9 million as consideration for a royalty-free, fully paid-up license for Intuniv. Concurrently, each of our NEOs prepared an assessment of his or her performance against his or her personal performance goals and discussed them with our CEO, who then made a recommendation to our board. Our board reviewed these recommendations, undertook a similar process with our CEO regarding his personal performance goals and made a determination of overall performance against these goals for each NEO. Taking into account the relative weighting of the corporate and personal performance objectives, with

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60% for corporate objectives and 40% for individual performance objectives for each NEO, other than our CEO, we paid each NEO the following 2009 annual performance bonus in 2010:

Name	2009 Annual Performance Bonus		
	Target Bonus Percent	Target Bonus Amount (\$)	Actual Bonus Payout (\$)
Jack A. Khattar	40%	\$ 158,424	\$ 158,424
Russell P. Wilson(1)	25	65,000	41,600
Paolo Baroldi, M.D., Ph.D.(2)	25	71,250	69,825
Padmanabh Bhatt, Ph.D.	25	64,612	64,353
Jones W. Bryan, Ph.D.	25	51,103	49,876

- (1) The bonus payment for Mr. Wilson, who joined us as our Vice President, Chief Financial Officer on May 4, 2009, was prorated for time worked.
- (2) The bonus payment for Dr. Baroldi, who joined us as our Senior Vice President, Chief Medical Officer on January 12, 2009, was prorated for time worked.

For 2010, our board has set the following target annual performance bonus amounts:

Name	2010 Annual Performance Bonus	
	Target Bonus Percent	Target Bonus Amount (\$)
Jack A. Khattar	40%	\$ 163,177
Russell P. Wilson	25	66,293
Paolo Baroldi, M.D., Ph.D.	25	73,323
Padmanabh Bhatt, Ph.D.	25	66,550
Jones W. Bryan, Ph.D.	25	52,636

We expect that following this offering, our Compensation Committee will more directly assess the performance of our NEOs. Many of the personal performance goals either are qualitative in nature or have a single value or accomplishment as the determinant. Accordingly, the final evaluation made by our board often combines subjective assessments of each of the NEO's goals and does not necessarily involve a mathematical analysis or pre-established weighting of each goal. Our board ultimately determines a single percentage representing overall performance against each NEO's personal goals in the aggregate.

The target bonus percentages for our NEOs under our annual cash incentive plan for 2010 are the same as under the annual cash incentive plan for 2009. Because the components of our performance goals for 2010 contain highly sensitive data, such as regulatory, strategic partnering and other non-financial operational goals, we believe that such disclosure would result in serious competitive harm and be detrimental to our operating performance. Our performance goals are intended to be realistic and reasonable, but challenging, in order to drive performance by our NEOs.

### *Equity Incentives*

All of our NEOs have received equity incentive grants under our 2005 Stock Plan, which is described below, in the form of restricted stock and stock options. To date, we have used restricted stock and/or stock option grants as our principal form of equity incentives because we believe they are an effective means to align the long-term interests of our executive officers with those of our stockholders. The offer of restricted stock and/or options attempts to achieve this alignment by

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providing our NEOs with equity incentives that vest over time or upon the occurrence of certain events. The restricted stock and options serve also to reward our NEOs for performance.

In connection with the hiring of Dr. Baroldi and Mr. Wilson in 2009, the board approved the award of stock options to each of these NEOs under our 2005 Stock Plan. In determining the amounts for such new hire equity incentive grants, the board primarily considered their prominent positions and significant responsibilities with our company.

Prior to this offering, we have used stock options and, to a very limited degree, restricted stock, as the primary long-term equity incentive vehicle. In 2005, we made our only grant of restricted stock when the fair value of our stock was lower and the awards had less income tax consequence to the executive upon vesting. Since then, we have made option grants to executive officers who are newly hired, and generally made stock option grants to existing executives at times when the board deemed appropriate in accordance with the compensation principles outlined above.

The value of an option is at risk for the NEO and is entirely dependent on the value of a share of our stock above the option's strike price. The value of our stock is dependent in many ways on management's success in achieving our goals. If the price of our common stock drops, for any reason, over the option's vesting period, the value of the option to the executive will drop and could become worthless if the price of the underlying stock remains below the option's strike price. In determining the number of stock options to be granted to executives, we take into account the individual's position, scope of responsibility, ability to affect profits and shareholder value, the individual's historic and recent performance and the value of stock options in relation to other elements of the individual executive's total compensation.

We may in the future grant other forms of equity incentives, such as restricted stock or performance shares (shares that vest only upon achievement of performance goals established at the time of grant), subject to the Compensation Committee's discretion, to ensure that our executives are focused on long-term stockholder value. We expect that following completion of the offering, the Compensation Committee will periodically review the equity awards previously awarded to management, the performance of our business and the performance of our stock. We expect that the Compensation Committee will establish levels of equity incentive holdings for our NEOs such that the portion of overall compensation that is variable is consistent with our pay-for-performance philosophy and competitive within our industry. The Compensation Committee is expected to determine appropriate levels of equity awards based on these factors and may make additional grants.

Stock options granted by us to date have an exercise price equal to or greater than the fair market value of our common stock on the date of grant and generally expire ten years after the date of grant. Stock options are subject to vesting, and most of our options vest over time at a rate of 25% of the total grant on each of the first four anniversaries of the vesting start date, although we have granted some performance options that vest upon attaining certain predetermined company objectives.

The amount of each of these awards was designed to establish a desired percentage ownership level for each of our NEOs that our board believed was commensurate with their respective roles and responsibilities and based on similarly situated employees of other companies that members of our board had experience with.

***Additional Employee Benefits***

We provide our executive officers with employee benefits that the board believes are reasonable and in the best interests of the company and its stockholders, which consist of the following benefits:

health insurance;

vacation and sick days;

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long-term disability; and

a 401(k) plan.

We have no structured perquisite benefits, such as club memberships or company vehicles, for any executive officer, including our NEOs. We believe the benefits we provide are generally equivalent to the benefits provided by comparable companies.

**Accounting and Tax Considerations**

In determining which elements of compensation are to be paid, and how they are weighted, we will take into account whether a particular form of compensation will be deductible under Section 162(m) of the Code. Section 162(m) generally limits the deductibility of compensation paid to our NEOs to \$1 million during any fiscal year unless such compensation is "performance-based" under Section 162(m). However, under a Section 162(m) transition rule for compensation plans or agreements of corporations which are privately held and which become publicly held in an initial public offering, compensation paid under a plan or agreement that existed prior to the initial public offering will not be subject to Section 162(m) until the earliest of (1) the expiration of the plan or agreement; (2) a material modification of the plan or agreement; (3) the issuance of all employer stock and other compensation that has been allocated under the plan; or (4) the first meeting of stockholders at which directors are to be elected that occurs after the close of the third calendar year following the year of the initial public offering. We refer to the earliest of these events to occur as the "Transition Date." After the Transition Date, rights or awards granted under the plan will not qualify as "performance-based compensation" for purposes of Section 162(m) unless such rights or awards are granted or vest upon pre-established objective performance goals, the material terms of which are disclosed to and approved by our stockholders.

Our compensation program is intended to maximize the deductibility of the compensation paid to our NEOs to the extent that we determine it is in our best interests. Consequently, we may rely on the exemption from Section 162(m) afforded to us by the transition rule described above for compensation paid pursuant to our pre-existing plans.

Many other Code provisions, SEC regulations and accounting rules affect the payment of executive compensation and are generally taken into consideration as we develop our compensation programs. Our goal is to create and maintain plans that are efficient, effective and in full compliance with these requirements.

When determining our compensation policies and practices, our board considered various matters relative to the development of a reasonable and prudent compensation program, including whether the policies and practices were reasonably likely to have a material adverse effect on us. We believe that the mix and design of our executive compensation plans and policies do not encourage management to assume excessive risks and are not reasonably likely to have a material adverse effect on us for the following reasons: we offer an appropriate balance of short and long-term incentives and fixed and variable amounts; our variable compensation is based on a balanced mix of criteria; and our Compensation Committee has the authority to adjust variable compensation as appropriate.

**Compensation Tables**

The following tables provide information regarding the compensation earned during our most recently completed fiscal year by our NEOs.

Table of Contents**Summary compensation table**

The following table shows the compensation earned by our NEOs during the fiscal year ended December 31, 2009.

Name and Principal Position	Year	Base Salary (\$)	Non-Equity Incentive Plan Compensation Bonus (\$)(3)	Option Awards (\$)(4)	All Other Compensation (\$)(5)	Total (\$)
Jack A. Khattar <i>Chief Executive Officer, President</i>	2009	\$ 395,737	\$ 158,424		\$ 11,931	\$ 566,092
Russell P. Wilson(1) <i>Vice President, Chief Financial Officer</i>	2009	161,667	41,600	262,650	7,225	473,142
Paolo Baroldi, M.D., Ph.D.(2) <i>Senior Vice President, Chief Medical Officer</i>	2009	265,635	69,825	51,750	15,001	402,211
Padmanabh Bhatt, Ph.D. <i>Vice President, Pharmaceutical Sciences</i>	2009	258,237	64,353		13,334	335,924
Jones W. Bryan, Ph.D. <i>Vice President, Business Development</i>	2009	204,243	49,876		11,195	265,314

- (1) The compensation for Mr. Wilson, who joined us on May 4, 2009, has been prorated for time worked.
- (2) The compensation for Dr. Baroldi, who joined us on January 12, 2009, has been prorated for time worked.
- (3) Amounts represent annual performance bonus compensation earned for the year ended December 31, 2009 based on pre-established performance objectives. Annual performance bonus compensation for 2009 was paid in 2010. Our annual performance bonus program is described in more detail under " Compensation Discussion and Analysis Performance-Based Cash Incentives."
- (4) In accordance with ASC Topic 718, or ASC 718, formerly Statement of Financial Accounting Standards No. 123R, our NEOs will only realize compensation to the extent the market price of our common stock is greater than the exercise price of such stock options. For information regarding assumptions underlying the valuation of equity awards, see note 8 to our financial statements appearing at the end of this prospectus.
- (5) Amounts include the premium amounts paid by us for life insurance and long-term disability insurance coverage for each NEO, plus the employer matching contributions made on behalf of each NEO to our 401(k) plan.

**Grants of Plan-Based Awards**

During fiscal year ended December 31, 2009, each of our NEOs participated in our performance-based cash incentive plan in which each officer was eligible for the awards set forth in the following table. For a detailed discussion of our performance-based cash incentive plan, refer to " Compensation Discussion and Analysis Performance-Based Cash Incentives." The following table also sets forth information regarding equity awards granted to our NEOs during the year ended December 31, 2009. Equity awards made to our NEOs are described in more detail under " Compensation Discussion and Analysis Equity Incentives" and non-equity incentive plan awards

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made to our NEOs are described in more detail under " Compensation Discussion and Analysis Performance-Based Cash Incentives."

