SUPERNUS PHARMACEUTICALS INC Form 424B4 November 30, 2012

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Filed Pursuant to Rule 424(b)(4) Registration No. 333-184930

#### PROSPECTUS

# 6,000,000 Shares

# Supernus Pharmaceuticals, Inc.

# **Common Stock**

We are offering 6,000,000 shares of our common stock. Our common stock is listed on The NASDAQ Global Market under the symbol "SUPN". On November 29, 2012, the last reported sale price of our common stock on The NASDAQ Global Market was \$9.83 per share.

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

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

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

	-	ER ARE	TOTAL
Public Offering Price	\$	8.00	\$ 48,000,000
Underwriting Discounts and Commissions <sup>(1)</sup>	\$	0.48	\$ 2,880,000
Proceeds to Supernus, before expenses	\$	7.52	\$ 45,120,000

(1)

See "Underwriting" for additional disclosure regarding underwriting commission and expenses.

Delivery of the shares of common stock is expected to be made on or about December 5, 2012. We have granted the underwriters an option for a period of 30 days to purchase an additional 900,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$3,312,000, and the total proceeds to us, before expenses, will be \$51,888,000.

Joint Book-Running Managers

Jefferies	Piper Jaffray	Cowen and Company
	Co-Managers	

Stifel Nicolaus Weisel

Prospectus dated November 30, 2012

Lazard Capital Markets

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

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#### SUMMARY

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

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

#### Supernus Pharmaceuticals, Inc.

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system, or CNS, diseases. Our extensive expertise in product development has been built over the past 20 years: initially as a stand alone development organization, then as a U.S. subsidiary of Shire plc and, upon our acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals, Inc. We are planning for the commercial launch of two neurology products for the treatment of epilepsy in 2013 and are developing multiple product candidates in psychiatry to address the large market opportunity in attention deficit hyperactivity disorder, or ADHD, including ADHD patients with impulsive aggression. We intend to market our products in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists, and to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

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

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

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

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

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

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

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

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

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

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

Oxtellar XR (extended release oxcarbazepine)

Oxtellar XR is a novel oral once-daily extended release formulation of oxcarbazepine for which we received final FDA approval in October 2012, as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age. Oxcarbazepine is marketed by Novartis under the brand name Trileptal and is available in a generic form. Trileptal is indicated for monotherapy and adjunctive therapy of epilepsy. Oxcarbazepine is an active voltage-dependent sodium channel blocker that, despite its effectiveness in treating epilepsy, is associated with many side effects that tend to limit its use. The side effects associated with taking oxcarbazepine include, among others, dizziness, double vision, somnolence, nausea and vomiting.

With a novel pharmacokinetic profile that delivers lower peak plasma concentrations, a slower rate of input and smoother, more consistent blood levels compared to immediate release products such as Trileptal, we believe Oxtellar XR has the potential of improving the tolerability of oxcarbazepine by reducing the side effects experienced by patients. We were granted three year market exclusivity for Oxtellar XR, and anticipate the commercial launch of Oxtellar XR during the first quarter of 2013.

(1)

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

(2)

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

- Balzac, F., Medication Noncompliance in Epilepsy, published March 2006 in Neurology Reviews.
- (4) Miller, A.D., *Improved CNS tolerability following conversion from immediate- to extended-release carbamazepine*, published June 2004 in *Acta Neurologica Scandinavia*.

# (5)

(3)

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

(6)

IMS Health data.

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#### Trokendi XR (extended release topiramate)

Trokendi XR is a novel oral once-daily extended release topiramate product for the treatment of epilepsy for which we received tentative FDA approval in June 2012, as initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures, and as adjunctive therapy in patients 6 years of age and older with similar seizures or with seizures associated with Lennox-Gastaut syndrome. Topiramate is marketed by Johnson & Johnson under the brand name Topamax and is available in a generic form. Topiramate is currently available only in immediate release form for monotherapy and adjunctive therapy of epilepsy and for the treatment of migraine. It works by enhancing the inhibitory effect of the GABA (Gamma-Aminobutyric Acid), neurotransmitter that regulates neuronal excitability throughout the nervous system, blocking the excitatory effect of the glutamate neurotransmitter, attenuating the sodium channels and inhibiting the carbonic anhydrase enzyme. The side effects associated with taking topiramate, which have tended to limit its use, include, among others, dizziness, fatigue, kidney stones, somnolence and slowing of certain cognitive functions.

Trokendi XR is designed to improve patient compliance and to have a better tolerability profile compared to the current immediate release products that are taken multiple times per day. Trokendi XR's pharmacokinetic profile delivers lower peak plasma concentrations and lower input rate over an extended time period, resulting in smoother and more consistent blood levels of topiramate during the entire day compared to immediate release Topamax. Trokendi XR was tentatively approved by the FDA in June 2012. The final approval for Trokendi XR may not be made effective until the expiration of the marketing exclusivity protection that Topamax has regarding safety information of topiramate in a specific pediatric population, which expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. We anticipate the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA.

#### **Our Psychiatry Portfolio**

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States.<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> There are currently no approved products for the treatment of impulsive aggression in individuals with ADHD.

#### SPN-810 (molindone hydrochloride)

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

(7)

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

(8)

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

(9)

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

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development. We will be analyzing the full dataset in depth, and subsequently planning on meeting with the FDA to discuss next steps in the development program and the design and protocol for Phase III clinical trials. If approved by the FDA, SPN-810 could be the first product available to address this serious, unmet medical need. SPN-810 is based on molindone hydrochloride, which was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. Molindone hydrochloride is unusual among anti-psychotics in that it is less likely to be associated with weight gain.

#### SPN-812

We are developing SPN-812, which is currently in Phase II development, as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. We completed a proof-of-concept Phase IIa trial of SPN-812 in the first quarter of 2011, in which SPN-812 was well tolerated and demonstrated a statistically significant improvement over placebo as a treatment for ADHD. The trial was a randomized, double-blind, placebo-controlled trial in 52 adults with a current diagnosis of ADHD, with 26 subjects per treatment group. Given the positive results of this Phase IIa trial, we are focused on developing an extended release formulation for testing in a future Phase IIb trial. SPN-812 has not been developed and marketed in the United States and, therefore, it would be considered and reviewed by the FDA as a new chemical entity, or NCE.

#### **Our Proprietary Technology Platforms**

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

#### **Our Strategy**

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

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

*Continue to advance our product candidates in our psychiatry portfolio, including SPN-810 and SPN-812.* As part of our longer term strategy, we intend to further develop our product candidates in our psychiatry portfolio to enable further diversification of our pipeline and future growth. For example, we completed a Phase IIb trial of SPN-810 for impulsive aggression in patients with ADHD for which we received positive topline results in November 2012.

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

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technologies and expand our patent portfolio to further develop and protect our diverse pipeline of product candidates.

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

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

#### **Risks Associated With Our Business**

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

Final marketing approval of Trokendi XR or any of our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

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

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

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

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

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

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

#### Implications of being an Emerging Growth Company

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

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

Reduced disclosure about our executive compensation arrangements.

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

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

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

#### **Corporate Information**

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

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

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

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#### THE OFFERING

Common stock we are offering	6.000.000 Shares
Common stock to be outstanding after this	0,000,000 binites
offering	30,466,049 Shares
Over-allotment option	We have granted the underwriters an option for a period of up to 30 days to purchase up to 900,000
	additional shares of common stock at the offering price.
Use of proceeds after expenses	We estimate that the net proceeds from this offering will be approximately \$44.7 million, or approximately \$51.5 million if the underwriters exercise their over-allotment option in full. We expect to use the net proceeds from this offering to fund the expected commercial launches of Oxtellar XR and Trokendi XR, the continued clinical development of SPN-810 and SPN-812, the repayment of a portion of the principal of the term loans under our secured credit facility and for other general corporate purposes. See "Use of Proceeds."
Risk factors	You should read the "Risk Factors" section of this prospectus beginning on page 10 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Global Market symbol	SUPN

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

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

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

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

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

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

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

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

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

Unless otherwise indicated, all information in this prospectus:

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

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

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#### SUMMARY FINANCIAL DATA

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

Our historical results are not necessarily indicative of future operating results, and the results for the first nine months of 2012 are not necessarily indicative of results expected for the full year or for any other period. You should read this summary consolidated financial data in conjunction with the sections entitled "Risk Factors," "Capitalization," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, all included elsewhere in this prospectus.

	Year Ended December 31, 2009 2010 2011					,	ľ	Ended • 30, 2012		
		2007		2010		2011		2011 (unau	dite	
	(in thousands, except share and p									
Consolidated Statement of Operations Data:										
Revenues										
Development and milestone revenues	\$	1,050	\$	106	\$	803	\$	761	\$	391
Royalty revenues		36,875								
Total revenues		37,925		106		803		761		391
Costs and expenses										
Research and development		29,260		35,149		30,627		23,126		18,367
Selling, general and administrative		4,649		5,080		7,928		5,143		11,450
Total costs and expenses		33,909		40,229		38,555		28,269		29,817
Operating income (loss) from continuing										
operations		4,016		(40,123)		(37,752)		(27,508)		(29,426)
Other income (expense):										
Interest income		122		107		31		29		91
Interest expense						(1,866)		(1,357)		(2,771)
Other				542		117		30		(665)
		100		640		(1 710)		(1.000)		(0.045)
Total other income (expense)		122		649		(1,718)		(1,298)		(3,345)
Income (loss) from continuing operations before		4 1 2 0		(20, 47,4)		(20, 470)		(20,000)		(20.771)
income taxes		4,138		(39,474)		(39,470)		(28,806)		(32,771)
Income tax benefit				399		16,245				
Income (loss) from continuing of the		4 1 2 0		(20.075)		(22.225)		$(\mathbf{a}, \mathbf{b}, \mathbf{a}, \mathbf{c})$		(20.771)
Income (loss) from continuing operations		4,138		(39,075)		(23,225)		(28,806)		(32,771)
Discontinued operations:										
Income (loss) from discontinued operations, net		(2 (70)		(12		0 100		CAC.		
of tax		(3,678)		612		2,188		646		

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

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		Year En	ded	Decemb	Nine Months Ended September 30,			
		2009		010		2011	2011 (unau	2012
		(in thousa	nds,	except s	sha	re and per	share infor	/
Income (loss) per common share			í	-		•		
Basic								
Continuing operations	\$	0.50	\$	(26.77)	\$	(16.60)	(19.68)	(2.36)
Discontinued operations		(2.60)		0.39		47.99	0.40	
Net income (loss)		(2.10)		(26.38)		31.39	(19.28)	(2.36)
Diluted								
Continuing operations	\$	0.29	\$	(26.77)	\$	(16.60)	(19.68)	(2.36)
Discontinued operations		(0.26)		0.39		47.99	0.40	
Net income (loss)		0.03		(26.38)		31.39	(19.28)	(2.36)
Weighted average number of								
common shares								
Basic		1,413,374	1,5	587,968	1	,605,324	1,594,288	14,356,546
Diluted	1	4,081,186	1,5	587,968	1	,605,324	1,594,288	14,356,546

The pro forma balance sheet data set forth below gives effect to the issuance and sale of 6,000,000 shares of our common stock in this offering at the offering price of \$8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of September 30, 2012					
	Actual Pro Forma (unaudited) (in thousands)					
Consolidated Balance Sheet Data:		(III thot	bui	<b>u</b> 5)		
Unrestricted cash and cash equivalents, and marketable securities	\$	62,472	\$	107,187		
Restricted cash and cash equivalents, and marketable securities		275		275		
Working capital		38,299		83,014		
Total assets		67,014		111,729		
Secured notes payable, including current portion		25,606		25,606		
Accumulated deficit		(72,742)		(72,742)		
Total stockholders' equity	\$	24,631	\$	69,346		

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#### **RISK FACTORS**

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below with all of the other information included in this prospectus before deciding to invest in our common stock. These risks may result in material harm to our business and our financial condition and results of operations. In this event, the market price of our common stock may decline and you could lose part or all of your investment.