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards		All Other Options Awards: Number of Securities Underlying Options(#)	Exercise or Base Price of Option Awards(1) (\$/sh)	Grant Date Fair Value of Stock and Options Awards(2) (\$)
		Target (\$)	Maximum (\$)			
Jack A. Khattar		\$ 158,424	\$ 158,424			
Russell P. Wilson	12/15/2009			230,000	\$ 1.76(3)	\$ 236,900
	12/15/2009			25,000	1.76(3)	25,750
		65,000	65,000			
Paolo Baroldi, M.D., Ph.D.	1/20/2009			200,000	0.40	46,000
	1/20/2009			25,000	0.40	5,750
		71,250	71,250			
Padmanabh Bhatt, Ph.D.		64,612	64,612			
Jones W. Bryan, Ph.D.		51,103	51,103			

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- (1) Amounts represent the fair value of our common stock as determined in good faith by our board on the date of the grant.
- (2) Amounts reflect the aggregate grant date fair value of the awards calculated in accordance with ASC 718.
- (3) Stock option was repriced by our board on November 2, 2010. The new exercise price is \$0.64 per share.

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### Outstanding Equity Awards at Fiscal Year-End

The table below sets forth certain information regarding the outstanding equity awards held by our NEOs as of December 31, 2009.

Name		Option Awards				Stock Awards	
		Number of Securities Underlying the Unexercised Options (#) Exercisable	Number of Securities Underlying the Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercisable Options (#)	Option Exercise Price (\$)(6)	Option Expiration Date	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares That Have Not Vested (#)
Jack A. Khattar	(1)(7)						411,765
Russell P. Wilson	(2)(3)		230,000		\$ 1.76	12/15/2019	
	(1)(3)			25,000	\$ 1.76	12/15/2019	
Paolo Baroldi, M.D., Ph.D.	(2)		200,000		\$ 0.40	1/19/2019	
	(1)			25,000	\$ 0.40	1/19/2019	
Padmanabh Bhatt, Ph.D.	(2)	200,000			\$ 0.10	1/17/2016	
	(4)	25,000			\$ 0.10	1/17/2016	
	(1)			25,000	\$ 0.10	1/17/2016	
	(5)	25,000			\$ 0.10	1/17/2016	
	(2)	6,000	6,000		\$ 0.10	2/13/2017	
Jones W. Bryan, Ph.D.	(2)	200,000			\$ 0.10	1/17/2016	
	(4)	25,000			\$ 0.10	1/17/2016	
	(1)			25,000	\$ 0.10	1/17/2016	
	(5)	25,000			\$ 0.10	1/17/2016	
	(2)	6,000	6,000		\$ 0.10	2/13/2017	

- (1) All of these vested equity awards originally vested based on the achievement of our filing our first NDA prior to December 22, 2010. On November 2, 2010, the performance condition for vesting of these non-vested awards was modified by our board to extend the performance date from December 22, 2010 to March 31, 2011.
- (2) These stock options vest over four years in four equal installments of 25% each on the first four anniversaries from the date of grant.
- (3) On November 2, 2010, this option was repriced from \$1.76 to \$0.64 per share.
- (4) These stock options vested upon the completion of our first clinical trial in humans and was satisfied in 2006.
- (5) These stock options vested upon the launch of a partnered product and was satisfied in 2006.
- (6) The market value of each equity award is based on the fair value of per share of our common stock as of the date of grant, as determined in good faith by our board.
- (7) There was no public market for our common stock at December 31, 2009. Accordingly, the value of unvested equity awards has been estimated based on an assumed initial public offering price of \$ per share, the midpoint of the range set forth on the cover page of this prospectus.

### Option Exercises and Stock Vested



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There were no option awards exercised by any of our NEOs during fiscal year ended December 31, 2009. Our CEO had 617,647 shares of restricted stock vest during fiscal year ended December 31, 2009.

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***Pension Benefits***

Our NEOs did not participate in or have account balances in any qualified or nonqualified defined benefit plans sponsored by us. Our board of directors or Compensation Committee may elect to adopt qualified or nonqualified benefit plans in the future if it determines that doing so is in our best interest.

***Deferred Compensation***

We do not currently provide any deferred compensation program or benefits but may elect to do so in the future.

**Employment Agreement and Severance Benefits**

***Jack A. Khattar***

On December 22, 2005, we entered into an Employment Agreement with Mr. Khattar, our President and Chief Executive Officer, providing for his continued employment, effective as of the signing date. This employment agreement provides that Mr. Khattar's employment is at-will and may be terminated by either us or him at any time for any or no reason. Mr. Khattar's base salary was originally set at \$359,000 per year, subject to review and increases from time to time by our board based on Mr. Khattar's and the company's performance. Mr. Khattar is also eligible to receive an annual bonus payment of up to 40% of his annual base salary, based on achievement of certain performance milestones identified by our board in consultation with Mr. Khattar. Furthermore, he is eligible to participate in our group benefits programs, including but not limited to, medical insurance, vacation and retirement plans, and will be provided with life insurance and the ability to participate in a 401(k) plan.

In the event Mr. Khattar is terminated by us without cause, as defined in the employment agreement, or he resigns with good reason, as defined in the employment agreement to include, among other things, any material reduction in base compensation or material diminution in title, duties or responsibilities as President and Chief Executive Officer, Mr. Khattar will be entitled to receive (i) continued payment of his base salary for 18 months, (ii) the most recent annual bonus paid to him, and (iii) continuation of his taxable and non-taxable benefits for 18 months, subject to the limits under applicable law. In the event that Mr. Khattar is terminated for cause or he terminates his employment without good reason, Mr. Khattar will not be entitled to the payments and benefits described above unless mutually agreed upon in writing. Mr. Khattar's employment agreement also includes a non-solicitation covenant and a non-compete covenant for at least one year following the termination of Mr. Khattar's employment.

In addition, the grant agreements for Mr. Khattar's restricted stock provided for 100% acceleration of unvested restricted stock in connection with a change in control because our board of directors believes that this accelerated vesting provides Mr. Khattar with additional incentive to assist in the successful completion of a change of control transaction.

***Other NEOs***

Pursuant to the terms of the offer letters with Dr. Bryan and Dr. Bhatt, they are each entitled to receive six months of severance pay in connection with a restructuring of Supernus that results in the elimination of their respective positions.

**Potential Payments Upon Termination and Change in Control**

Assuming Mr. Khattar's employment is terminated without cause or he resigns for good reason, or he resigns for good reason after a change of control, each such term as defined in Mr. Khattar's

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employment agreement, on December 31, 2009, the estimated values of payments and benefits to Mr. Khattar are set forth in the following table. See " Employment Agreement and Severance Benefits." In addition, the following table also sets forth (i) the amounts payable upon a change of control in connection with the acceleration of vesting of Mr. Khattar's restricted stock assuming the change of control occurred on December 31, 2009, and (ii) the amounts payable upon a restructuring of Supernus that results in the elimination of Dr. Bryan's or Dr. Bhatt's respective positions assuming the restructuring occurred on December 31, 2009.

		Termination Upon a Restructuring	Termination Without Cause or Resignation for Good Reason	Resignation for Good Reason After a Change of Control	Acceleration Upon a Change of Control
Jack A. Khattar	Base salary continuation		\$ 594,090	\$ 594,090	
	Bonus(1)		158,424	158,424	
	Continuation of benefits(2)		16,947	16,947	
	Vesting of restricted stock(3)				\$
	<b>Total</b>		<b>\$ 769,461</b>	<b>\$</b>	<b>\$</b>
Padmanabh Bhatt, Ph.D.	Severance	\$ 129,224			
Jones W. Bryan, Ph.D.	Severance	\$ 102,205			

- (1) Amount shown for bonus in connection with a change in control represents the bonus payment Mr. Khattar would have earned based on the assumption that his employment terminated as of the last day of fiscal 2009, in accordance with his employment agreement. The amount set forth in the table reflects the most recent bonus paid to Mr. Khattar (which was the 2009 bonus paid in early 2010) because this table assumes that he was terminated as of the last day of the fiscal year and we had not yet determined the amount of the bonuses payable to him under our annual cash incentive plan for fiscal 2010.
- (2) Amounts shown for continuation of benefits represent estimates for the continuation of health, medical, life and group life insurance benefits afforded to Mr. Khattar and eligible family members in accordance with his employment agreement.
- (3) There was no public market for our common stock at December 31, 2009. Accordingly, the value of accelerated equity awards has been estimated based on an assumed initial public offering price of \$ per share, the midpoint of the range set forth on the cover page of this prospectus.

## Director Compensation

Upon election to our board, each of our non-employee directors who are not affiliated with any 5% or greater stockholder was granted options to purchase shares of our common stock, subject to an annual vesting over a four-year period from the date of grant. The exercise price of the options was greater than or equal to the fair market value of a share of our common stock at the time of grant. In addition, our non-employee directors who are not affiliated with any 5% or greater stockholder receive \$20,000 annually. All directors have received and will continue to receive reimbursement for reasonable out-of-pocket expenses incurred in connection with attendance at meetings of the board.

The following table sets forth a summary of the compensation we paid to Mr. Nuerge in 2009. None of the other members of our board received any compensation from us for their service on our board, other than reimbursement for reasonable out-of-pocket expenses as described above.

Name	Fees Earned or Paid in Cash	Total (\$)
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	(\$)	
William A. Nuerge	20,000	20,000

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**Benefit Plans**

Our officers, employees, non-employee directors and other key persons (including consultants and prospective employees) are entitled to participate in various benefit plans as described below, subject to the discretion of the administrators of the plans. Our equity awards are granted under our 2005 Stock Plan. There are an aggregate of 8,000,000 shares of common stock authorized under this plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. Generally, shares that are forfeited or canceled from awards under the 2005 Stock Plan also will be available for future awards.

***2005 Stock Plan***

***Introduction.*** Our 2005 Stock Plan was adopted by our board and approved by our stockholders on December 21, 2005. The 2005 Stock Plan permits us to make grants of stock options (both incentive stock options and non-qualified stock options), purchase rights of common stock and awards of common stock to our executives, employees, directors, consultants and advisors.

***Share Reserve.*** 8,000,000 shares of common stock are reserved for the issuance of awards under our 2005 Stock Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. Generally, shares that expire or terminate for any reason without having been exercised in full shall be available for subsequent grants under our 2005 Stock Plan.

***Administration.*** Our 2005 Stock Plan is administered by either our board or a committee of our board. The administrator has full power and authority to select the participants to whom awards will be granted, to make any combination of awards to participants, to accelerate the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 2005 Stock Plan.

***Eligibility.*** All officers, employees, directors and other key persons (including consultants and advisors) are eligible to participate in the 2005 Stock Plan, subject to the discretion of the administrator.

***Types of Awards.*** The types of awards that are available for grant under the 2005 Stock Plan are:

incentive stock options;

non-qualified stock options;

purchase rights; and

common stock awards.

The exercise price of stock options awarded under the 2005 Stock Plan may not be less than either (i) 100% of the fair market value of our common stock on the date of the option grant, with the term of each option not exceeding ten years from the date of grant, or (ii) for any employee who is the owner, at the time of the grant of such options, of more than 10% of the total combined voting power of all classes of stock of the Company (after taking into account the attribution of stock ownership rules of Section 424(d) of the Code), 110% of fair market value of our common stock on the date of the option grant, with the term of each option not exceeding five years from the date of grant. The administrator will determine at what time or times each option may be exercised and, subject to the provisions of the 2005 Stock Plan, the period of time, if any, after retirement, death, disability or other termination of employment during which options may be exercised. To qualify as incentive stock options, stock options must meet additional federal tax requirements, including a \$100,000 limit on the value of shares subject to incentive options which first become exercisable in any one calendar year, and a shorter term and higher minimum exercise price in the case of certain large stockholders.