#### **Risks Related to Our Business and Industry**

#### We are dependent on the commercial success of Oxtellar XR and Trokendi XR which may never be successfully commercialized.

To date, we have expended significant time, resources, and effort on the development of Oxtellar XR and Trokendi XR, and a substantial majority of our resources are now focused on preparing for the commercial launch in the United States of our approved product, Oxtellar XR, in the first quarter of 2013 and our tentatively approved product, Trokendi XR, in the third quarter of 2013. All of our other product candidates are in earlier stages of development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully commercialize Oxtellar XR and our ability to successfully obtain final marketing approval for and commercialize Trokendi XR. We may not sell Trokendi XR in the United States until the FDA grants final marketing approval and, therefore, our planned commercial launch of Trokendi XR in the United States could experience unanticipated delays or problems and may be prohibited altogether, notwithstanding its tentative approval by the FDA.

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

establish commercial manufacturing arrangements with third-party manufacturers for Trokendi XR;

produce, through a validated process, sufficiently large quantities and inventory of our products to permit successful commercialization;

build and maintain a wide variety of internal sales, distribution and marketing capabilities sufficient to build commercial sales of our products;

establish collaborations with third parties for the commercialization of our products in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;

secure widespread acceptance of our products from physicians, health care payors, patients and the medical community;

properly price and obtain adequate coverage and reimbursement of the product by governmental authorities, private health insurers, managed care organizations and other third-party payors;

maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements; and

manage our growth and spending as costs and expenses increase due to commercialization.

There are no guarantees that we will be successful in completing these tasks. Successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the

emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective. If we are unable to successfully complete these tasks, we may not be able to commercialize Oxtellar XR or Trokendi XR in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

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

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

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

The rate of adoption of Oxtellar XR and, if approved by the FDA, Trokendi XR will be dependent on several factors including our ability to educate and increase physician awareness of the benefits and cost-effectiveness of our products relative to competing therapies. The degree of market acceptance of any of our approved product candidates among physicians, patients, health care payors and the medical community will depend on a number of factors, including:

acceptable evidence of safety and efficacy;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability of alternative treatments;

pricing and cost effectiveness;

the effectiveness of our sales and marketing capability and strategies; and

ability to obtain sufficient third-party coverage or reimbursement.

In addition, Oxtellar XR and, if approved by the FDA, Trokendi XR will be subject to continual review by the FDA, and we cannot assure you that newly discovered or developed safety issues will not arise. With the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. Any safety issues could cause us to suspend or cease marketing of our approved products, cause us to modify how we market our approved products, subject us to substantial liabilities and adversely affect our revenues and financial condition. In the event of a withdrawal of either Oxtellar XR or Trokendi XR from the market, our revenues would decline significantly and our business would be seriously harmed and could fail.

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# We are rapidly expanding our operations to support commercial launch of Oxtellar XR and, if approved by the FDA, Trokendi XR, which has significantly increased our costs, and until we achieve economies of scale, we will incur negative margins on sales of Oxtellar XR and Trokendi XR.

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

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

To date, we have expended significant time, resources, and effort on the development of our product candidates, and a substantial majority of our resources are now focused on planning for the commercialization of our approved product, Oxtellar XR, and our tentatively approved product, Trokendi XR, in the United States. All of our other product candidates are in earlier stages of development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully commercialize Oxtellar XR and our ability to successfully obtain final marketing approval for and commercialize Trokendi XR. Trokendi XR has received tentative approval from the FDA and may never be commercialized until we receive final marketing approval from the FDA.

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

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

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

establish commercial manufacturing arrangements with third-party manufacturers;

build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;

establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;

secure acceptance of our product candidates from physicians, health care payors, patients and the medical community;

successfully complete our clinical trials; and

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

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize Oxtellar XR, Trokendi XR or any of our other product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business. In addition, if we experience unanticipated delays or

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problems, development costs could substantially increase and our business, financial condition and results of operations will be adversely affected.

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

We are building our commercial infrastructure to launch Oxtellar XR, our first approved product, and Trokendi XR, our tentatively approved product, in the United States. We have limited sales and marketing experience and have been building such capabilities by investing significant amounts of financial and management resources. We have committed and will commit additional resources to develop internal sales and marketing capabilities prior to any confirmation that Trokendi XR has received final approval from the FDA or any other of our product candidates have been approved by the FDA. We believe that net proceeds from this offering, together with cash on hand, will be sufficient to complete the development of and to fund the expected commercialization of Oxtellar XR and, upon final approval, Trokendi XR. We anticipate the commercial launch of Oxtellar XR will occur during the first quarter of 2013 and the commercial launch of Trokendi XR will occur during the third quarter of 2013 assuming the receipt of final approval by the FDA. If final FDA approval of Trokendi or the commercial launch of Oxtellar XR or Trokendi XR is delayed for any reason, we could incur significant additional expenses prior to being able to realize any revenues. Further, we could face a number of additional risks in establishing internal sales and marketing capabilities, including:

we may not be able to attract talented and qualified personnel to build an effective marketing or sales force capability;

the cost of establishing a marketing and sales force capability may not be justifiable in light of the revenues generated by Oxtellar XR, Trokendi XR if it receives final approval, or any of our product candidates if approved by the FDA; and

our direct sales and marketing efforts may not be successful.

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

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

Physicians may not prescribe Oxtellar XR, Trokendi XR, if approved by the FDA, or any of our product candidates if approved by the FDA, in which case we would not generate the revenues we anticipate. Market acceptance of any of our products or product candidates by physicians, patients, third-party payors and the medical community depends on, among other things:

our ability to provide acceptable evidence of safety and efficacy;

acceptance by physicians and patients of each product or product candidate as a safe and effective treatment;

perceived advantages of our products or product candidates over alternative treatments;

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

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

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

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

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

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

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

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

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

pricing and cost effectiveness; and

the availability of adequate reimbursement by third parties.

For example, new anti-epileptic drugs, or AEDs, that were introduced in the market as NCEs historically have not quickly gained significant market share against existing molecules in the epilepsy market, because physicians are often reluctant to change a stable patient's existing therapy (even for a NCE) and risk a breakthrough seizure or tolerability issues in their patients. Although Oxtellar XR and Trokendi XR are not NCEs, if commercially launched, they would be subject to the risk that they will not be able to gain significant market share against existing AEDs. If our products or product candidates do not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenues from these products or product candidates to become or remain profitable on a timely basis, if at all.

# Final marketing approval of Trokendi XR, or any of our product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

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

With respect to Trokendi XR (extended release topiramate), we submitted an NDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which allows us to rely in our submissions on the existing data from the NDA of Topamax. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and effectiveness. The FDA could refuse to file or approve our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and effectiveness. For example, we initially submitted an NDA for Trokendi XR in January 2011, but the FDA refused to file the NDA and raised questions relating to chemistry and manufacturing controls issues. Although, the FDA accepted the NDA for filing in November 2011, it granted only tentative approval for Trokendi XR in June 2012 citing the need for inclusion on the product's label of certain pediatric safety information of the reference listed drug Topamax, which is the subject of marketing exclusivity until June 2013. There can be

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no assurance that the FDA will grant final approval of our NDA when this marketing exclusivity expires or at any time thereafter.

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

could determine that we cannot rely on Section 505(b)(2) for any of our product candidates;

could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;

may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;

may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;

may determine that we have identified the wrong reference listed drug or drugs or that approval of our Section 505(b)(2) application for Trokendi XR, or any of our other product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;

may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the active pharmaceutical ingredient, or API, used in our product candidates;

may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;

may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;

may change its approval policies or adopt new regulations; or

may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Our trials may fail to demonstrate acceptable levels of safety, efficacy or any other requirements of our product candidates, which could prevent or significantly delay regulatory approval.

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

In addition, the results from the trials that we have completed for our product candidates may not be replicated in future trials, or we may be unable to demonstrate sufficient safety and efficacy to obtain the

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requisite regulatory approvals for our product candidates. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced development, even after promising results in earlier trials. If our product candidates are not shown to be safe and effective, our clinical development programs could be delayed or might be terminated.

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

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt development and could result in the denial of regulatory approval by the FDA or other regulatory authorities, and potential products liability claims. Immediate release oxcarbazepine and topiramate, drug compounds upon which Oxtellar XR and Trokendi XR are based, respectively, are known to cause various side effects, including dizziness, paresthesia, headaches, cognitive deficiencies such as memory loss and speech impediment, digestive problems, somnolence, double vision, gingival enlargement, nausea, weight gain, and fatigue. The use of Oxtellar XR and Trokendi XR may cause similar side effects as compared to their reference products, or may cause additional or different side effects. Any undesirable side effects that are caused by any of our product candidates could have a material adverse effect upon that product candidate's development program and our business as a whole.

In addition, if any of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by the product candidate, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw approvals of the product candidate or otherwise require us to take the approved product off the market;

regulatory authorities may require additional warnings, or a narrowing of the indication, on the product label;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

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

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

sales of approved products may decrease significantly;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining the commercial success of our products and product candidates and could substantially increase commercialization costs.

# If other versions of extended or controlled release oxcarbazepine or topiramate are approved and successfully commercialized, especially if an extended or controlled release topiramate anti-epileptic drug is approved before Trokendi XR, our business would be materially harmed.