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Purchase rights allow the recipient the opportunity to make direct purchases of the Company's common stock in accordance with terms and conditions established by the administrator. Awards of common stock are awards entitling the grantee to receive shares of the Company's common stock in accordance with terms and conditions established by the administrator.

**Transferability.** Our 2005 Stock Plan does not allow for the transfer of incentive stock options and all other options granted to Reporting Persons, and may be exercisable only by the grant holder during his or her lifetime, except that non-qualified options may be transferred pursuant to a qualified domestic relations order (as defined in the Code).

**Change in Control.** Except as otherwise provided by the administrator and evidenced in a particular award, in the event of a consolidation or merger or sale of all or substantially all of the assets of the Company in which outstanding shares of common stock are exchanged for securities, cash or other property of any other corporation or business entity, or in the event of a liquidation of the Company, the administrator may, in its discretion, terminate all stock options granted under the 2005 Stock Plan unless the successor entity agrees to assume the awards. In the event the awards are to be terminated, the administrator may provide for payment in exchange for the termination of the awards. Furthermore, at any time the administrator may provide for the acceleration of exercisability and/or vesting of an award.

**Term.** Unless earlier terminated by our board of directors, the 2005 Stock Plan will terminate, with respect to incentive stock options only, upon the earlier of (A) the close of business on the day next preceding the tenth anniversary of the date the Board of Directors approved the 2005 Stock Plan, or (B) the date on which all shares available for issuance under the 2005 Stock Plan shall have been issued. Unless sooner terminated, the 2005 Stock Plan will terminate with respect to options, purchase rights and awards of common stock which are not incentive stock options on the date specified in (B) above.

**Amendment or Termination.** Our board of directors may amend, suspend, or terminate the 2005 Stock Plan in any respect at any time, subject to stockholder approval where such approval is required by applicable law or stock exchange rules. Further, any material amendments to the 2005 Stock Plan will be subject to approval by our stockholders, including any amendment that increases the number of shares available for issuance under the 2005 Stock Plan or expands the types of awards available under, the eligibility to participate in, or the duration of, the plan. No amendment to the 2005 Stock Plan may materially impair any of the rights of a participant under any awards previously granted without his or her consent.

**Limitation of Liability and Indemnification Arrangements**

As permitted by the Delaware General Corporation Law, we intend to adopt provisions in our amended and restated certificate of incorporation and amended and restated bylaws, which will be effective upon the completion of this offering, that limit or eliminate the personal liability of our directors. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

any breach of the director's duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or

any transaction from which the director derived an improper personal benefit.

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These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our amended and restated bylaws, which will be effective upon the completion of this offering, provide that:

we will indemnify our directors, officers and, at the discretion of our board, certain employees to the fullest extent permitted by the Delaware General Corporation Law; and

advance expenses, including attorneys' fees, to our directors and, at the discretion of our board, to our officers and certain employees, in connection with legal proceedings, subject to limited exceptions.

We also intend to enter into indemnification agreements with each of our executive officers and directors. These agreements will provide that we will indemnify each of our directors to the fullest extent permitted by the Delaware General Corporation Law and advance expenses to each indemnitee in connection with any proceeding in which indemnification is available.

We also maintain management liability insurance to provide insurance coverage to our directors and officers for losses arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or persons controlling the registrant pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

These provisions may discourage stockholders from bringing a lawsuit against our directors in the future for any breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors, officers and certain employees pursuant to these indemnification provisions. We believe that these provisions, the indemnification agreements and the insurance are necessary to attract and retain talented and experienced directors and officers.

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that might result in a claim for such indemnification.

### **Rule 10b5-1 Sales Plans**

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information. However, pursuant to the terms of the lock-up agreements described under "Underwriting," no Rule 10b5-1 plan may provide for the transfer of common stock during the restricted period ending 180 days after the date of this prospectus (as such period may be extended under certain circumstances).

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**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

Other than the compensation agreements and other arrangements described under "Compensation Discussion and Analysis" in this prospectus and the transaction set forth below, since January 1, 2007, there has not been any transaction or series of transactions to which we were or are a party in which the amount involved exceeded or exceeds \$120,000 and in which any director, executive officer, holder of more than 5% of any class of our voting securities or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest. We believe the transaction set forth below was executed on terms no less favorable to us than we could have obtained from unaffiliated third parties.

In May 2009, we entered into an amendment to a license agreement with Shire LLC, a holder of Series A convertible preferred stock, whereby Shire LLC and its affiliates paid us a one-time, lump-sum payment of \$36.9 million in return for a fully paid-up license for one of its products that utilizes our proprietary technologies. All four criteria necessary to recognize revenue in accordance with ASC 605-10-S25, *Revenue Recognition Overall Recognition*, were met during 2009 related to this transaction. Accordingly, the entire amount was recorded as royalty revenue in the consolidated statement of operations.

**Transactions with Our Executive Officers, Directors and 5% Stockholders**

***Indemnification Agreements***

We intend to enter into indemnification agreements with each of our directors and certain of our executive officers. These agreements will require us to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

***Registration Rights***

After the expiration of the 180-day period following the completion of this offering (as may be extended under certain circumstances), certain of our directors and 5% stockholders are party to an investor rights agreement providing for rights to register under the Securities Act certain shares of our capital stock. For more information regarding the registration rights granted pursuant to this agreement, see the section entitled "Description of Capital Stock Registration Rights."

***Employment Agreement and Offer Letters***

We have entered into an employment agreement with our chief executive officer and offer letters with certain of our named executive officers, or NEOs, each of which provides for certain severance benefits, among other things. For more information regarding this agreement and the offer letters with certain of our NEOs, see the section entitled "Executive Compensation Employment Agreement and Severance Benefits."

***Stock Option Awards***

Our 2005 Stock Plan permits us to make grants of stock options, purchase rights of common stock and awards of common stock to our executives, employees, directors, consultants and advisors. For more information regarding stock option awards and restricted stock granted to our named executive officers and directors, see the sections entitled "Executive Compensation Outstanding Equity Awards at Fiscal Year End" and "Director Compensation."



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**Procedures for Related Party Transactions**

Upon the closing of this offering, our audit committee will be responsible for reviewing and approving all material transactions with any related party on a continuing basis. Related parties can include any of our directors or officers, holders of 5% or more of our voting securities and their immediate family members. This obligation is set forth in writing in our Audit Committee Charter. We may not enter into a related person transaction unless our audit committee has reviewed and approved such transaction. Currently, such transactions are reviewed by management on a case-by-case basis.

Table of Contents**PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding the beneficial ownership of our common stock as of September 30, 2010, before and after the completion of this offering, and gives effect to 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, by: (i) our named executive officers and our directors individually, (ii) all of our executive officers and directors, as a group, and (iii) any person who, to our knowledge, owns 5% or more of the common stock on an as-converted basis. Unless otherwise indicated, the address for each of the stockholders listed in the table below is c/o Supernus Pharmaceuticals, Inc., 1550 East Gude Drive, Rockville, Maryland 20850.

Beneficial ownership is determined in accordance with the rules and regulations of the United States Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options held by that person that are currently exercisable or exercisable within sixty (60) days of September 30, 2010 are deemed outstanding. These shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, we believe each stockholder named in the table has sole voting and investment power with respect to the shares set forth opposite that stockholders' name.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>5% Stockholders:</b>			
New Enterprise Associates 11, Limited Partnership and its affiliates(1) c/o New Enterprise Associates 1954 Greenspring Drive Suite 600 Timonium, MD 21093	25,000,000	45.1%	
OrbiMed Private Investments II, LP and its affiliates(2) c/o OrbiMed Advisors LLC 767 Third Avenue, 30th Floor New York, NY 10017	10,000,000	18.1%	
Abingworth Bioventures IV LP and its affiliates(3) c/o Abingworth Management Inc 890 Winter Street, Suite 150 Waltham, MA 02451	10,000,000	18.1%	
Shire LLC(4) 9200 Brookfield Court Suites 105 & 108 Florence, KY 41042	4,000,000	7.2%	

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Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>Executive Officers and Directors:</b>			
Jack A. Khattar(5)	6,088,235	10.9%	
Russell P. Wilson		*	
Paolo Baroldi, M.D., Ph.D.(6)	50,000	*	
Padmanabh P. Bhatt, Ph.D.(7)	259,000	*	
Jones W. Bryan, Ph.D.(8)	259,000	*	
M. James Barrett, Ph.D.(9)	25,000,000	45.1%	
Michael Bigham(10)	10,000,000	18.1%	
Frederick M. Hudson(11)		*	
Charles W. Newhall, III(12)	25,000,000	45.1%	
William A. Nuerge	35,000	*	
Michael B. Sheffery, Ph.D.(13)	10,000,000	18.1%	
All executive officers and directors as a group (12 persons)(14)	51,766,235	92.4%	

\*

Less than one percent.

(1)

Consists of (a) 24,965,000 shares of common stock issuable upon the automatic conversion of 24,965,000 shares of Series A convertible preferred stock held by New Enterprise Associates 11, Limited Partnership, or NEA 11; and (b) 35,000 shares of common stock issuable upon the automatic conversion of 35,000 shares of Series A convertible preferred stock held by NEA Ventures 2005, L.P., or Ven 2005. The shares directly held by NEA 11 are indirectly held by NEA Partners 11, Limited Partnership, or NEA Partners 11, the sole general partner of NEA 11, NEA 11 GP, LLC, or NEA 11 LLC, the sole general partner of NEA Partners 11, and each of the individual Managers of NEA 11 LLC. The individual Managers (collectively, the "Managers") of NEA 11 LLC are M. James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Krishna "Kittu" Kolluri, C. Richard Kramlich, Charles W. Newhall III, Mark W. Perry and Scott D. Sandell. NEA Partners 11, NEA 11 LLC and the Managers share voting and dispositive power over the shares directly held by NEA 11. The shares directly held by Ven 2005 are indirectly held by J. Daniel Moore, the general partner of Ven 2005, who holds voting and dispositive power over the shares directly held by Ven 2005. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein, if any.

(2)

Consists of 6,673,891 shares of common stock issuable upon the automatic conversion of 6,673,891 shares of Series A convertible preferred stock held by OrbiMed Private Investments II, LP; 2,498,842 shares of common stock issuable upon the automatic conversion of 2,498,842 shares of Series A convertible preferred stock held by OrbiMed Private Investments II (QP), LP; and 827,267 shares of common stock issuable upon the automatic conversion of 827,267 shares of Series A convertible preferred stock held by UBS Juniper Crossover Fund, L.L.C. OrbiMed Advisors LLC, or OrbiMed, a registered investment adviser under the Investment Advisers Act of 1940, as amended, is the managing member of OrbiMed Capital GP II LLC, which is the general partner of OrbiMed Private Investments II, LP and OrbiMed Private Investments II (QP), LP. Investment professionals employed by OrbiMed manage UBS Juniper Crossover Fund, L.L.C.'s investment portfolio on behalf of UBS Juniper Management, L.L.C. under the oversight of UBS Fund Advisor, L.L.C. Mr. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed. Accordingly, OrbiMed and Mr. Isaly may be deemed to have voting and investment power over the shares held by OrbiMed Private Investments II, LP, OrbiMed Private

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Investments II (QP), LP, and UBS Juniper Crossover Fund, L.L.C. noted above. OrbiMed and Mr. Isaly disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.