Other third parties may seek approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate anti-epileptic drugs in the United States. If any of these parties obtain FDA approval of an extended release topiramate product before we do, they may be entitled to three years of marketing exclusivity. Such exclusivity would, for example, delay the commercialization of Trokendi XR and, as a result, we may never achieve significant market share for this tentatively approved product. Consequently, revenues from product sales

of these products would be similarly delayed and our business, including our development programs, and growth prospects would suffer. For example, we are aware that Upsher-Smith Laboratories, Inc.'s, or Upsher-Smith, USL255 (extended release topiramate) is in Phase III clinical development for the treatment of epilepsy in adults. If Upsher-Smith's USL255 product is approved

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by the FDA before Trokendi XR, then Upsher-Smith may obtain three years of marketing exclusivity based on its Phase III clinical trial, which would significantly delay our entry into the U.S. market. Even if Trokendi XR is approved before USL255, we may not be entitled to any marketing exclusivity and, other than under circumstances in which third parties may infringe or are infringing our patents, we may not be able to prevent the submission or approval of another full NDA for any competitor's extended or controlled release topiramate product candidate, including USL255. In addition, we are aware of companies who are marketing modified-release oxcarbazepine products outside of the United States, such as Apydan, which is developed by Desitin Arzneimittel GmbH and requires twice-daily administration. If companies with modified-release oxcarbazepine products outside of the United States pursue or obtain approval of their products within the United States, such competing products may limit the potential success of Oxtellar XR in the United States, and our business and growth prospects would be materially impaired. Accordingly, if any third party is successful in obtaining approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate in the United States, we may not be able to recover expenses incurred in connection with the development of or realize revenues from Oxtellar XR or Trokendi XR.

#### If we do not obtain marketing exclusivity for our product candidates, our business may suffer.

Under the Hatch-Waxman Amendments, three years of marketing exclusivity may be granted for the approval of new and supplemental NDAs, including Section 505(b)(2) applications, for, among other things, new indications, dosage forms, routes of administration, or strengths of an existing drug, or for a new use, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product or Section 505(b)(2) product that did not incorporate the exclusivity-protected changes of the approved drug product. Under the Hatch-Waxman Amendments, newly-approved drugs and indications may also benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Amendments provide five-year marketing exclusivity to the first applicant to gain approval of an NDA for an NCE, meaning that the FDA has not previously approved any other drug containing the same active API, or active moiety, which is the molecule responsible for the action of the drug substance. Although protection under the Hatch-Waxman Amendments will not prevent the submission or approval of another full Section 505(b)(1) NDA, such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. While the FDA granted a three year marketing exclusivity period for Oxtellar XR, the FDA has not yet determined whether it will grant marketing exclusivity for Trokendi XR and we cannot assure you that we will receive any such marketing exclusivity from the FDA. If we are unable to obtain marketing exclusivity for our products or product candidates, our competitors may obtain approval of competing products more easily than if we had such marketing exclusivity, and our future revenues could be reduced, possibly materially.

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

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

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



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

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

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

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

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

difficulty retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues; and

clinical holds imposed by the FDA.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, clinical trials may be suspended or terminated by us, an institutional review board or ethics committee overseeing the clinical trial at a trial site (with respect to that site), the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols;

observations during inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that ultimately result in the imposition of a clinical hold;

unforeseen safety issues; or

lack of adequate funding to continue the trial.

In addition, failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols may also result in the inability to use the data to support product approval. For instance, the efficacy demonstrated by SPN-810 in its most recent Phase IIb study was not statistically significant for all efficacy measures for the study. Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of, or if we terminate any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues will be diminished.

We expect intense competition and, if our competitors develop or market alternatives for treatments of our target indications, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products and product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. The availability of competing products will limit the demand and the price we are able to charge for any of our products or product candidates that are commercialized unless we are able to differentiate them. We anticipate that we will face intense competition when our product candidates are approved by regulatory authorities and we begin the commercialization process for our products. For instance, there are over 15 branded products, as well as their generic counterparts, on the U.S. market indicated to treat epilepsy. In addition, competition in the ADHD market in the United States has increased with the commercial launch of several products in recent years, including the launch of generic versions of branded drugs such as Adderall XR. As a result, we may

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not be able to recover expenses incurred in connection with the development of our product candidates or realize revenues from any commercialized product.

In addition to already marketed competing products, we believe certain companies are developing other products which could compete with our product candidates should they be approved by regulatory authorities. For example, according to Datamonitor, as of April 2010, there were 47 compounds in preclinical and clinical development for epilepsy across the United States, Japan, France, Germany, Italy, Spain and the United Kingdom. Datamonitor reported that approximately 15 were in late-stage (Phase II or later) clinical trials as of April 2010. We are also aware that Upsher-Smith's USL255 (extended release topiramate) is in Phase III clinical development for the treatment of epilepsy in adults. If successful, such competing product could limit the potential success of Trokendi XR, and our growth prospects would be materially impaired. In addition, we are aware of companies who are marketing outside of the United States modified-release oxcarbazepine products, such as Apydan, which is developed by Desitin Arzneimittel GmbH and requires twice-daily administration. We are also aware that Qsymia, an oral drug containing ER topiramate and another API, is available in extended release for treatment of weight management. If companies with modified-release oxcarbazepine products outside of the United States obtain approval for their products within the United States, then such competing products may limit the potential success of Oxtellar XR. Further, new developments, including the development of other drug technologies, may render our product candidates obsolete or noncompetitive. As a result, our product candidates may become obsolete before we recover expenses incurred in connection with their development or realize revenues from any commercialized product.

Further, many competitors have substantially greater:

capital resources;

research and development resources and experience, including personnel and technology;

drug development, clinical trial and regulatory resources and experience;

sales and marketing resources and experience;

manufacturing and distribution resources and experience;

name recognition; and

resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop drugs that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively with the products of our competitors or if such competitors are successful in developing products that compete with any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated at competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment.

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#### Our products and our product candidates, if they receive regulatory approval, may be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Our product candidates would also be, and our approved product and our collaborators' approved products are, subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP regulations. If we, our collaborators or a regulatory authority discovers previously unknown problems with a product, such as side effects of unanticipated severity or frequency, or problems with the facility where the product from the market or suspension of manufacturing. If we or our collaborators, or our or our collaborators' approved products or product candidates, or the manufacturing facilities for our or our collaborators, approved products or product candidates fail to comply with applicable regulatory requirements, a regulatory authority may:

issue warning letters or untitled letters;

impose civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing bioequivalence and/or clinical trials;

refuse to approve pending applications or supplements to applications filed by us;

impose restrictions on operations, including costly new manufacturing requirements, or suspension of production; or

seize or detain products or require us to initiate a product recall.

In addition, our product labeling, advertising and promotion of our approved product, and our tentatively approved product and our product candidates upon FDA approval, are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Physicians may nevertheless prescribe our products and, upon receiving FDA approval, our product candidates to their patients in a manner that is inconsistent with the approved label. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we are found to have promoted off-label uses, we may be enjoined from such off-label promotion and become subject to significant liability, which would have an adverse effect on our reputation, business and revenues, if any.

# If we fail to produce our products and product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our products and product candidates.

We do not currently own or operate manufacturing facilities for the production of any of our products or product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently depend on third-party contract manufacturers for the supply of the APIs for our products or product candidates, including drug substance for our preclinical research and clinical trials. For Oxtellar XR and Trokendi XR, we currently rely on single suppliers for raw materials including API and single manufacturers

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to produce and package final dosage forms. Any future curtailment in the availability of raw materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Pharmaceutical companies often encounter difficulties in manufacturing, particularly in scaling up production of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In responding to the FDA's refusal-to-file letter for the Trokendi XR NDA, we had to address chemistry and manufacturing controls issues. If we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our products and product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our bioequivalence and/or clinical trials, increase the costs associated with conducting our bioequivalence and/or clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial.

Manufacturers of pharmaceutical products need to comply with cGMP requirements enforced by the FDA through their facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of products or product candidates is comproval, product seizure or recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for such product candidate or successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates. Furthermore, for our tentatively approved product, Trokendi XR, we are presently negotiating agreements with a leading contract manufacturing organization, or CMO, headquartered in North America for the manufacture of the final commercial product. If we fail to obtain the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for our approved products or product candidates, and would lose potential revenues.

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

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at



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lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our product candidates.

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

Outside of the United States, we currently plan to utilize strategic partners or contract sales forces, where appropriate, to assist in the commercialization of our product candidates, if approved. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. By entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Our collaborators may fail to develop or effectively commercialize our product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our product candidates outside of the United States would diminish our revenues and harm our results of operations.

#### Limitations on our patent rights relating to our product candidates may limit our ability to prevent third parties from competing against us.

Our success will depend on our ability to obtain and maintain patent protection for our proprietary technologies and our product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. To that end, we seek patent protection in the United States and internationally for our product candidates. Our policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad (including Europe, Canada and certain other countries when appropriate) relating to proprietary technologies that are important to the development of our business.

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

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



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

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell their approved products and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our collaborators' approved products and our product candidates may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware, that may be infringed by our collaborators' approved products or Oxtellar XR, Trokendi XR or any of our product candidates, which could prevent us from being able to commercialize Oxtellar XR, Trokendi XR or any of our product candidates, that our collaborators' approved products applications which may later result in issued patents that our collaborators' approved product candidates may give and the many years to issue, there may be currently pending applications which may later result in issued patents that our collaborators' approved products and patents applications which may later result in issued patents that our collaborators' approved product candidates may infringe.

We may be exposed to, or threatened with, future litigation by third parties alleging that our collaborators' approved products or our products or products or product candidates infringe their intellectual property rights. If one of our collaborators' approved products or our products or product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize the applicable approved products and product candidates unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our approved products, pending a trial on the merits, which may not occur for several years.

There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

a court prohibiting us from selling Oxtellar XR, Trokendi XR, or any product candidate approved in the future, if any, unless the third party licenses its rights to us, which it is not required to do;

if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and

redesigning Oxtellar XR, Trokendi XR, or any of our product candidates so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. For example, we are involved in the following matters related to Paragraph IV Certification Notice Letters that we have received in connection with our collaborators' products. In connection with an ANDA, a Paragraph IV Certification Notice Letter notifies the FDA that one or more patents listed in the FDA's Approved Drug Product List (Orange Book) is alleged to be invalid, unenforceable or will not be infringed by the ANDA product.

Sanctura XR Litigation. We are involved in a patent infringement matter filed in response to three Paragraph IV Certification Notice Letters that we received in June 2009, November 2009 and April 2010 regarding an ANDA submitted to the FDA by each of Watson Laboratories, Inc., Sandoz Inc. and Paddock Laboratories, Inc., respectively, requesting approval to market and sell generic versions of Sanctura XR trospium chloride extended release capsules, a product that is manufactured and sold by Allergan, Inc., which is the marketing partner of Endo Pharmaceuticals Solutions Inc. The ANDA filers alleged in their respective original notice letters that U.S. Patent Number 7,410,978 issued to us is invalid, unenforceable and/or will not be infringed by the respective company's manufacture, use or sale of the product described in its ANDA submission. Our patent covers extended-release formulations containing trospium chloride and expires on February 1, 2025, and is licensed to Endo Pharmaceuticals Solutions Inc. Each of the ANDA filers subsequently amended their respective notice letters to include other U.S. patents related to Sanctura XR trospium chloride (specifically, U.S. Patent Nos. 7,759,359; 7,763,635; 7,781,448; and 7,781,449). In March 2012, the court ruled that the defendants' proposed products infringe the patents-in-suit and that the patents-in-suit are invalid. Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. filed an appeal, and the Federal Circuit heard argument on June 14, 2012. The Federal Circuit issued a Rule 36 summary affirmance of the District Court's decision that the patents were invalid on June 18, 2012. Allergan, Inc. and Endo Pharmaceuticals Solutions Inc. filed a petition for writ of certiorari on September 17, 2012, which was denied by the U.S. Supreme Court on October 15, 2012, thereby declining to disturb the earlier judicial finding that the patents are invalid. We do not expect the resulting entry of competitive generic products to have a material adverse effect on our business as we have monetized the future revenues associated with Sanctura XR.

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

Intuniv Litigation. We are involved in several patent infringement actions in district courts throughout the United States, which were filed in response to Paragraph IV Certification Notice Letters that we

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received in March, April and October 2010, and February, March and October 2011, regarding ANDAs submitted to the FDA requesting approval to market and sell generic versions of Intuniv, a product that is manufactured and sold by Shire LLC. The defendants in these cases are Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd; Actavis Elizabeth LLC and Actavis, Inc.; Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. Florida Watson Pharma, Inc. and ANDA, Inc.; Impax Laboratories, Inc.; Sandoz Inc. and Mylan Pharmaceuticals Inc. and Mylan Inc. The ANDA filers allege that our U.S. Patent Nos. 6,287,599 and 6,811,794 are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product described in its ANDA submissions. A bench trial was held on September 17-20, 2012 in the District of Delaware in the case against defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Actavis Elizabeth LLC and Actavis, Inc. No decision has yet been issued by the district court in that case. Prior to the trial in the District of Delaware, Shire LLC settled all claims against defendants Anchen Pharmaceutical, Inc., Anchen Inc. and TWi Pharmaceuticals, Inc. in connection with TWi's ANDA for a generic version of Intuniv. Our patents cover extended-release formulations containing guanfacine hydrochloride, with the latest patent expiration in July 2022. Both of these patents are licensed to Shire LLC. We intend to support Shire LLC in its efforts to contest this matter. We do not expect an adverse decision in the foregoing matter will have a material adverse effect on our business as we have monetized the future revenues associated with Intuniv.

In any infringement proceeding including the foregoing, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not issuing.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceeding or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. There can be no assurance that our product candidate will not be subject to same risks.

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

We have a license agreement with United Therapeutics Corporation, or United Therapeutics, to use one of our proprietary technologies for an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension, or PAH, as well as for other indications. This oral formulation was the subject of an NDA for PAH submitted by United Therapeutics and accepted for filing by the FDA in February 2012. On October 23, 2012, United Therapeutics received a complete response letter from the FDA declining to approve the product. Accordingly, we do not expect to receive any royalties for this formulation in this indication unless and until final marketing approval from the FDA is received and until United Therapeutics launches this product. We are entitled to receive milestones and royalties for use of



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this formulation in other indications. If we materially breach any of our obligations under the license agreement, however, we could lose the potential to receive any future royalty payments thereunder, which could be financially significant to us.

We also have license agreements with Especificos Stendhal, S.A., DE C.V. and we may enter into additional collaborations in the future. Our future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties. Much of the potential revenues from these future collaborations may consist of contingent payments, such as payments for achieving development milestones and royalties payable on sales of developed products. The milestone and royalty revenues that we may receive under these collaborations will depend upon our collaborators' ability to successfully develop, introduce, market and sell new products. Future collaboration partners may fail to develop or effectively commercialize products using our product candidates or technologies because they, among other things:

may change the focus of their development and commercialization efforts or may have insufficient resources to effectively develop our product candidates. Pharmaceutical and biotechnology companies historically have re-evaluated their development and commercialization priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of some of our product candidates to reach their potential could be limited if our future collaborators decrease or fail to increase development or commercialization efforts related to those product candidates;

may decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise or limited cash resources, or the belief that other drug development programs may have a higher likelihood of obtaining marketing approval or may potentially generate a greater return on investment;

may develop and commercialize, either alone or with others, drugs that are similar to or competitive with the product candidates that are the subject of their collaborations with us;

may not have sufficient resources necessary to carry the product candidate through clinical development, marketing approval and commercialization;

may fail to comply with applicable regulatory requirements;

may not be able to obtain the necessary marketing approvals; or

may breach or terminate their arrangement with us.

If collaboration partners fail to develop or effectively commercialize our products or product candidates for any of these reasons, we may not be able to replace the collaboration partner with another partner to develop and commercialize the product or product candidate under the terms of the collaboration. Further, even if we are able to replace the collaboration partner, we may not be able to do so on commercially favorable terms. As a result, the development and commercialization of the affected product or product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on our own, which could adversely affect our results of operations.

# We rely and will continue to rely on outsourcing arrangements for certain of our activities, including clinical research of our product candidates and manufacturing of our compounds and product candidates beyond Phase II clinical trials.

We rely on outsourcing arrangements for some of our activities, including manufacturing, preclinical and clinical research, data collection and analysis. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner. Our reliance on third parties, including third-party CROs and CMOs entails risks including, but not limited to:

non-compliance by third parties with regulatory and quality control standards;

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sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third party supplier or manufacturer fail to comply with applicable regulatory standards;

the possible breach of the agreements by the CROs or CMOs because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and

termination or non-renewal of an agreement by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

We do not own or operate manufacturing facilities for the production of any of our products or product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently depend on third-party CMOs for all of our required raw materials and drug substance for our preclinical research and clinical trials. For Oxtellar XR and Trokendi XR, we currently rely on single suppliers for raw materials including API, and expect to rely on third-party suppliers and manufacturers for the final commercial products. If any of these vendors is unable to perform its obligations to us, including due to violations of the FDA's requirements, our ability to meet regulatory requirements or projected timelines and necessary quality standards for successful manufacture of the various required lots of material for our development and commercialization efforts would be adversely affected. For example, in responding to the FDA's refusal-to-file letter for the Trokendi XR NDA, we had to address chemistry and manufacturing controls issues. Further, if we were required to change vendors, it could result in delays in our regulatory approval efforts and significantly increase our costs. Accordingly, the loss of any of our current or future third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition and prospects.

We have entered into a supply agreement for Oxtellar XR and are negotiating an agreement for Trokendi XR with leading CMOs headquartered in North America for the manufacture of the final commercial products. However, there is a risk that the counterparties to these agreements will not perform their respective obligations or will terminate these agreements. In addition, we do not have contractual relationships for the manufacture of commercial supplies of all of our product candidates. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture drug substance and final drug product on a commercial scale is limited. Therefore, we may not be able to enter into such arrangements with third-party manufacturers in a timely manner, on acceptable terms or at all. Failure to secure such contractual arrangements would harm the commercial prospects for our product candidates, our costs could increase and our ability to generate revenues could be delayed.

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

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

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

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

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

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

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

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

Our ability or our collaborators' ability to successfully commercialize our products and product candidates, including Oxtellar XR and Trokendi XR, will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers, managed care organizations and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. Government authorities and these third-party payors have attempted to control costs, in some instances, by limiting coverage and the amount of reimbursement for particular medications or encouraging the use of lower-cost generic AEDs. We cannot be sure that reimbursement will be available for any of the products that we develop and, if reimbursement is available, the level of reimbursement. Reduced or partial payment or reimbursement coverage could make our products or product candidates, including Oxtellar XR and Trokendi XR, less attractive to patients and prescribing physicians. We also may be required to sell our products or product candidates at a discount,



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which would adversely affect our ability to realize an appropriate return on our investment in our products or product candidates or compete on price.

We expect that private insurers and managed care organizations will consider the efficacy, cost effectiveness and safety of our products or product candidates, including Oxtellar XR and Trokendi XR, in determining whether to approve reimbursement for such products or product candidates and at what level. Because each third-party payor individually approves payment or reimbursement, obtaining these approvals can be a time consuming and expensive process that could require us to provide scientific or clinical support for the use of each of our products or product candidates separately to each third-party payor. In some cases, it could take several months or years before a particular private insurer or managed care organization reviews a particular product, and we may ultimately be unsuccessful in obtaining coverage. Our competitors generally have larger organizations, as well as existing business relationships with third-party payors relating to their products. Our business would be materially adversely affected if we do not receive approval for reimbursement of our product candidates from private insurers on a timely or satisfactory basis. Our products and product candidates, may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products or product candidates on a profitable basis. Our business would also be adversely affected if private insurers, managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which our products or product candidates will be reimbursed to a smaller set than we believe they are effective in treating.

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products or product candidates to other available therapies. If reimbursement for our products or product candidates is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

In addition, many managed care organizations negotiate the price of products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. If our products or product candidates are not included within an adequate number of formularies or adequate payment or reimbursement levels are not provided, or if those policies increasingly favor generic products, our market share and gross margins could be negatively affected, which would have a material adverse effect on our overall business and financial condition.

We expect to experience pricing pressures due to the potential healthcare reforms discussed elsewhere in this prospectus, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

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

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

decreased demand for any product or product candidate that has received approval and is being commercialized;

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impairment of our business reputation and exposure to adverse publicity;

withdrawal of bioequivalence and/or clinical trial participants;

initiation of investigations by regulators;

costs of related litigation;

distraction of management's attention from our primary business;

substantial monetary awards to patients or other claimants;

loss of revenues; and

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

Our product liability insurance coverage for our clinical trials is limited to \$5 million per occurrence, and \$10 million in the aggregate, and covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. We intend to expand our insurance coverage to include the sale of commercial products prior to the commercialization of our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

#### Our failure to successfully develop and market products or product candidates would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products.

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

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

exposure to unknown liabilities;

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

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

higher than expected acquisition and integration costs;

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

increased amortization expenses;

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

inability to motivate key employees of any acquired businesses.

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

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

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce healthcare costs may adversely affect our ability to set prices for any approved product candidate which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell any approved product profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010. This law, which we refer to as the PPACA, may have far reaching consequences for biopharmaceutical companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, including our products and product candidates. If reimbursement for our approved products is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. In July 2012, the Food and Drug Administration Safety and Innovation Act was enacted, expanding drug supply chain requirements and strengthening FDA's response to drug shortages, among other things. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance

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with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of any approved product candidates.

Future federal and state proposals and health care reforms could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the PPACA by reducing the amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

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

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

manage our regulatory approvals and clinical trials effectively;

manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;

develop internal sales and marketing capabilities;

commercialize our product candidates;

improve our operational, financial and management controls, reporting systems and procedures; and

attract and motivate sufficient numbers of talented employees.