- (3) Consists of 9,915,000 shares of common stock issuable upon the automatic conversion of 9,915,000 shares of Series A convertible preferred stock held by Abingworth Bioventures IV LP, or ABV IV; and 85,000 shares of common stock issuable upon the automatic conversion of 85,000 shares of Series A convertible preferred stock held by Abingworth Bioventures IV Executives LP, or ABV IV Executives. Abingworth Management Limited, or AML, serves as investment manager of each of ABV IV and ABV IV Executives and may be deemed to share voting and dispositive power with respect to the securities owned by ABV IV and ABV IV Executives.
- (4) Consists of 4,000,000 shares of common stock issuable upon the automatic conversion of 4,000,000 shares of Series A convertible preferred stock held by Shire LLC. Shire LLC is an indirect, wholly-owned subsidiary of Shire plc. The directors of Shire plc are Mr. Matthew Emmens, Mr. Angus Russell, Mr. Graham Hetherington, Mr. David Kappler, Dr. Jeffrey Leiden, Mr. Bill Burns, Dr. David Ginsberg, Ms. Anne Minto, Mr. Patrick Langlois and Mr. David Stout. The board of directors of Shire plc may be deemed to have voting and investment control over the shares held by Shire LLC. The individuals noted above disclaim beneficial ownership of such shares.
- (5) Excludes 411,765 shares of non-vested restricted stock held by Mr. Khattar, which are subject to vesting based on the achievement of certain performance measures.
- (6) Consists of 50,000 shares of common stock issuable to Dr. Baroldi upon the exercise of options within 60 days of September 30, 2010.
- (7) Consists of 259,000 shares of common stock issuable to Dr. Bhatt upon the exercise of options within 60 days of September 30, 2010.
- (8) Consists of 259,000 shares of common stock issuable to Dr. Bryan upon the exercise of options within 60 days of September 30, 2010.
- (9) Consists of 25,000,000 shares of common stock issuable as described in note (1) above. Dr. Barrett, a member of our board, is a Manager of NEA 11 LLC, and disclaims beneficial ownership of the shares of capital stock held by NEA 11, except to the extent of his pecuniary interest therein, if any.
- (10) Consists of 10,000,000 shares of common stock issuable as described in note (3) above. Michael Bigham is a director of AML, and in such capacity may be deemed to beneficially own the securities owned of record by ABV IV and ABV IV Executives, but disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein, if any.
- (11) Mr. Hudson was appointed to our board on November 16, 2010.
- (12) Consists of 25,000,000 shares of common stock issuable as described in note (1) above. Mr. Newhall, a member of our board, is a Manager of NEA 11 LLC and disclaims beneficial ownership of the shares of capital stock held by NEA 11, except to the extent of his pecuniary interest therein, if any.
- (13) Consists of 10,000,000 shares of common stock issuable as described in note (2) above. Dr. Sheffery, a member of our board, is a member of OrbiMed, and disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein, if any.
- (14) Consists of 49,000,000 shares of common stock issuable upon the automatic conversion of 49,000,000 shares of Series A convertible preferred stock, and includes 643,000 shares of common stock issuance to our of directors and executive officers upon the exercise of options within 60 days of September 30, 2010.



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**DESCRIPTION OF CAPITAL STOCK**

**General**

Our Amended and Restated Certificate of Incorporation, which will become effective upon the closing of this offering, authorizes the issuance of up to        shares of common stock, par value \$0.001 per share, and        shares of preferred stock, par value \$0.001 per share. As of September 30, 2010, there were        shares of common stock outstanding (after giving effect to the automatic conversion of all outstanding shares of preferred stock into shares of common stock and the        for reverse stock split). As of September 30, 2010, we had approximately        record holders of our capital stock. All of our outstanding shares of preferred stock will automatically convert into shares of common stock upon the closing of this offering. After the closing of this offering and after giving effect to the conversion of our preferred stock and the        for reverse stock split, we will have        shares of common stock and no shares of preferred stock outstanding. In addition, as of September 30, 2010,        shares of our common stock were reserved for future grants under our 2005 Stock Plans, and options to purchase        shares of our common stock were outstanding.

The description below gives effect to the adoption of our Amended and Restated Bylaws and is qualified in its entirety by reference to these documents, copies of which are filed as exhibits to the registration statement of which this prospectus is a part.

**Common Stock**

Upon the completion of this offering, we will be authorized to issue one class of common stock. Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Except as described under " Antitakeover Effects of Delaware Law and Provisions of Our Certificate of Incorporation and Bylaws" below, a majority vote of the holders of common stock is generally required to take action under our amended and restated certificate of incorporation and amended and restated bylaws.

**Preferred Stock**

Upon the completion of this offering, our board of directors will be authorized, without action by the stockholders, to designate and issue up to an aggregate of        shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes, could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of our company, which might harm the market price of our common stock.

Our board of directors will make any determination to issue such shares based on its judgment as to our company's best interests and the best interests of our stockholders. Any shares of our Series A

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convertible preferred stock outstanding immediately prior to this offering will automatically convert into shares of our common stock on a one-for-one basis in connection with this offering. Upon the completion of this offering, we will have no shares of preferred stock outstanding and we have no current plans to issue any shares of preferred stock.

**Warrants**

In connection with our new secured credit facility, the lenders received from us ten-year warrants to purchase an aggregate of 375,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. These warrants will expire on January 26, 2021. In connection with any drawdown of additional term loans under our new secured credit facility, we would be required to issue to the lenders additional warrants to purchase up to 250,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. Upon completion of this offering, each warrant 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 of \$1.00. All of our warrant holders are subject to lock-up agreements with the underwriters that restrict the sale of our securities for 180 days. See "Underwriting" for a description of these lock-up agreements.

**Registration Rights**

***Demand Registration Rights***

After the expiration of the 180-day period following the completion of this offering (as may be extended under certain circumstances), the holders of approximately \_\_\_\_\_ shares of our common stock will be entitled to certain demand registration rights. If holders of registrable securities then outstanding request a registration having a reasonably anticipated aggregate offering price to the public of at least \$ \_\_\_\_\_, we may be required to register their shares. After the expiration of the 180-day period following the completion of this offering (as may be extended under certain circumstances), certain holders have the right to make two requests that we register all or a portion of their shares of our common stock.

***Piggyback Registration Rights***

After expiration of the 180-day period following the completion of this offering (as may be extended under certain circumstances), in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other stockholders, the holders of approximately \_\_\_\_\_ shares of our common stock will be entitled to certain "piggyback" registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to the shares issuable upon conversion of debt securities or employee benefit plans, the holders of these shares of our common stock are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

***Form S-3 Registration Rights***

After the expiration of a 180-day period following the completion of this offering (as may be extended under certain circumstances), the holders of approximately \_\_\_\_\_ shares will be entitled to certain Form S-3 registration rights if we are eligible to file a registration statement on Form S-3. As a result, these holders will have the right to demand that we file a registration statement on Form S-3 so long as the aggregate value of the securities to be sold under the registration statement on Form S-3 is at least \$500,000, subject to specified exceptions.

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**Antitakeover Effects Of Delaware Law And Provisions Of Our Certificate Of Incorporation And Bylaws**

***Delaware Takeover Statute***

We are subject to Section 203 of the Delaware General Corporation Law. This statute regulating corporate takeovers prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for three years following the date that the stockholder became an interested stockholder, unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the interested stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers, and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66<sup>2</sup>/<sub>3</sub>% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is any person who, together with such person's affiliates and associates (i) owns 15% or more of a corporation's voting securities or (ii) is an affiliate or associate of a corporation and was the owner of 15% or more of the corporation's voting securities at any time within the three year period immediately preceding a business combination of the corporation governed by Section 203. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board does not approve in advance. We also anticipate that Section 203 may discourage takeover attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

**Certificate Of Incorporation And Bylaw Provisions**

Provisions of our certificate of incorporation and bylaws, which will be effective upon the closing of this offering, may have the effect of making it more difficult for a third party to acquire, or discourage a third party from attempting to acquire, control of our company by means of a tender offer, a proxy contest or otherwise. These provisions may also make the removal of incumbent officers and directors more difficult. These provisions are intended to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with us. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions may make it more difficult for stockholders to take specific corporate actions and could have the effect of delaying or preventing a change in control.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is .

**Listing**

We have applied to list our shares of common stock for quotation on The NASDAQ Global Market under the symbol "SUPN."



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**SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has been no public market for our common stock, and there can be no assurance that a significant public market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding options or warrants, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon completion of this offering, we will have \_\_\_\_\_ shares of common stock outstanding, assuming (1) the conversion of all outstanding shares of preferred stock, (2) no exercise of any options outstanding as of September 30, 2010, (3) no exercise of any warrants to purchase shares outstanding as of the date of this prospectus and (4) no exercise of the underwriters' option to purchase additional shares from us. All shares sold in this offering, plus any shares issued upon exercise of the underwriters' option to purchase additional shares from us, will be freely tradable without restriction under the Securities Act, unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act. The remaining \_\_\_\_\_ shares of common stock outstanding are "restricted securities" within the meaning of Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 701 or meet the safe harbor qualifications under Rule 144 under the Securities Act as summarized below.

The holders of \_\_\_\_\_ shares of outstanding common stock as of the closing of this offering and the holders of \_\_\_\_\_ shares of common stock underlying options or warrants as of the closing of this offering, including all of our officers and directors, have entered into lock-up agreements with the underwriters pursuant to which they have generally agreed, subject to certain exceptions, not to offer or sell any shares of common stock or securities convertible into or exchangeable or exercisable for shares of common stock for a period of 180 days from the date of this prospectus without the prior written consent of Citigroup Global Markets Inc. and Barclays Capital Inc. At any time and without public notice, Citigroup Global Markets Inc. and Barclays Capital Inc. may, in their sole discretion, release some or all of the securities from these lock-up agreements. In general, if (i) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to our company occurs; or (ii) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event. See "Underwriting."

**Rule 144**

In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, a person who is one of our affiliates and has beneficially owned shares of our common stock for at least six months would be entitled to sell within any three month period a number of shares that does not exceed the greater of:

one percent of the number of shares of common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after the completion of this offering; or

the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

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In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than an affiliate, is entitled to sell the shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, and will be subject only to the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144.

Shares of our common stock will qualify for resale under Rule 144 within 180 days of the date of this prospectus, subject to the lock-up agreements as described herein and under "Underwriting" in this prospectus, and to the extent such shares have been released from any repurchase option that we may hold.

**Rule 701**

Any of our employees, officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701. Rule 701 permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. Rule 701 further provides that non-affiliates may sell such shares in reliance on Rule 144 without having to comply with the holding period, public information, volume limitation or notice provisions of Rule 144.

Neither Rule 144 nor Rule 701 supersedes the contractual obligations of our security holders set forth in the lock-up agreements described above.

**Lock-up Agreements**

We, our officers and directors, and our other stockholders have agreed, subject to certain exceptions, that, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup Global Markets Inc. and Barclays Capital Inc., dispose of or hedge any shares or any securities convertible into or exchangeable for our common stock. Citigroup Global Markets Inc. and Barclays Capital Inc. in their sole discretion may release any of the securities subject to these lock-up agreements at any time without notice. Notwithstanding the foregoing, if (i) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to our company occurs; or (ii) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

**Registration Rights**

After the expiration of the 180-day period following the completion of this offering (as may be extended under certain circumstances), holders of our preferred stock convertible into 49,000,000 shares of our common stock have demand and piggyback registration rights with respect to the shares of common stock to be issued upon conversion of their preferred stock. By exercising their registration rights and causing a large number of shares to be registered and sold in the public market, these holders could cause the price of our common stock to fall. In addition, any demand to include such shares in our registration statements could have a material adverse effect on our ability to raise needed capital. For more information about these registration rights, see "Description of Capital Stock Registration Rights."

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**Stock Options**

As of September 30, 2010, under our 2005 Stock Plan, we had outstanding options to purchase                shares of common stock.

As soon as practicable after completion of this offering, we intend to register the shares of our common stock subject to the options outstanding or reserved for issuance under this plan on a registration statement on Form S-8 under the Securities Act. Subject to the lock-up agreements and the restrictions imposed under the 2005 Stock Plan, shares of common stock issued pursuant to this plan after the effective date of the registration statement on Form S-8 will be available for sale in the public market without restriction to the extent that they are held by persons who are not our affiliates.

**Warrants**

As of September 30, 2010, we had no outstanding warrants to purchase shares of Series A convertible preferred stock. In connection with our new secured credit facility, the lenders received from us ten-year warrants to purchase an aggregate of 375,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. In connection with any drawdown of additional term loans under our new secured credit facility, we would be required to issue to the lenders additional warrants to purchase up to 250,000 shares of our Series A convertible preferred stock at an exercise price of \$1.00 per share. Upon completion of this offering, each warrant 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 of \$1.00.

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**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS  
FOR NON-U.S. HOLDERS OF COMMON STOCK**

The following is a summary of certain material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our common stock by Non-U.S. Holders, but does not purport to be a complete analysis of all the potential tax considerations. For purposes of this summary, a "Non-U.S. Holder" means a beneficial owner of common stock that for U.S. federal income tax purposes is:

a non-resident alien individual;

a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of a jurisdiction other than the U.S., any state thereof, or the District of Columbia;

an estate, other than an estate the income of which is subject to U.S. federal income tax regardless of its source; or

a trust, other than a trust (a) the administration of which is subject to the primary supervision of a court within the United States and which has one or more U.S. persons have the authority to control all substantial decisions of the trust, or (b) that has a valid election to be treated as a U.S. person.

If a partnership (or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner will generally depend upon the status of the partners and the activities of the partnership. Accordingly, we urge partnerships that hold our common stock and partners in such partnerships to consult their tax advisors.

This summary assumes that a Non-U.S. Holder will hold our common stock issued by this offering as a capital asset. This summary is general in nature and thus does not purport to deal with all aspects of U.S. federal income taxation that might be relevant to a particular Non-U.S. Holder in light of their particular investment circumstances or status, nor does it address specific tax considerations that may be relevant to particular persons (including, for example, financial institutions, broker-dealers, insurance companies, partnerships or other pass-through entities, regulated investment companies, real estate investment trusts, grantor trusts, certain U.S. expatriates, pension plans, tax-exempt organizations, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, persons that receive shares of our common stock in connection with services provided, or persons in special situations, such as those who have elected to mark securities to market or those who hold common stock as part of a straddle, hedge, conversion transaction or other integrated investment). In addition, this summary does not address U.S. federal alternative minimum, estate and gift tax considerations (except to the extent discussed below) or considerations under the tax laws of any state, local or non-U.S. jurisdiction.

This summary is based on the Internal Revenue Code of 1986, as amended (the "Code"), the Treasury regulations promulgated or proposed thereunder and administrative and judicial interpretations thereof, all as of the date hereof and all of which are subject to change at any time, possibly on a retroactive basis. Any change could alter the tax consequences to Non-U.S. Holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this prospectus.

**This summary is for general information only. Non-U.S. Holders are urged to consult their tax advisors concerning the U.S. federal, state, local and non-U.S. taxation and other tax consequences to them of the purchase, ownership and disposition of our common stock, as well as the application of U.S. federal, state, local and non-U.S. income and other tax laws.**

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**Distributions**

In the event that we do make a distribution of cash or property with respect to our common stock, any such distributions will be treated as a dividend for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Any distribution not treated as a dividend will be treated first as a tax-free return of capital to the extent of the Non-U.S. Holder's tax basis in our common stock and thereafter as capital gain from the sale or exchange of such stock as described in the next section. Dividends paid to a Non-U.S. Holder generally will be subject to a 30% U.S. federal withholding tax unless such Non-U.S. Holder provides us, or our agent, as the case may be, with a properly executed:

1. IRS Form W-8BEN (or successor form) claiming, under penalties of perjury, a reduction in withholding under an applicable income tax treaty, or
2. IRS Form W-8ECI (or successor form) stating that a dividend paid on common stock is not subject to withholding tax because it is effectively connected with a U.S. trade or business of the Non-U.S. Holder (in which case such dividend generally will be subject to regular graduated U.S. tax rates as described below).

The certification requirement described above also may require a Non-U.S. Holder to obtain a U.S. taxpayer identification number. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the Non-U.S. Holder's behalf, the Non-U.S. Holder will be required to provide appropriate documentation to such agent. The agent will then be required to provide certification to us, or our paying agent, as the case may be, either directly or through other intermediaries.

Each Non-U.S. Holder is urged to consult its own tax advisor about the specific methods for satisfying these requirements. A claim for exemption will not be valid if the person receiving the applicable form has actual knowledge or reason to know that the statements on the form are false.

If a Non-U.S. Holder is eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty, such holder may obtain a refund or credit of any excess amount withheld by timely filing an appropriate claim for refund with the IRS.

If dividends are effectively connected with a U.S. trade or business of the Non-U.S. Holder (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment), the Non-U.S. Holder, although exempt from the withholding tax described above (provided that the certifications described above are satisfied), will be subject to U.S. federal income tax on such dividends on a net income basis in the same manner as if it were a resident of the United States. In addition, if such Non-U.S. Holder is a non-U.S. corporation and dividends are effectively connected with its U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment), such Non-U.S. Holder may be subject to an additional "branch profits tax" equal to 30% (unless reduced by an applicable income treaty) in respect of such effectively-connected income.

**Taxable Disposition of Our Common Stock**

A Non-U.S. Holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of a share of our common stock, unless:

the gain is effectively connected with a trade or business of the Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment);

the Non-U.S. Holder is a nonresident alien who is present in the United States for 183 days or more in the taxable year of the disposition and meets certain other conditions; or

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we are or have been a "United States real property holding corporation," as defined in the Code (a "USRPHC"), at any time within the shorter of the five-year period preceding the disposition and the Non-U.S. Holder's holding period the share our common stock.

If a Non-U.S. Holder is engaged in a trade or business in the U.S. and gain recognized by the Non-U.S. Holder on a sale or other disposition of our common stock is effectively connected with the conduct of such trade or business, the Non-U.S. Holder will generally be subject to regular U.S. income tax as if the Non-U.S. Holder were a U.S. person, subject to an applicable income tax treaty providing otherwise. Additionally, a non-U.S. corporation may also, under certain circumstances, be subject to an additional "branch profits tax" imposed at a rate of 30% (or, if applicable, a lower income tax treaty rate). Non-U.S. Holders whose gain from dispositions of our common stock may be effectively connected with the conduct of a trade or business in the United States are urged to consult their own tax advisors with respect to the U.S. tax consequences of the purchase, ownership and disposition of our common stock.

A nonresident alien who is subject to U.S. federal income tax because such individual was present in the United States for 183 days or more in the taxable year of the taxable disposition of our common stock will be subject to a flat 30% tax on the gain derived from such disposition, which may be offset by U.S. source capital loss.

We believe that we are not, and do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, a Non-U.S. Holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock so long as our common stock continues to be regularly traded on an established securities market and such Non-U.S. Holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of our common stock at any time during the shorter of the five year period ending on the date of disposition and the holder's holding period. There can be no assurance that our common stock will qualify as regularly traded on an established market.

**Information Reporting and Backup Withholding**

Generally, we must report annually to the IRS and to each Non-U.S. Holder certain information including the Non-U.S. Holder's name, address and taxpayer identification number, the aggregate amount of distributions on our common stock paid to that Non-U.S. Holder during the calendar year and the amount of tax withheld, if any. Pursuant to tax treaties and certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Backup withholding tax is imposed on dividends and certain other types of payments to certain U.S. persons. Backup withholding tax will not apply to payments of dividends on common stock or proceeds from the sale of common stock payable to a Non-U.S. Holder if the certification described above in "Distributions" is duly provided by such Non-U.S. Holder or the Non-U.S. Holder otherwise establishes an exemption, provided that the payor does not have actual knowledge or reason to know that the Holder is a U.S. person or that the conditions of any claimed exemption are not satisfied. Certain information reporting may still apply to distributions even if an exemption from backup withholding is established.

Backup withholding is not an additional tax and any amounts withheld under the backup withholding tax rules from a payment to a Non-U.S. Holder will be allowed as a refund or a credit against such Non-U.S. Holder's U.S. federal income tax liability, provided that the requisite procedures are followed.

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Non-U.S. Holders are urged to consult their own tax advisors regarding their particular circumstances and the availability of and procedure for obtaining an exemption from backup withholding.

**Recently enacted legislation affecting taxation of our common stock held by or through foreign entities**

Recently enacted legislation generally will impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to (a) a foreign financial institution unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners), or (b) a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. Holders are encouraged to consult with their own tax advisors regarding the possible implications of the legislation on their investment in our common stock.

**U.S. Federal Estate Tax**

Common stock owned or treated as owned by an individual who is a Non-U.S. Holder at the time of death generally will be included in the individual's gross estate for U.S. federal estate tax purposes and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise.

**THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW.**

Table of Contents**UNDERWRITING**

Citigroup Global Markets Inc. and Barclays Capital Inc. are acting as joint book-running managers of the offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter's name.

<b>Underwriter</b>	<b>Number of Shares</b>
Citigroup Global Markets Inc.	
Barclays Capital Inc.	
Cowen and Company, LLC	
Stifel, Nicolaus & Company, Incorporated	
Total	

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the shares (other than those covered by the over-allotment option described below) if they purchase any of the shares.

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed \$ \_\_\_\_\_ per share. If all the shares are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

If the underwriters sell more shares than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to \_\_\_\_\_ additional shares at the public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional shares approximately proportionate to that underwriter's initial purchase commitment. Any shares issued or sold under the option will be issued and sold on the same terms and conditions as the other shares that are the subject of this offering.