This future growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy.

# We may not be able to manage our business effectively if we are unable to attract and motivate key members or if we lose key members of our current management team.

We may not be able to attract or motivate qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our objectives.

We are highly dependent on the development, regulatory, commercial and financial expertise of our management, particularly Jack A. Khattar, our President and Chief Executive Officer. We do not have any employment agreements with any member of our senior management team except Mr. Khattar. If we lose key members of our management team, we may not be able to find suitable replacements in a timely fashion, if at all. We cannot be certain that future management transitions will not disrupt our operations and generate concern among employees and those with whom we do business.

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

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

# If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a supplier of pharmaceuticals, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations include:

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

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

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

the federal transparency requirements under the PPACA requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

the FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations could be costly. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur

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significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

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

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

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

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

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

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

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



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# We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. We have in the past been required to change a proposed product name. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

#### Provisions in our agreement with Shire impose restrictive covenants on us, which could limit our ability to operate effectively in the future.

In 2005, we purchased substantially all of the assets of Shire Laboratories Inc. Pursuant to this agreement, we agreed to perpetually refrain from engaging in any research, formulation development, analytical testing, manufacture, technology assessment or oral bioavailability screening that relate to five specific drug compounds (amphetamine, carbamazepine, guanfacine, lanthanum and mesalamine) and any derivative thereof. In addition, we have agreed not to provide any services to, license any intellectual property rights to, or otherwise perform any work for certain pharmaceutical companies primarily engaged in the development and marketing of generic products through 2012. Although these various restrictions and covenants on us do not currently impact our product candidates or business, they could in the future limit or delay our ability to take advantage of business opportunities that may relate to such compounds or such companies.

#### **Risks Related to Our Finances and Capital Requirements**

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

In recent years, we have focused primarily on developing our current products and product candidates, with the goal of commercializing these products and supporting regulatory approval for these product candidates. We have financed our operations primarily through private placements of convertible preferred stock, our collaboration and license arrangements, the monetization of certain future royalty streams under our existing licenses for Oracea, Sanctura XR and Intuniv, the sale of our subsidiary, TCD Royalty Sub LLC, or Royalty Sub, which held the license rights to Oracea and Sanctura XR, borrowing via secured loans and the completion of our initial public offering in May 2012. We have incurred significant operating losses since our inception in 2005. We incurred net losses of approximately \$17.3 million, \$33.5 million, \$38.5 million and \$32.8 million in the years ended December 31, 2007, 2008 and 2010 and the nine months ended September 30, 2012, respectively. We incurred net income of approximately \$0.5 million and \$53.8 million in the years ended December 31, 2009 and 2011, respectively, due to one-time items. As of September 30, 2012, we had an accumulated deficit of approximately \$72.7 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs and from selling, general and administrative costs associated with our operations. For example, the expenses that we have incurred relating to the research and development of Oxtellar XR and Trokendi XR from inception to September 30, 2012 are approximately \$52.3 million and \$31.6 million, respectively. We expect our research and development costs to continue to be substantial and to increase with respect to our product candidates as we advance those product candidates through preclinical studies, clinical trials,



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manufacturing scale-up and other pre-approval activities. We expect to incur significant and increasing marketing and selling costs prior to and during the commercial launch of our current products. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when, or if, we will become profitable.

Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Furthermore, since the completion of our initial public offering in May 2012, we have incurred additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. In this regard, the report of our independent registered public accounting firm with respect to our consolidated financial statements as of and for the period ended December 31, 2011 contains an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this public offering will eliminate this doubt. However, while we believe that the proceeds of this offering, together with our cash, cash equivalents and marketable securities and anticipated future product revenues will be sufficient to fund the commercialization of Oxtellar XR and, if we receive final approval by the FDA, Trokendi XR, there can be no assurance that we will not need additional capital in order to become cash flow positive. In addition, we may need to obtain additional funds to develop and commercialize our other product candidates. The inclusion of a going concern statement by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

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

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

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

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

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

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

the timing of any regulatory approvals of our product candidates;

our ability to successfully launch our products and to continue to increase the level of sales in the marketplace;

the actions of our competitors and their success in selling competitive product offerings;

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the costs of establishing sales, marketing, manufacturing and distribution capabilities for our products; and

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

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

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

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

Our ability to generate product revenues is dependent on our ability to receive regulatory approval of our products and product candidates, including Oxtellar XR and Trokendi XR, and to successfully commercialize these products. Our ability to successfully commercialize our products depends on, among other things:

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

our obtaining regulatory approvals for our product candidates, including final approval of Trokendi XR; and

our manufacturing of commercial quantities of our approved products, including Oxtellar XR, at acceptable cost levels.

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

#### Our operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly and annual fluctuations. Prior to commercializing any of our product candidates, we expect that any revenues we generate will fluctuate from quarter to quarter and year to year as a result of the timing and amount of development milestones and royalty revenues received under our collaboration license agreements, as our revenues from these arrangements are principally based on the achievement of clinical and commercial milestones outside of our control.

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

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

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

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

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

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

our ability to establish an effective sales and marketing infrastructure;

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

competition from existing products or new products that may emerge;

regulatory developments affecting our products and product candidates;

our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;

the achievement and timing of milestone payments under our existing collaboration and license agreements; and

the level of market acceptance for any approved product candidates and underlying demand for that product and wholesalers' buying patterns.

Due to the various factors mentioned above, and others, the results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

# Prior to May 1, 2012 we operated as a private company and therefore, have limited experience operating as a public company and complying with public company obligations. Complying with these requirements has increased our costs and requires additional management resources, and we still may fail to meet all of these obligations.

We face increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act of 2010, as well as rules of the Securities and Exchange Commission and Nasdaq, for example, has resulted in significant initial cost to us as well as ongoing increases in our legal, audit and financial compliance costs, particularly after we are no longer an "emerging growth company." The Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and require us to incur substantial costs to maintain the same or similar coverage.

As a public company, we are subject to Section 404 of the Sarbanes-Oxley Act relating to internal controls over financial reporting and we expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other reports on a timely basis, could increase our

operating costs and could materially impair our ability to operate our business. We cannot assure you that our internal controls over financial reporting will prove to be effective.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm after we no longer qualify as an "emerging growth company," may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the recently enacted JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. See "Summary Implications of being an Emerging Growth Company." An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

# Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the transactions contemplated by this offering.

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

In addition, it is possible that the transactions described in this offering, either on a standalone basis or when combined with future transactions, including issuances of new shares of our common stock, will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 and those attributes already subject to limitations as a result of our prior ownership changes may be subject to more stringent limitations. As of December 31, 2011, we had approximately \$37.5 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of approximately \$5.0 million available to offset future taxable income. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates

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beginning in 2025, if not utilized. In 2011, we completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception. Due to the significant costs and complexities associated with such study, we have not updated this study in 2012. Accordingly, our ability to utilize the aforementioned carryforwards and tax credits may be limited. As a result, we may not be able to take full advantage of these carryforwards or tax credits for federal and state tax purposes.

#### **Risks Related to Our Indebtedness**

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

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

we will need to repay our debt by making payments of interest and principal, including a final payment of \$750,000 representing 2.5% of the aggregate principal amount of the term loans borrowed under our secured credit facility, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities;

we may have difficulty obtaining financing in the future for working capital, capital expenditures, acquisitions or other purposes;

our failure to comply with the restrictive covenants in our loan and security agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the lenders could seek to enforce their security interests in the assets securing such indebtedness; and

we will be charged a prepayment premium of 2.0% if we prepay the debt within 15 months after the respective amortization dates of the term loans, and a prepayment premium of 1.0% if such prepayment is made thereafter.

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

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

Since our inception in 2005, we have generated no revenue from product sales and have incurred significant operating losses. As of September 30, 2012, we had an accumulated deficit of \$72.7 million. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to develop and seek marketing approval for our product candidates. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our secured credit facility. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or

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principal payments on our debt obligations would be significantly limited, and we may be required to delay, significantly curtail or eliminate one or more of our programs.

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

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

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

dispose of certain assets;

change our lines of business;

engage in mergers or consolidations;

incur additional indebtedness;

create liens on assets, including our intellectual property;

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

engage in certain transactions with affiliates.

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

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

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

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

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

Sales of our common stock, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock which would impair our ability to raise future capital through the sale of additional equity securities. Immediately after this offering, we will have outstanding 30,466,049 shares of common stock, based on the number of outstanding shares of common stock as of September 30, 2012, of which approximately 8,561,241 shares are currently freely tradeable and another 6,000,000 shares sold in this offering will be freely tradeable immediately after this offering unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities who are subject to lock-up agreements. Approximately 15,904,808 shares held by executive officers, directors and certain significant stockholders may be sold upon expiration of lock-up agreements 90 days after the date of this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. In addition, as of September 30, 2012, we had outstanding options to purchase 574,820 shares of common stock and warrants to purchase 143,749 shares of common stock, that, if exercised, will result in these additional shares becoming available for sale. Of the options to purchase 574,820 shares of common stock, a total of 415,500 of these shares would be subject to the lock-up agreements funds. Moreover, after the date of this offering, certain holders of shares of common stock will have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold, or to include these shares in registration statements that we may file for ourselves or other stockholders.

We have also registered all common stock subject to options outstanding or reserved for issuance under our 2005 Stock Plan, 2012 Equity Incentive Plan and 2012 Employee Stock Purchase Plan. An aggregate of 2,391,750 and 250,000 shares of our common stock are reserved for future issuance under the 2012 Equity Incentive Plan and the 2012 Employee Stock Purchase Plan, respectively. These shares may now be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock. See "Shares Eligible for Future Sale" for a more detailed description of sales that may occur in the future.

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have very limited research coverage by securities and industry analysts. If securities or industry analysts presently covering our business do not continue such coverage or if additional securities or industry analysts do not commence coverage of our Company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us

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downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

# The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit your ability to influence certain corporate matters.

Following this proposed public offering of our common stock, our directors and their affiliated entities, and our executive officers will beneficially own, in the aggregate, approximately 74.0% of our outstanding common stock. As a result, these stockholders are collectively able to significantly influence or control all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets. The concentration of ownership may delay, prevent or deter a change in control of our Company even when such a change may be in the best interests of some stockholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our Company or our assets and might adversely affect the prevailing market price of our common stock.

# Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could negatively impact the market price of our common stock.

Provisions in our certificate of incorporation and bylaws, as amended, may have the effect of delaying or preventing a change of control. These provisions include the following:

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

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

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

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

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

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

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

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, our bylaws and in

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the Delaware General Corporation Law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors.

#### We may not be able to maintain an active public market for our common stock.

If you purchase shares of our common stock in this offering, you may not be able to resell those shares at or above the offering price. There was no public market for our common stock prior to the closing of our initial public offering in May 2012. We cannot predict the extent to which investor interest in our Company will allow us to maintain an active trading market on The NASDAQ Global Market or otherwise or how liquid that market might become. If an active public market is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products, product candidates or technologies by using our shares of common stock as consideration.

#### To the extent outstanding stock options or warrants are exercised, there will be dilution to new investors.

As of September 30, 2012, we had options to purchase 574,820 shares of common stock outstanding, with exercise prices ranging from \$0.40 to \$12.92 per share and a weighted average exercise price of \$4.89 per share. Upon the vesting of each of these options, the holder may exercise his or her options, which would result in dilution to investors. You will also experience dilution if we issue additional shares of common stock under the warrants that we issued to our lenders. Of the outstanding lender warrants to purchase 93,750 shares of common stock at an exercise price of \$4.00 per share and 49,999 shares of common stock at an exercise price of \$5.00 per share as of September 30, 2012, warrants to purchase 18,750 shares and 23,332 shares at exercise prices of \$4 per share and \$5 per share, respectively, remain outstanding following the October 2012 net exercise by one of the lenders.

#### The price of our common stock may fluctuate substantially.

Following this offering, the market price for our common stock is likely to be volatile, in part because our common stock has been previously traded publicly for only a short time. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, including:

the commercial performance of Oxtellar XR, Trokendi XR, or any of our product candidates that receive marketing approval;

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

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

announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;

market conditions in the pharmaceutical and biotechnology sectors;

fluctuations in stock market prices and trading volumes of similar companies;

variations in our quarterly operating results;

changes in accounting principles;

litigation or public concern about the safety of our potential products;

actual and anticipated fluctuations in our quarterly operating results;

deviations in our operating results from the estimates of securities analysts;

additions or departures of key personnel;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

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any third-party coverage and reimbursement policies for our product candidates, and

discussion of us or our stock price in the financial or scientific press or in online investor communities.

The realization of any of the risks described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility. Any such litigation brought against us could result in substantial costs and a diversion of management attention, which could hurt our business, operating results and financial condition.

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

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

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#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this prospectus other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "seek," "anticipate," "should," "could," "potential," or the negative of those terms and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. These forward-looking statements include, among other things, statements about:

our ability to commercialize our products and achieve profitability;

the implementation of our corporate strategy;

our future financial performance and projected expenditures;

our ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies;

our product research and development activities, including the timing and progress of our clinical trials, and projected expenditures;

our ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize our product candidates;

our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;

our expectations regarding federal, state and foreign regulatory requirements;

the therapeutic benefits, effectiveness and safety of our product candidates;

the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidates;

our ability to increase our manufacturing capabilities for our product candidates;

our projected markets and growth in markets;

our product formulations and patient needs and potential funding sources;

our staffing needs;

our use of the proceeds from this offering; and

our plans for sales and marketing.

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

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

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#### **USE OF PROCEEDS**

We estimate that the net proceeds from the sale of common stock that we are offering will be approximately \$44.7 million. This projection is based upon a public offering price of \$8.00 per share, and after deducting underwriting discounts and commissions as well as estimated offering expenses payable by us.

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

approximately \$23.0 million for sales and marketing expenses to provide continued support of the commercial launch of Oxtellar XR and, after approval by the FDA, Trokendi XR;

approximately \$4.0 million for the manufacture and supply of commercial quantities of Oxtellar XR and Trokendi XR inventory to be sold in connection with such commercial launch;

approximately \$3.5 million to fund the continued clinical development of SPN-810, including: preclinical carcinogenicity testing; process development and scale up for commercial bulk active pharmaceutical ingredient;

approximately \$2.5 million to fund the continued clinical development of SPN-812, including preclinical carcinogenicity testing, process development for commercial bulk active pharmaceutical ingredient, continued Phase II testing and formulation development;

approximately \$3.0 million to fund Phase IV studies, and post-marketing formulation development and clinical work for Oxtellar XR and Trokendi XR;

approximately \$4.5 million to fund our payment obligations under the term loans under our secured credit facility; and

the remainder, if any, for general corporate purposes including general and administrative expenses, capital expenditures and working capital.

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

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

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

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

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



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#### MARKET PRICE OF COMMON STOCK

Our common stock has been listed on The NASDAQ Global Market under the symbol "SUPN" since May 1, 2012. Prior to that date, there was no public trading market for our common stock. The following table sets forth for the periods indicated the high and low intra-day sales prices per share of our common stock as reported on the Nasdaq Global Market.

	High		Low	
Second Quarter 2012 (from May 1, 2012)	\$	15.20	\$	4.30
Third Quarter	\$	16.68	\$	8.70
Fourth Quarter (through November 29, 2012)	\$	14.98	\$	9.81

On November 29, 2012, the last reported sale price of our common stock on The NASDAQ Global Market was \$9.83 per share. As of November 29, 2012, we had 43 holders of record of our common stock. The actual number of common stockholders is greater than these numbers of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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# **DIVIDEND POLICY**

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

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# CAPITALIZATION

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

on an actual basis; and

on a pro forma basis to reflect our receipt of the estimated net proceeds from our sale of 6,000,000 shares of common stock offered hereby at the offering price of \$8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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

	-	Actual in thousai sha and pe inform	r share		
Balance Sheet Data:					
Unrestricted cash and cash equivalents and marketable securities	\$	62,472	\$	107,187	
Restricted cash and cash equivalents and marketable securities		275		275	
Debt outstanding Stockholders' equity: Series A convertible preferred stock, \$0.001 par value 65,000,000 shares authorized, 0 shares issued and outstanding, actual	\$	25,606	\$	25,606	
Common stock, \$0.001 par value 130,000,000 shares authorized, 24,466,049 shares issued and					
outstanding; and 130,000,000 shares authorized, 30,466,049 shares issued and outstanding, pro forma		24		30	
Additional paid-in capital		97,378		142,087	
Accumulated other comprehensive income (loss)		(29)		(29)	
Accumulated deficit		(72,742)		(72,742)	
Total stockholders' equity Total capitalization	\$	24,631 50,237	\$	69,346 94,952	

The table above does not include:

574,820 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2012 at a weighted average exercise price of \$4.89 per share;

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

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

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

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

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

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

# SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth selected consolidated financial data that is qualified in its entirety by and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes thereto appearing elsewhere in this prospectus. The consolidated financial data as of December 31, 2010 and 2011 and for the fiscal years ended December 31, 2009, 2010 and 2011 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The consolidated financial statements appearing elsewhere in this prospectus. The consolidated financial statements appearing elsewhere in this prospectus. The consolidated financial data as of December 31, 2007, 2008 and 2009 and for the fiscal years ended December 31, 2007 and 2008 are derived from our audited consolidated financial statements not included in this prospectus. The consolidated financial data as of September 30, 2012 and for the nine months ended September 30, 2011 and 2012 are derived from our unaudited consolidated financial statements and have been prepared on the same basis as the audited consolidated financial statements and the notes thereto, and include, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the information for the unaudited interim periods. The operating results for the nine months ended September 30, 2012 may not be indicative of the operating results for the full year or any other period.

Our historical results are not necessarily indicative of future operating results. You should read this selected consolidated financial data in conjunction with the sections entitled "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, all included elsewhere in this prospectus.

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

Nino Months Endod

Income (loss) from continuing operations								
before income taxes								
Income tax benefit					399	16,245		
Income (loss) from								
continuing operations Discontinued		(17,274)	(29,705)	4,138	(39,075)	(23,225)	(28,806)	(32,771)
operations:								
Income (loss) from discontinued								
operations, net of tax			(3,777)	(3,678)	612	2,188	646	
Gain on disposal of discontinued								
operations, net of tax						74,852		
Income (loss) from discontinued								
operations			(3,777)	(3,678)	612	77,040	646	
Net income (loss)	\$	(17,274) \$	(33,482) \$	460 \$	6 (38,463) \$	5 53,815 \$	(28,160) \$	(32,771)
Cumulative dividends on Series A convertible preferred								
stock		(3,430)	(3,430)	(3,430)	(3,430)	(3,430)	(2,573)	(1,143)
Net income (loss) attributable to		(-))	(-))	(- ) )	(-))	(-))		() -)
common stockholders	\$	(20,704) \$	(36,912) \$	(2,970) \$	6 (41,893) \$	50,385 \$	(30,733) \$	6 (33,914)
Income (loss) per common share: Basic								
Continuing operations	\$	(19.47) \$	(26.94) \$	0.50 \$	6 (26.77) \$	6 (16.60) \$	(19.68) \$	(2.36)
Discontinued	Ψ	(1).17)4	(20.91)φ	0.20 4	(20.77)4	γ (10.00) ψ	(19:00) ¢	(2.30)
operations			(3.07)	(2.60)	0.39	47.99	0.40	
Net income (loss)		(19.47)	(30.01)	(2.10)	(26.38)	31.39	(19.28)	(2.36)
Diluted Continuing obligations	\$	(19.47) \$	(26.94) \$	0.29 \$	6 (26.77) \$	6 (16.60) \$	(19.68) \$	6 (2.36)
Discontinued	Ψ	(1).17)4	(20.91) ¢	0.27 4	(20.11)4	γ (10.00) ψ	(19:00) ¢	(2.50)
obligations			(3.07)	(0.26)	0.39	47.99	0.40	
Net income (loss)		(19.47)	(30.01)	0.03	(26.38)	31.39	(19.28)	(2.36)
Weighted average		(17.77)	(30.01)	0.05	(20.30)	51.57	(17.20)	(2.50)
number of common								
shares: Basic	1	063,433	1,229,956	1,413,374	1,587,968	1,605,324	1,594,288	14,356,546
Diluted		063,433	1,229,936	1413,374	1,587,968		1,594,288	14,356,346
Difficu	1,	000,100	1,227,750	51	1,507,900	1,000,027	1,591,200	1,550,570

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

(1)

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

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# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing at the end of this prospectus. In addition to historical information, some of the information in this discussion and analysis contains forward-looking statements reflecting our current expectations and involves risk and uncertainties. For example, statements regarding our expectations as to our plans and strategy for our business, future financial performance, expense levels and liquidity sources are forward-looking statements. Our actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under the "Risk Factors" section and elsewhere in this prospectus.

## Overview

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system, or CNS diseases. Our extensive expertise in product development has been built over the past 20 years: initially as a standalone development organization, then as a U.S. subsidiary of Shire plc and, upon our acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals, Inc. We are planning for the commercial launch of two neurology products for the treatment of epilepsy in 2013 and are developing multiple product candidates in psychiatry to address the large market opportunity in the treatment of ADHD, including ADHD patients with impulsive aggression. We intend to market our products in the United States through our focused sales force targeting specialty physicians, including neurologists and psychiatrists, and to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

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

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

In addition to Oxtellar XR, Trokendi XR, SPN-810 and SPN-812, we have several additional product candidates in various stages of development, including SPN-809 for which we submitted an IND in 2008. SPN-809 would represent a novel mechanism of action for the U.S. anti-depressant market. We believe our broad and diversified portfolio of products and product candidates provides us with multiple opportunities to achieve our goal of becoming a leading specialty pharmaceutical company focused on CNS diseases.