We, our officers and directors, and our other stockholders have agreed, subject to certain exceptions, that, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup Global Markets Inc. and Barclays Capital Inc., dispose of or hedge any shares or any securities convertible into or exchangeable for our common stock. Citigroup Global Markets Inc. and Barclays Capital Inc. in their sole discretion may release any of the securities subject to these lock-up agreements at any time without notice. Notwithstanding the foregoing, if (i) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to our company occurs; or (ii) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

Prior to this offering, there has been no public market for our shares. Consequently, the initial public offering price for the shares will be determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price will be our results of operations, our current financial condition, our future prospects, our markets, the



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economic conditions in and future prospects for the industry in which we compete, our management, and currently prevailing general conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our company. We cannot assure you, however, that the price at which the shares will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our shares will develop and continue after this offering.

We have applied to have our shares listed on the Nasdaq Global Market under the symbol "SUPN."

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option.

<b>Paid by Supernus Pharmaceuticals, Inc.</b>		
	<b>No Exercise</b>	<b>Full Exercise</b>
<b>Per share</b>	<b>\$</b>	<b>\$</b>
<b>Total</b>	<b>\$</b>	<b>\$</b>

In connection with the offering, the underwriters may purchase and sell shares in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the over-allotment option, and stabilizing purchases.

Short sales involve secondary market sales by the underwriters of a greater number of shares than they are required to purchase in the offering.

"Covered" short sales are sales of shares in an amount up to the number of shares represented by the underwriters' over-allotment option.

"Naked" short sales are sales of shares in an amount in excess of the number of shares represented by the underwriters' over-allotment option.

Covering transactions involve purchases of shares either pursuant to the over-allotment option or in the open market after the distribution has been completed in order to cover short positions.

To close a naked short position, the underwriters must purchase shares in the open market after the distribution has been completed. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

To close a covered short position, the underwriters must purchase shares in the open market after the distribution has been completed or must exercise the over-allotment option. In determining the source of shares to close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Stabilizing transactions involve bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum.

Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the shares. They may also cause the price of the shares to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may



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conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

Certain of the underwriters have performed commercial banking, investment banking and advisory services for us from time to time for which they have received customary fees and reimbursement of expenses. The underwriters may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. Cowen Healthcare Royalty Partners (CHRP), an affiliate of Cowen and Company, LLC, holds certain of the Non-recourse Notes issued by our subsidiary, TCD Royalty Sub LLC.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

**Notice to Prospective Investors in the European Economic Area**

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of shares described in this prospectus may not be made to the public in that relevant member state prior to the publication of a prospectus in relation to the shares that has been approved by the competent authority in that relevant member state or, where appropriate, approved in another relevant member state and notified to the competent authority in that relevant member state, all in accordance with the Prospectus Directive, except that, with effect from and including the relevant implementation date, an offer of securities may be offered to the public in that relevant member state at any time:

to any legal entity that is authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity that has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

to fewer than 100 natural or legal persons (other than qualified investors as defined below) subject to obtaining the prior consent of the representatives for any such offer; or

in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each purchaser of shares described in this prospectus located within a relevant member state will be deemed to have represented, acknowledged and agreed that it is a "qualified investor" within the meaning of Article 2(1)(e) of the Prospectus Directive.

For purposes of this provision, the expression an "offer to the public" in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

The sellers of the shares have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares as contemplated in this prospectus. Accordingly, no

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purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of the sellers or the underwriters.

**Notice to Prospective Investors in the United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a "relevant person"). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

**Notice to Prospective Investors in France**

Neither this prospectus nor any other offering material relating to the shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares has been or will be:

released, issued, distributed or caused to be released, issued or distributed to the public in France; or

used in connection with any offer for subscription or sale of the shares to the public in France.

Such offers, sales and distributions will be made in France only:

to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;

to investment services providers authorized to engage in portfolio management on behalf of third parties; or

in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).

The shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

**Notice to Prospective Investors in Hong Kong**

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the



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contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

**Notice to Prospective Investors in Japan**

The shares offered in this prospectus have not been registered under the Securities and Exchange Law of Japan. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan, except (i) pursuant to an exemption from the registration requirements of the Securities and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

**Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;

where no consideration is or will be given for the transfer; or

where the transfer is by operation of law.

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**LEGAL MATTERS**

Our counsel, Ropes & Gray LLP, Boston, Massachusetts, will pass on the validity of the shares of common stock offered by this prospectus. Goodwin Procter LLP, Boston, Massachusetts, has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

**EXPERTS**

The consolidated financial statements of Supernus Pharmaceuticals, Inc. at December 31, 2009 and 2008, and for each of the three years in the period ended December 31, 2009, appearing in this prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

**MARKET AND INDUSTRY DATA**

Market data and certain industry data and forecasts included in this prospectus were obtained from internal company surveys, market research, consultant surveys, publicly available information and industry publications and surveys. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions we use are appropriate, neither such research nor these definitions have been verified by any independent source. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors."

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all of the information set forth in the registration statement and the exhibits filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The reports and other information we file with the SEC can be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C. 20549. Copies of these materials can be obtained at prescribed rates from the SEC's Public Reference Room at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. The SEC also maintains a web site (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Upon completion of this offering, we will become subject to the reporting and information requirements of the Exchange Act and, as a result, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference room and the web site of the SEC referred to above.

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**Supernus Pharmaceuticals, Inc.**

**Index to Consolidated Financial Statements**

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<u>Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2007, 2008 and 2009 and the Nine Months Ended September 30, 2010 (unaudited)</u>	<u>F-5</u>
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**Report of Independent Registered Public Accounting Firm**

The Board of Directors  
Supernus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Supernus Pharmaceuticals, Inc. as of December 31, 2008 and 2009, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Supernus Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2009, and the consolidated results of their operations and their cash flows for the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

McLean, Virginia  
April 28, 2010

Table of Contents**Supernus Pharmaceuticals, Inc.****Consolidated Balance Sheets**

	December 31,		September 30,	Pro Forma Stockholders' Deficit at September 30,
	2008	2009	2010	2010
			(unaudited)	(unaudited)
<b>Assets</b>				
Current assets:				
Cash and cash equivalents	\$ 52,876,864	\$ 31,405,680	\$ 25,255,918	
Cash and cash equivalents restricted	6,110,718	1,850,912	1,442,101	
Marketable securities	7,502,636	35,118,047	20,566,385	
Marketable securities restricted	169,621	224,861	237,656	
Accounts receivable	2,276,420	3,407,770	3,033,067	
Interest receivable		334,417	85,802	
Prepaid expenses	252,511	266,924	351,086	
Deferred financing costs	268,560	270,934	270,934	
Total current assets	69,457,330	72,879,545	51,242,949	
Property and equipment, net	1,987,578	1,859,186	1,469,005	
Purchased patents, net	1,599,950	1,370,725	1,198,806	
Other assets	108,822	82,150	63,845	
Deferred financing costs, long-term	3,980,073	3,707,375	3,527,616	
Total assets	\$ 77,133,753	\$ 79,898,981	\$ 57,502,221	
<b>Liabilities and stockholders' deficit</b>				
Current liabilities:				
Accounts payable and accrued expenses	\$ 4,468,426	\$ 6,244,516	\$ 14,092,113	
Accrued compensation	1,305,572	1,287,620	815,598	
Interest payable	2,500,000	2,500,000	2,500,000	
Total current liabilities	8,273,998	10,032,136	17,407,711	
Deferred rent	437,439	797,145	773,664	
Supplemental executive retirement plan	169,621	224,861	237,656	
Non-recourse notes payable	75,000,000	75,000,000	75,000,000	
Total liabilities	83,881,058	86,054,142	93,419,031	
Stockholders' deficit:				
Series A convertible preferred stock, \$0.001 par value 49,000,000 shares authorized, issued and outstanding at December 31, 2008 and 2009 and September 30, 2010; aggregate liquidation preference of \$59,230,260, \$62,660,260 and \$65,232,760 at December 31, 2008, 2009, and September 30, 2010, respectively	49,000	49,000	49,000	
Common stock, \$0.001 par value 62,000,000 shares authorized, 5,520,591 and 6,336,061 shares issued and outstanding at December 31, 2008 and 2009, respectively and 6,371,061 shares issued and outstanding at September 30, 2010	5,521	6,337	6,372	55,372
Additional paid-in capital	48,980,411	49,110,087	49,237,544	49,237,544
Accumulated deficit	(55,782,237)	(55,320,585)	(85,209,726)	(85,209,726)
Total stockholders' deficit	(6,747,305)	(6,155,161)	(35,916,810)	(35,916,810)

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Total liabilities and stockholders' deficit	\$ 77,133,753	\$ 79,898,981	\$ 57,502,221
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See accompanying notes.

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Table of Contents**Supernus Pharmaceuticals, Inc.****Consolidated Statements of Operations**

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
	(unaudited)				
Revenues:					
Development and milestone revenue	\$ 1,405,098	\$ 2,697,048	\$ 1,549,886	\$ 1,181,058	\$ 97,174
Royalty revenue	2,828,313	6,191,616	44,963,260	41,883,532	8,634,848
Total revenues	4,233,411	8,888,664	46,513,146	43,064,590	8,732,022
Costs and expenses:					
Research and development	19,268,757	30,462,808	29,260,067	21,804,118	26,079,702
General and administrative	4,011,693	4,286,501	4,648,906	3,502,539	3,388,768
Total costs and expenses	23,280,450	34,749,309	33,908,973	25,306,657	29,468,470
Income (loss) from operations	(19,047,039)	(25,860,645)	12,604,173	17,757,933	(20,736,448)
Other income (expense):					
Interest income	1,772,999	1,057,462	514,327	100,640	622,854
Interest expense		(8,678,508)	(12,658,262)	(9,209,699)	(9,830,537)
Other					53,576
Total other income (expense)	1,772,999	(7,621,046)	(12,143,935)	(9,109,059)	(9,154,107)
Net income (loss)	\$ (17,274,040)	\$ (33,481,691)	\$ 460,238	\$ 8,648,874	\$ (29,890,555)
Cumulative dividends on preferred Series A convertible preferred stock					
	\$ (3,430,000)	\$ (3,430,000)	\$ (3,430,000)	\$ (2,572,500)	\$ (2,572,500)
Net income (loss) attributable to common stockholders	\$ (20,704,040)	\$ (36,911,691)	\$ (2,969,762)	\$ 6,076,374	\$ (32,463,055)
Net income (loss) per common share:					
Basic	\$ (4.21)	\$ (6.61)	\$ (0.53)	\$ 1.08	\$ (5.12)
Diluted	\$ (4.21)	\$ (6.61)	\$ 0.01	\$ 0.15	\$ (5.12)
Weighted average number of common shares:					
Basic	4,921,376	5,587,467	5,653,506	5,610,047	6,345,420
Diluted	4,921,376	5,587,467	56,324,761	56,282,411	6,345,420
Net income (loss) used to compute pro forma net income (loss) per common share basic and diluted (unaudited)(Note 2)					
			\$ 460,238		\$ (29,890,555)
Weighted-average number of shares used in calculating pro forma net income (loss) per share basic and diluted (unaudited)(Note 2)					
			56,324,761		55,345,420

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Pro forma net income (loss)  
per share basic and diluted  
(unaudited)(Note 2)

\$	0.01	\$	(0.54)
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See accompanying notes.