We use our proprietary technologies to enhance the therapeutic benefits of approved drugs through advanced extended release formulations. Oxtellar XR and Trokendi XR are novel oral once-daily extended release formulations of oxcarbazepine and topiramate, respectively, for the treatment of epilepsy. Immediate release formulations of oxcarbazepine and topiramate are available in generic form and are marketed under the brand names of Trileptal and Topamax, respectively. According to IMS Health, peak sales of Trileptal and Topamax represented an estimated 8.1% and 25.8% of the total seizure disorder market in 2006 and



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2008, respectively. We believe there is a significant unmet need for extended release products, such as Oxtellar XR and Trokendi XR, for the treatment of epilepsy. Extended release products have been shown to improve compliance, increase seizure control,<sup>(1)</sup> reduce side effects and improve tolerability as compared to immediate release products.<sup>(2)</sup>

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

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

# History of our Company

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

(1)

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

(2)

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

(3)

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

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

Pursuant to a Unit Purchase Agreement executed on December 14, 2011, we sold 100% of our equity ownership interests in Royalty Sub to an entity affiliated with OrbiMed Advisors LLC, one of our stockholders, hereafter referred to as the "Purchase Transaction." The purchase price consisted of \$27.0 million and a milestone payment of \$3.0 million payable within 10 days of the occurrence of the earlier of the following conditions:

the purchaser receives royalty payments equal to at least \$35.1 million, the purchaser has not entered into a transaction to sell, refinance or monetize its equity interests in Royalty Sub, and no generic formulations of the products underlying the royalty payments and related license agreements have entered the market, or

the purchaser receives proceeds in excess of the aggregate of (a) \$27.0 million, plus (b) the purchase price paid by the purchaser, if any, to acquire a beneficial interest in one or more of the non-recourse notes, plus (c) the aggregate redemption price paid, if any, to redeem any of the non-recourse notes, from any transaction that refinances or liquidates the equity interests in Royalty Sub or the non-recourse notes.

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

Pursuant to the Purchase Transaction, we retained duties and obligations under the non-recourse notes and related agreements, including the Purchase and Sale Agreement, the Residual License Agreements and the Servicing Agreement, for so long as the non-recourse notes remain outstanding. For example, pursuant to the Purchase Transaction, we have an obligation to use commercially reasonable efforts to preserve, maintain, and maximize the commercial value of our licensed patents covering Sanctura XR and Oracea, which includes the obligation to pay patent office maintenance fees in order to keep these patents in force.

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

At the time the non-recourse notes cease to be outstanding, the purchaser must make an election to either (1) terminate the Servicing Agreement and execute the New Servicing Agreement, which was contemplated and drafted at the time of the Purchase Transaction, or (2) obtain from us the assignment and transfer of

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

We accounted for the Purchase Transaction as a sale of a subsidiary and recorded the resulting gain of approximately \$74.9 million as "gain on disposal of discontinued operations, net of tax" in our consolidated statements of operations. The gain on disposal of discontinued operations was calculated as the aggregate of the fair value of the consideration and the carrying value of Royalty Sub's assets and liabilities, less our fees and expenses. Since the assets and liabilities of Royalty Sub had identifiable operations, the sale of Royalty Sub is reported as discontinued operations in our consolidated statements of operations. Accordingly, the gain on the sale of Royalty Sub, as well as any results of operations related to Royalty Sub, are presented as discontinued operations for all periods presented. If we receive the milestone payment, the fair value of amounts received, less any related fees and expenses, will be recorded as "gain on disposal of discontinued operations, net of tax," a component of discontinued operations.

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

In January 2011, we entered into a secured credit facility pursuant to a loan and security agreement with certain lenders, which was subsequently amended in December 2011, providing for term loans of up to an aggregate of \$30.0 million. On January 26, 2011 and December 30, 2011, we drew down \$15.0 million and a second \$15.0 million, respectively, of term loans under this secured credit facility. The term loans bear interest at a fixed rate per annum of 11.0%. The initial \$15.0 million of term loans drawn down in January 2011 will mature on August 1, 2014. The second \$15.0 million of term loans drawn down in December 2011 will mature on January 1, 2015. In connection with the initial drawdown in January 2011, we issued to the lenders warrants that are exercisable for an aggregate of 93,750 shares of common stock at an exercise price of \$4.00 per share. In connection with the drawdown of the second \$15.0 million under our secured credit facility on December 31, 2011, we issued the lenders warrants that are exercisable for an aggregate of common stock at an exercise price of \$5.00 per share. The warrants expire on December 30, 2021. In October 2012, one of the lenders exercised both tranches of its warrants for an aggregate of 101,667 shares of common stock using a cashless net share settlement, resulting in the issuance of 64,309 shares of common stock to this lender.

These warrants are accounted for as a derivative liability, and as such, we reflect the liability at its estimated fair value in the consolidated balance sheets. The fair value of this derivative liability is re-measured at the end of every reporting period and the change in fair value is reported in the consolidated statements of operations as other income (expense).

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



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

# **Financial Overview**

## Revenue

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

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

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

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

		Year E	nde	d Decem	31,	Nine Months Ended September 30,					
	,	2009		2010	,	2011	2011		2	2012	
							(unaudited)				
				(i	n th	ousands	5)				
Continuing operations:											
Development and milestone revenues collaboration arrangements	\$	1,050	\$	106	\$	803	\$	761	\$	391	
Royalty revenues Intuniv		36,875									
Total continuing operations revenues		37,925		106		803		761		391	
Discontinued operations:											
Development and milestone revenues Oracea & Sanctura XR		500									
Royalty revenues Oracea & Sanctura XR		8,088		13,404		14,398		9,887			
Total discontinued operations revenues		8,588		13,404		14,398		9,887			
Total revenues	\$	46,513	\$	13,510	\$	15,201	\$	10,648	\$	391	

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

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

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

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

## **Research and Development Expense**

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

employee-related expenses, which include salaries and benefits;

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

the cost of acquiring and manufacturing clinical trial materials;

the cost of manufacturing validation tests, if these materials are manufactured prior to obtaining regulatory approval;

costs related to facilities, depreciation and other allocated expenses;

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

stock-based compensation expense to employees and consultants engaged in research and development activities; and

costs associated with non-clinical activities and regulatory approvals.

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

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

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

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

													From		
									Nine N	101	nths	]	Inception		
									En	dec	l		to		
		Y	ear En	r Ended December 31,					Septem	be	r 30,	September 30			
		2	2009		2010		2011		2011 2012			2012			
									(unau	dit	ed)	(unaudited)			
							(in th	ous	sands)						
Trokendi XR		\$	6,464	\$	9,864	\$	6,262	\$	5,675	\$	3,205	\$	6 31,642		
Oxtellar XR			10,027		12,664		10,959		8,475		3,458		52,252		
SPN-810			3,333		2,150		4,152		2,919		3,970		17,995		
SPN-812 and SPN-809			680		2,042		1,166		623		1,461		10,705		
Other research and develo	pment														
programs			426		690		204		3		37		7,491		
Development expenses	general		8,330		7,739		7,884		5,431		6,236		52,086		
Total research and develop	oment														
expenses		\$	29,260	\$	35,149	\$	30,627	\$	23,126	\$	18,367	\$	5 172,171		

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

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

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

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

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

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

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

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

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

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

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

## Selling, General and Administrative Expenses

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

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

## Other Income and Expense

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

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

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



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## Net Operating Losses and Tax Carryforwards

As of December 31, 2011, we had approximately \$37.5 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of approximately \$5.0 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2025, if not utilized. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

## Net Income and Loss

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

## **Results of Operations**

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

	N	Inc	ncrease/					
		2011 (unau		,	(decrease)			
		(in thou	Isa	nds)				
Revenues:								
Development and milestone revenues	\$	761	\$	391	\$	(370)		
Total revenues		761		391				
Operating Expenses:								
Research and development		23,126		18,367		(4,759)		
Selling, general and administrative		5,143		11,450		6,307		
6, 6.		- , -		,		- )		
Total operating expenses		28,269		29,817				
				_,,				
Operating loss from continuing operations		(27,508)		(29,426)				
Interest income and other income (expense), net		59		(574)		(633)		
Interest expense		(1,357)		(2,771)		1,414		
		(1,007)		(_,, , , 1)		1,.11		
Total other income (expense)		(1,298)		(3,345)				
Total other meonie (expense)		(1,2)0)		(3,343)				
Loss from continuing operations	\$	(28,806)	¢	(32,771)				
Income from discontinued operations, net of tax	ф	(28,800)	φ	(32,771)		(646)		
income from discontinued operations, net of tax		040				(040)		
NT - T	¢	(20, 100)	٩	(22 771)				
Net Loss	\$	(28,160)	\$	(32,771)				
		6	1					

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#### Revenues

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

## Research and Development Expense

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

## Selling, General and Administrative Expense

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

## Interest Income and Other Income (Expense), Net

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

### Interest Expense

Interest expense was approximately \$2.8 million for the nine months ended September 30, 2012, compared to \$1.4 million for the same period in 2011. This increase is primarily due to the drawdown of the second \$15.0 million under our secured credit facility in December 2011.

## Loss from continuing operations

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

#### Income from discontinued operations

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

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

	Year I Decem 2010 (in the		(dec	rease/ crease) s)	
Revenues:					
Development and milestone revenues	\$ 106	\$	803	\$	697
Total revenues	106		803		
Operating Expenses:					
Research and development	35,149		30,627		(4,522)
Selling, general and administrative	5,080		7,928		2,848
Total operating expenses	40,229		38,555		
Operating loss from continuing operations	(40,123)		(37,752)		
Interest income and other income (expense), net	(40,123) 649		(37,732)		(501)
Interest expense	047		(1,866)		(1,866)
increst expense			(1,000)		(1,000)
Loss from continuing operations before income taxes	(39,474)		(39,470)		
Income tax benefit	399		16,245		
Loss from continuing operations	\$ (39,075)	\$	(23,225)		
Discontinued operations:					
Income from discontinued operations, net of tax	612		2,188		1,576
Gain on disposal of discontinued operations, net of tax			74,852		74,852
Income from discontinued operations	612		77,040		
Net income (loss)	\$ (38,463)	\$	53,815		

#### Revenues

Our revenues were approximately \$0.8 million for the year ended December 31, 2011 compared to approximately \$0.1 million for the same period in 2010, representing an increase of \$0.7 million. This increase was principally attributable to a one-time milestone payment of \$750,000 in 2011 under our license agreement with United Therapeutics.

## Research and Development

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

#### Selling, General and Administrative

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

# Interest Income and Other Income (Expense), Net

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

#### Interest Expense

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

## Loss from continuing operations

Loss from continuing operations was \$23.2 million for the year ended December 31, 2011 compared to a loss of \$39.1 million for the same period in 2010. This decrease was primarily due to the income tax benefit of \$16.2 million in 2011, which was utilized to reduce income tax expense from discontinued operations income.

## Income from discontinued operations

Income from discontinued operations was \$2.2 million for the year ended December 31, 2011 compared to \$0.6 million for the same period in 2010, representing an increase of approximately \$1.6 million. This increase is mainly due to increased royalty revenues of approximately \$1.0 million from Oracea and Sanctura XR for the year ended December 31, 2011. Additionally, in 2011, we realized a gain on sale of Royalty Sub of approximately \$74.9 million, net of taxes, calculated as the aggregate of the fair value of consideration of \$27.0 million and the carrying value of Royalty Sub's assets and liabilities, less its fees and expenses. Results for prior years have been restated for discontinued operations. For additional details on our discontinued operations, refer to Note 8 to our consolidated financial statements.

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

		Year Decem			Increase/			
		2009		2010				
		(in th	ous	ands of d	lolla	rs)		
Revenues:								
Development and milestone revenues	\$	1,050	\$	106	\$	(944)		
Royalty revenues		36,875				(36,875)		
Total revenues		37,925		106				
Operating Expenses:								
Research and development		29,260		35,149		5,889		
Selling, general and administrative		4,649		5,080		431		
Total operating expenses		33,909		40,229				
Operating income (loss) from continuing operations		4,016		(40,123)				
Interest income and other income (expense), net		122		649		527		
Income (loss) from continuing operations before income taxes		4,138		(39,474)				
Income tax benefit				399				
Income (loss) from continuing operations		4,138		(39,075)		(43,213)		
Discontinued operations:		,		(				
Income (loss) from discontinued operations, net of tax		(3,678)		612				
· · · · · · · · · · · · · · · · · · ·		,						
Income (loss) from discontinued operations		(3,678)		612		4,296		
		(2,070)		012		.,_>0		
Net income (loss)	\$	460	\$	(38,463)				
ret neonie (1655)	Ψ	100	Ψ	(50, -05)				

#### Revenues

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

#### Research and Development

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

## Selling, General and Administrative

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

## Interest Income and Other Income (Expense), Net

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

## Income (Loss) from continuing operations

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

## Income (loss) from discontinued operations

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

# Liquidity and Capital Resources

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



# Financing History and Future Capital Requirements

## Non-recourse Notes

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

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

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

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

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



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enforcing the related provisions under the license agreements. Specifically, we are required to monitor receipt of the royalty payments due under the license agreements and to confirm that the payments are received on a timely basis, calculated properly and made available to the trustee.

#### Sale of Intuniv Royalties

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

## Secured Credit Facility

In January 2011, we entered into a secured credit facility pursuant to a loan and security agreement with certain lenders which was subsequently amended in December 2011, providing for term loans of up to an aggregate of \$30.0 million. In connection with the initial drawdown of \$15.0 million under our secured credit facility on January 26, 2011, the lenders received from us ten-year warrants that are exercisable for an aggregate of 93,750 shares of our common stock at an exercise price of \$4.00 per share. The warrants expire on January 26, 2021. In December 2011, in connection with the drawdown of the second \$15.0 million under our secured credit facility, as amended, we issued to the lenders warrants that are exercisable for an aggregate of 49,999 shares of our common stock at an exercise price of \$5.00 per share. The warrants expire on December 30, 2021. In October 2012, one of the lenders exercised both tranches of its warrants to purchase an aggregate of 101,667 shares using cashless net share method. As a result of this exercise, we issued 64,309 shares of common stock to this warrant holder. We have primarily used the proceeds of the term loans under our secured credit facility to fund ongoing clinical trials for Oxtellar XR, Trokendi XR and SPN-810, to prepare for manufacturing validation of Oxtellar XR and Trokendi XR, to support formulation for various clinical stage products, to prepare commercial marketing of Oxtellar XR and Trokendi XR and for regulatory filing fees. The term loans bear interest at a fixed rate per annum of 11.0%. The initial \$15.0 million of term loans drawn down in January 2011 will mature in August 2014. The second \$15.0 million of term loans drawn down in December 2011 will mature in January 2015. In March 2011, we made the first of twelve monthly interest-only payments on the initial \$15.0 million of term loans drawn down in January 2011. Thereafter, beginning in March 2012, which is the amortization date for these term loans, we will make principal and interest payments to fully amortize the balance over the term of these term loans. In February 2012, we made the first of six monthly interest-only payments on the second \$15.0 million of term loans drawn down in December 2011. Thereafter, beginning in August 2012, which is the amortization date for these term loans, we will make principal and interest payments to fully amortize the balance over the term of these term loans.

We may voluntarily prepay all, but not less than all, outstanding term loans under our secured credit facility at any time, subject to the payment of a premium. With respect to any prepayment, the premium is 5.0% if such prepayment is made before the amortization date, 2.0% if such prepayment is made during the 15-month period after the amortization date and 1.0% if such prepayment is made thereafter. Upon the maturity of any outstanding term loans or the acceleration or prepayment thereof, we will also be required to make a final payment equal to 2.5%, or \$750,000, of the aggregate principal amount of the term loans borrowed under our secured credit facility. This payment is being recorded as additional interest expense over the life of the loan.

All obligations under our secured credit facility are secured by substantially all of our existing property and assets (excluding our intellectual property) and by a pledge of the capital stock of, subject to certain exceptions, our U.K. subsidiary and any future subsidiary. Our secured credit facility includes negative covenants that, subject to certain exceptions, limit our ability and the ability of our subsidiaries to, among



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

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

## Stendhal License

In August 2011, we executed a Development and Licensing Agreement with Especificos Stendhal, S.A., DE C.V. (Stendhal) that provided Stendhal an exclusive license to our licensed intellectual property underlying our Oxtellar XR product, in Mexico, Venezuela, Colombia and other select markets in Central and South America. The agreement included the right to our patents, proprietary information, and know-how of our drug-delivery technology and pharmaceutical product underlying our Oxtellar XR product. Stendhal is responsible for all costs associated with clinical development, approval, commercialization and distribution of the product in the defined territory, which may be expanded upon certain events. We have received \$750,000 from Stendhal, which is being recognized as revenue on a straight-line basis over the substantive obligation period until approval, which is estimated to be December 2013. We monitor this estimate on a quarterly basis to determine if facts and circumstances may have changed that would require a prospective adjustment of the recognition period. We may receive up to \$3.0 million in additional milestone payments, based on certain regulatory and commercial milestones defined in the agreement. As of September 30, 2012, \$456,000 remained recorded as deferred revenue.

In September 2012, the Company executed a Development and Licensing Agreement (Stendhal License Agreement) with Stendhal that provided Stendhal with an exclusive license of the Company's intellectual property underlying the Trokendi XR product in the defined territory. The license included the right to the Company's patents, proprietary information, and know-how of the Company's drug-delivery technology and pharmaceutical product underlying its Trokendi XR product. Stendhal is responsible for all costs associated with clinical development approval, commercialization and distribution of the product in the defined territory. The Company will receive \$1.8 million of deferred revenue that will be recognized as revenue in a straight-line basis over its substantive obligation period of twelve years. As of September 30, 2012, \$0.5 million of this amount has been recorded as deferred revenue. The Company monitors this estimate on a quarterly basis to determine if facts and circumstances may have changed that would require a prospective adjustment to the recognition period. The Company may receive up to \$1.8 million in future milestone payments, based on certain milestones defined in the Stendhal License Agreement.

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## United Therapeutics License

We have a license agreement with United Therapeutics to use one of our proprietary technologies for an oral formulation of Remodulin for the treatment of PAH, and potentially for additional indications. Remaining milestone payments to us could total up to approximately \$6.0 million, which includes milestone payments that could total \$2.0 million based on the satisfaction of development milestones of oral treprostinil in PAH and up to approximately \$4.0 million for the development of additional treprostinil products for a second indication. United Therapeutics has stated that this oral formulation of treprostinil diethanolamine, or treprostinil, is the subject of an NDA for PAH that was submitted in December 2011, and accepted for filing by the FDA in February 2012. On October 23, 2012, United Therapeutics received a complete response letter from the FDA declining to approve the product. We do not expect to receive any royalties for this formulation in this indication unless and until final marketing approval from the FDA is received and until United Therapeutics launches this product. Through September 30, 2012, we have received \$1.5 million in pre-commercial milestone payments under the agreement. If United Therapeutics receives approval to market and sell oral treprostinil for additional indications and/or any additional combination products that utilizes our technologies, we will receive royalties in the single digits based on net sales worldwide. Any revenues received under this agreement will fluctuate as a result of the timing and amount of milestone and other payments received under this agreement, and the amount and timing of payments that we receive upon the sale of covered products, to the extent any are successfully commercialized by United Therapeutics or its sub licensees. Our license agreement with United Therapeutics will expire, on a country-by-country and product-by-product basis, 12.5 years from the first commercial sale of each product in such country. United Therapeutics may terminate the agreement for a technical, strategic or market-related cause after giving us a reasonable opportunity to cure. We may terminate the agreement if, after having launched a product in a country, United Therapeutics or its sub-licensee discontinues the sale of such product for a prolonged period of time for reasons unrelated to force majeure, regulatory or safety issues. In addition, either party may terminate the agreement for the material, uncured breach by the other party and in certain events of bankruptcy or insolvency of the other party.

# Funding Requirements

As of September 30, 2012, we had unrestricted cash, cash equivalents and marketable securities of \$62.5 million, an increase of \$14.0 million from \$48.5 million at December 31, 2011. This increase is primarily due to the proceeds received from our initial public offering in May 2012, offset by ongoing losses from operations as we continue to build towards two product launches in 2013. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. In this regard, the report of our independent registered public accounting firm with respect to our consolidated financial statements as of and for the period ended December 31, 2011 contains an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. Furthermore, since the completion of our initial public offering in May 2012, we have incurred additional costs associated with operating as a public company. We believe that the successful completion of this public offering will eliminate this doubt. However, while we believe that the proceeds of this offering, together with our cash, cash equivalents and marketable securities and anticipated future product revenues will be sufficient to commercialize both Oxtellar XR and Trokendi XR, there can be no assurance that we become cash flow positive. In addition, we may need to obtain additional funds to develop and commercialize our other product candidates. The inclusion of a going concern statement by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.



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

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

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

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

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

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

The receipt of marketing approval from the FDA for Trokendi XR;

The costs of our commercialization activities for Oxtellar XR and Trokendi XR, if it receives final approval from the FDA;

The cost of building and maintaining a wide variety of internal sales, distribution and marketing capabilities for the commercial launch of our products;

The terms of third-party commercial manufacturing arrangements and cost of purchasing manufacturing and other capital equipment for our potential products