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Table of Contents**Supernus Pharmaceuticals, Inc.****Consolidated Statements of Changes in Stockholders' Equity (Deficit)**

	<b>Series A Convertible Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity (Deficit)</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>			
Balance, December 31, 2006	49,000,000	\$ 49,000	4,235,303	\$ 4,235	\$ 48,803,670	\$ (5,026,506)	\$ 43,830,399
Vesting of unvested stock issued to officer			617,644	618	61,146		61,764
Exercise of stock options			50,000	50	4,950		5,000
Stock-based compensation					12,336		12,336
Net loss						(17,274,040)	(17,274,040)
Balance, December 31, 2007	49,000,000	49,000	4,902,947	4,903	48,882,102	(22,300,546)	26,635,459
Vesting of unvested stock issued to officer			617,644	618	61,146		61,764
Stock-based compensation					37,163		37,163
Net loss						(33,481,691)	(33,481,691)
Balance, December 31, 2008	49,000,000	49,000	5,520,591	5,521	48,980,411	(55,782,237)	(6,747,305)
Vesting of unvested stock issued to officer			617,644	618	61,146		61,764
Exercise of stock options			197,826	198	19,585		19,783
Stock-based compensation					48,945		48,945
Net income						460,238	460,238
Other comprehensive income						1,414	1,414
Balance, December 31, 2009	49,000,000	49,000	6,336,061	6,337	49,110,087	(55,320,585)	(6,155,161)
Exercise of stock options (unaudited)			35,000	35	3,465		3,500
Stock-based compensation (unaudited)					123,992		123,992
Net loss (unaudited)						(29,890,555)	(29,890,555)
Other comprehensive income (unaudited)						1,414	1,414
Balance, September 30, 2010 (unaudited)	49,000,000	\$ 49,000	6,371,061	\$ 6,372	\$ 49,237,544	\$ (85,209,726)	\$ (35,916,810)

See accompanying notes

Table of Contents**Supernus Pharmaceuticals, Inc.****Consolidated Statements of Cash Flows**

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
				(unaudited)	
Operating activities					
Net income (loss)	\$ (17,274,040)	\$ (33,481,691)	\$ 460,238	\$ 8,648,874	\$ (29,890,555)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:					
Other					(53,576)
Unrealized gain (loss) on marketable securities			1,414	(2,778)	1,414
Depreciation and amortization	932,211	1,115,853	1,072,102	789,597	889,648
Amortization of deferred financing costs		178,508	270,324	202,742	179,759
Stock-based compensation expense	74,100	98,927	110,709	83,031	123,992
Changes in operating assets and liabilities:					
Accounts receivable	(413,853)	(1,163,482)	(1,131,350)	857,110	374,703
Interest receivable			(334,417)	(314,296)	248,615
Notes receivable from employee	(63,250)	63,250			
Prepaid expenses and other assets	88,602	(72,217)	12,259	(183,741)	(65,858)
Accounts payable, accrued expenses, and supplemental executive retirement plan	2,448,174	1,088,129	1,813,378	1,505,631	7,375,575
Interest payable		2,500,000			
Deferred rent	227,638	21,157	359,706	408,054	(23,481)
Net cash provided by (used in) operating activities	(13,980,418)	(29,651,566)	2,634,363	11,994,224	(20,839,764)
Cash flows from investing activities					
Purchases of marketable securities	(48,380,712)	(89,513,351)	(56,288,673)	(26,616,159)	(30,746,029)
Sales and maturities of marketable securities	64,297,060	105,128,173	28,618,022	7,510,559	45,297,692
Other					55,000
Purchases of property and equipment	(1,062,374)	(134,381)	(714,485)	(512,441)	(328,972)
Net cash provided by (used in) investing activities	14,853,974	15,480,441	(28,385,136)	(19,618,041)	14,277,691
Cash flows from financing activities					
Change in restricted cash and cash equivalents		(6,110,718)	4,259,806	2,526,002	408,811
Proceeds from issuance of common stock	5,000		19,783	19,383	3,500
Proceeds from issuance of note payable		75,000,000			
Deferred financing costs		(4,427,141)			
Net cash provided by financing activities	5,000	64,462,141	4,279,589	2,545,385	412,311
Net change in cash and cash equivalents	878,556	50,291,016	(21,471,184)	(5,078,432)	(6,149,762)
Cash and cash equivalents at beginning of period	1,707,292	2,585,848	52,876,864	52,876,864	31,405,680
Cash and cash equivalents at end of period	\$ 2,585,848	\$ 52,876,864	\$ 31,405,680	\$ 47,798,431	\$ 25,255,918
Supplemental cash flow information:					
Cash paid for interest	\$	\$ 6,000,000	\$ 12,000,000	\$ 9,000,000	\$ 9,090,378

See accompanying notes.





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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**1. Organization and Nature of Operations**

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

The Company is currently focused on attaining regulatory approval and bringing its two late-stage epilepsy product candidates, SPN-538 and Epliga, to market. Except for a one time profit in 2009, the Company has incurred net losses from operations since its inception. The Company had net income of approximately \$0.5 million during the year ended December 31, 2009 and a net loss of \$29.9 million during the nine months ended September 30, 2010. The Company has financed its operations primarily through the sale of equity securities, non-recourse debt arrangements, and payments received under its royalty and development agreements. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenues from product sales. Management expects operating losses to continue for the foreseeable future. The Company may need to obtain additional capital through equity offerings, debt financings and/or payments under new or existing licensing and research and development collaboration agreements. The Company expects its progress in the development of its pipeline to provide sufficient value inflection milestones, based on which the Company can continue to seek additional funding. The type, timing, and terms of financing, if required, selected by the Company will be dependent upon the Company's cash needs, the availability of financing sources, and the prevailing conditions in the financial markets. There can be no assurance that such financing will be available to the Company at any given time or available on favorable terms. If sufficient funds on acceptable terms are not available when needed, the Company could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs, which may have a material adverse effect on the Company's business, results of operations and financial condition.

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

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The Company's consolidated financial statements include the accounts of Supernus Pharmaceuticals, Inc. and its wholly-owned subsidiary, TCD Royalty Sub LLC, collectively referred to herein as "Supernus" or "the Company". All significant intercompany transactions and balances have been eliminated in consolidation. The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The Company currently operates in one business segment.

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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)**

**Use of Estimates**

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

**Unaudited Interim Financial Information**

The accompanying unaudited interim consolidated balance sheet as of September 30, 2010, the consolidated statements of operations and cash flows for the nine months ended September 30, 2010 and 2009, the consolidated statement of changes in stockholders' equity (deficit) for the nine months ended September 30, 2010, and the related interim information contained within the notes to the consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and the notes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of the Company's financial position at September 30, 2010 and results of its operations and its cash flows for the nine months ended September 30, 2010 and 2009. The results for the nine months ended September 30, 2010 are not necessarily indicative of future results. All references to September 30, 2010 or to the nine months ended September 30, 2010 and 2009 in the notes to the consolidated financial statements are unaudited.

**Unaudited Pro Forma Balance Sheet Presentation**

The unaudited pro forma balance sheet as of September 30, 2010, reflects the expected automatic conversion of the outstanding shares of Series A convertible preferred stock into 49,000,000 shares of common stock as though the completion of the Company's initial public offering (IPO) had occurred on September 30, 2010. The shares of common stock issued in the IPO and any related estimated net proceeds are excluded from such pro forma information.

**Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, TCD Royalty Sub LLC (TCD). TCD was formed for the purpose of issuing non-recourse notes payable secured by certain royalty payment and license rights (see Note 6). All intercompany balances and transactions have been eliminated in consolidation.

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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
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**2. Summary of Significant Accounting Policies (Continued)**

**Cash and Cash Equivalents and Restricted Cash**

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

Under the terms of a non-recourse note agreement, TCD is required to maintain a cash account to cover interest payments (see Note 6). These cash and cash equivalents are restricted as to their withdrawal or use and, therefore, are segregated and presented as restricted cash and cash equivalents.

**Marketable Securities**

Marketable securities consist of investments in U.S. Treasuries and various government agency debt securities, which mature in one year or less. At December 31, 2008, the Company held approximately \$7.5 million of auction rate securities which were sold at par value on January 2, 2009. Management classifies the Company's short-term investments as available-for-sale. Such securities are carried at estimated fair value, with any material unrealized holding gains or losses reported, net of any tax effects, as accumulated other comprehensive income (loss), which is a separate component of stockholders' equity (deficit). Realized gains and losses and declines in value judged to be other-than-temporary, if any, are included in results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income is recognized as interest income when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with highly rated financial institutions.

**Marketable Securities Restricted**

On January 21, 2006, the Company established the Supernus Supplemental Executive Retirement Plan (SERP) for the sole purpose of receiving funds for two executives from the Shire Laboratories, Inc. SERP and providing a continuing deferral program under the Supernus SERP. As of December 31, 2008 and 2009, the estimated fair value of the mutual fund investment securities within the SERP have been recorded as restricted marketable securities. A corresponding non-current liability is also included in the consolidated balance sheet to reflect the Company's obligation for the SERP. The Company has not made, and has no plans to make, contributions to the SERP. The securities can only be used for purposes of paying benefits under the SERP.

**Accounts Receivable**

Accounts receivable are reported in the balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company extends credit without requiring collateral. The Company writes off uncollectible receivables when the likelihood of collection is remote. The Company evaluates the collectability of accounts receivable on a regular basis. An allowance, when needed, is based upon various factors including the financial condition and payment history of customers, an overall review of

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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)**

collections experience on other accounts, and economic factors or events expected to affect future collections experience. No allowance was recorded as of December 31, 2008 and 2009.

**Concentration of Credit Risk**

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

Substantially all of the Company's cash and cash equivalents are maintained with major financial institutions in the United States. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, management believes they bear minimal risk. The Company has not experienced any losses on its deposits of cash, cash equivalents, short-term investments and restricted investments and management believes that its guidelines for investment of its excess cash maintain safety and liquidity through diversification and investment maturity.

**Fair Value of Financial Instruments**

The carrying amounts of financial instruments, including cash and cash equivalents, accounts receivable, and accounts payable and accrued expenses approximate fair value due to their short-term maturities. The carrying value and the estimated fair value of the non-recourse notes payable, was approximately \$75.0 million and \$66.0 million, respectively, at December 31 2008, December 31, 2009, and September 30, 2010. The fair value was estimated based on actual trade information as well as quoted prices provided by bond traders.

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

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. The Company reports assets and liabilities that are measured at fair value using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Table of Contents**Supernus Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)**

Level 2 Inputs are quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 Unobservable inputs that reflect the Company's own assumptions, based on the best information available, including the Company's own data.

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

<b>Fair Value Measurements at December 31, 2008</b>				
	<b>Total Carrying Value at December 31, 2008</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Cash and cash equivalents	\$ 52,876,864	\$ 52,876,864	\$	\$
Cash equivalents restricted	6,110,718	6,110,718		
Marketable securities	7,502,636		7,502,636	
Marketable securities restricted	169,621		169,621	
Total assets at fair value	\$ 66,659,839	\$ 58,987,582	\$ 7,672,257	\$

<b>Fair Value Measurements at December 31, 2009</b>				
	<b>Total Carrying Value at December 31, 2009</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Cash and cash equivalents	\$ 31,405,680	\$ 31,405,680	\$	\$
Cash equivalents restricted	1,850,912	1,850,912		
Marketable securities	35,118,047	35,118,047		
Marketable securities restricted	224,861		224,861	
Total assets at fair value	\$ 68,599,500	\$ 68,374,639	\$ 224,861	\$

Table of Contents**Supernus Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)**

	Fair Value Measurements at September 30, 2010			
	Total Carrying Value at September 30, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	\$ 25,255,918	\$ 25,255,918	\$	\$
Cash equivalents restricted	1,442,101	1,442,101		
Marketable securities	20,566,385	20,566,385		
Marketable securities restricted	237,656		237,656	
Total assets at fair value	\$ 47,502,060	\$ 47,264,404	\$ 237,656	\$

The Company's Level 1 assets include money market funds and U.S. Treasuries and government agency debt securities with quoted prices in active markets. At December 31, 2008, Level 2 assets include auction rate securities and mutual funds the SERP assets are invested in. At December 31, 2009 and September 30, 2010, Level 2 assets include mutual funds the SERP assets are invested in. Mutual funds and auction rate securities are valued using third-party pricing sources that apply applicable inputs and other relevant data into their models to estimate fair value.

**Property and Equipment**

Property and equipment are stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are computed using the straight-line method over the following average useful lives:

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

**Intangible Assets**

Intangible assets consist primarily of patents. Patents are carried at cost less accumulated amortization which is calculated on a straight-line basis over the estimated useful lives of the patents, estimated to be 10 years. The carrying value of the patents is assessed for impairment annually during the fourth quarter of each year, or more frequently if impairment indicators exist.

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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)**

**Impairment of Long-Lived Assets**

Long-lived assets consist primarily of patents and property and equipment. The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. Evaluating for impairment requires judgment, including the estimation of future cash flows, future growth rates and profitability and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of the intangible asset over its estimated fair value. For the years ended December 31, 2007, 2008 and 2009, the Company determined that there was no impairment of the Company's intangible assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. As of December 31, 2008 and 2009, and September 30, 2010, the Company determined that there were no impaired assets and had no assets intended for disposal.

**Preclinical Study and Clinical Trial Accruals and Deferred Advance Payments**

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

**Income Taxes**

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

The Company accounts for uncertain tax positions in the financial statements when it is more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. The adoption had no impact on the Company's

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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)**

results of operations, financial position or cash flows. The Company's policy is to recognize any interest and penalties related to income taxes in income tax expense.

**Revenues**

The Company's revenues have been generated through research and development agreements. These agreements included fees for development services provided to customers and payments for achievement of specified development, regulatory and sales milestones, which comprise our development and milestone revenues, as well as royalties on product sales of licensed products, Oracea®, SancturaXR®, and Intuniv®, which comprise our royalty revenues. For multiple element arrangements, the Company evaluates the components of each arrangement as separate elements based on certain criteria. Accordingly, revenues from collaboration agreements are recognized based on the performance requirements of the agreements. The Company recognizes revenue when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collection is reasonably assured.

The Company's development revenues have been earned under contracts which were less than one year in duration. Development contracts generally take the form of fee-for-service arrangements based on an annual contractual full time equivalent billing rate. In cases where performance spanned multiple accounting periods, the Company has recognized revenue as services were performed, measured on a proportional-performance basis. Output measures, specifically labor hours, were used to measure performance as they reflect the Company's pattern of performance over the contractual term. Milestone payments are recognized as revenue when the collaborative partner acknowledges completion of the milestone and substantive effort was necessary to achieve the milestone.

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

In 2009, the Company recognized approximately \$36.9 million in royalty revenues related to an amendment to a license agreement with Shire plc for Intuniv, which is a novel ADHD product marketed by Shire plc and utilizes one of the Company's proprietary technologies. Under the terms of the license amendment, the parties agreed to delete all provisions regarding milestone and royalty payments and replaced those provisions with, among other things, (1) a commitment by Shire plc to make a one-time payment of \$36,875,000 within 15 days of signing the amendment, (2) an acknowledgement by the Company that no other sums would be payable to the Company, then or in the future, under the amended license; and (3) a statement that the amended license was permanent, irrevocable and paid-up. The Company determined to recognize this revenue immediately because



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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)**

(1) the executed contracted constituted persuasive evidence of an arrangement, (2) the delivery of the license amendment had occurred and Shire plc had assumed all risks and rewards regarding Intuniv, and the Company had no current or future performance obligations, (3) the total consideration for the license amendment was fixed and known at the time of its execution and there were not any extended payment terms or rights of return, and (4) collection was reasonably assured as the Company determined that Shire plc was creditworthy and had the financial ability to make the payment in accordance with the terms of the license amendment.

**Research and Development Costs**

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee related expenses, including salaries and benefits, expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct the Company's clinical trials, the cost of acquiring and manufacturing clinical trial materials, facilities that do not have an alternative future use, related depreciation and other allocated expenses, license fees for and milestone payments related to in-licensed products and technologies, stock-based compensation expense, and costs associated with non-clinical activities and regulatory approvals.

**Stock-Based Compensation**

Employee stock-based compensation is measured based on the estimated fair value on the grant date. The grant date fair value of options granted is calculated using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility, expected term, and the fair value of the underlying common stock. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures.

The Company has awarded non-vested stock. The estimated fair value of these awards is determined at the date of grant based upon the estimated fair value of the Company's common stock. The Company recognizes the estimated fair value on a straight-line basis over the requisite service period as the awards vest.

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

The Company records the expense of services rendered by non-employees based on the estimated fair value of the stock option using the Black-Scholes option-pricing model. The fair value of non-employee awards are remeasured at each reporting period. As a result, stock compensation expense for non-employee awards with vesting is affected by changes in the fair value of the Company's common stock.

Table of Contents**Supernus Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
nine month periods ended  
September 30, 2009 and 2010**

**2. Summary of Significant Accounting Policies (Continued)****Net Earnings (Loss) Per Share**

Basic net income (loss) per common share is determined by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants and the if-converted method is used to determine the dilutive effect of the Company's Series A convertible preferred stock. With the exception of the year ended December 31, 2009 and the nine month period ended September 30, 2009, the weighted-average shares used to calculate both basic and diluted loss per share are the same. The following common stock equivalents were excluded in the calculation of diluted net income (loss) per share because their effect would be anti-dilutive:

	<b>December 31,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>
Series A convertible preferred stock	49,000,000	49,000,000		49,000,000
Stock options and non-vested stock	2,382,389	2,183,152		1,791,290

The pro forma net income (loss) per share is computed using the weighted-average number of common shares outstanding and assumes 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 the Company's planned IPO, as if they had converted at the beginning of the period. The Company believes the unaudited pro forma net income (loss) per share provides material information to investors, as the conversion of the Company's Series A convertible preferred stock to common stock is expected to occur upon the closing of an IPO, and the disclosure of pro forma net

Table of Contents**Supernus Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
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**2. Summary of Significant Accounting Policies (Continued)**

income (loss) per share thus provides an indication of net income (loss) per share that is comparable to what will be reported by the Company as a public company.

	<b>December 31, 2009</b>	<b>September 30, 2010</b>
	<b>(unaudited)</b>	
<b>Pro forma net income (loss) per common share</b>		
Numerator:		
Net income (loss) used to compute pro forma net income (loss) per common share:		
Basic	\$ 460,238	\$ (29,890,555)
Diluted	\$ 460,238	\$ (29,890,555)
Denominator:		
Weighted-average number of common shares, used to calculate net income (loss) per common share:		
Basic	5,653,506	6,345,420
Diluted	*56,324,761	6,345,420
Add: Pro forma adjustments to reflect assumed weighted-average effect of conversion of Series A convertible preferred stock	49,000,000	49,000,000
Weighted-average number of common shares used in calculating pro forma net income (loss) per common share:		
Basic	56,324,761	55,345,420
Diluted	56,324,761	55,345,420
Pro forma net income (loss) per common share:		
Basic	\$ 0.01	\$ (0.54)
Diluted	\$ 0.01	\$ (0.54)

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The weighted-average number of common shares used to calculate diluted income (loss) per share at December 31, 2009 includes the following common stock equivalents, which were not included in the calculation of basic net income (loss) per share because their effect would be anti-dilutive:

Series A convertible preferred stock	49,000,000
Stock options and non-vested stock	1,671,255

### Recently Issued Accounting Pronouncements

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition Milestone Method* (ASU 2010-017). ASU 2010-017 provides guidance in applying the milestone method of revenue recognition to research or development arrangements. This guidance concludes that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance is effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this accounting standard is not expected to impact the Company's financial position or results of operations.

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**Supernus Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
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**2. Summary of Significant Accounting Policies (Continued)**

In February 2010, the FASB issued amended guidance on subsequent events. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and the Company adopted these new requirements upon issuance of this guidance.

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements* (ASU No. 2010-06). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances, and settlements be disclosed on gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities; and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 becomes effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances, and settlements of Level 3 assets and liabilities which will be effective for fiscal years beginning after December 15, 2010. The Company is currently assessing what impact, if any, ASU No. 2010-06 will have on its fair value disclosures. However, the Company does not expect the adoption of the guidance provided in this codification update to have any material impact on its consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (Topic 605) Multiple-Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force* (ASU 2009-13). ASU 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available, third-party evidence, if VSOE is unavailable, and estimated selling prices if neither VSOE or third-party evidence is available. In addition, ASU 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. ASU 2009-13 will be effective prospectively for multiple-deliverable revenue arrangements entered into, or materially modified, in fiscal years beginning on or after June 15, 2010. Presently, the Company is assessing what impact, if any, the adoption of ASU 2009-13 may have on its consolidated financial statements.

In August 2009, the FASB issued ASU No. 2009-05, *Fair Value Measurements and Disclosures (Topic 820) Measuring Liabilities at Fair Value* (ASU 2009-05). ASU 2009-05 provides guidance in measuring the fair value of a liability when a quoted price in an active market does not exist for an identical liability or when a liability is subject to restrictions on its transfer. ASU 2009-15 was effective for the Company beginning with the quarter ended December 31, 2009. The adoption of ASU 2009-05 had no impact on the fair value measurements of the Company's liabilities.

Table of Contents**Supernus Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)**

**December 31, 2007, 2008 and 2009 and the unaudited  
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**3. Marketable Securities**

Marketable securities held by the Company were as follows:

At December 31, 2008:

<b>Available-for-Sale</b>	<b>Amortized Cost</b>	<b>Unrealized Gains/(Losses)</b>	<b>Fair Value</b>
Auction rate securities	\$ 7,502,636	\$	\$ 7,502,636
Mutual funds for SERP	169,621		169,621
	\$ 7,672,257	\$	\$ 7,672,257

At December 31, 2009:

<b>Available-for-Sale</b>	<b>Amortized Cost</b>	<b>Unrealized Gains/(Losses)</b>	<b>Fair Value</b>
U.S. Treasuries and agencies	\$ 35,116,363	\$ 1,414	\$ 35,118,047
Mutual funds for SERP	224,861		224,861
	\$ 35,341,224	\$ 1,414	\$ 35,342,908

At September 30, 2010: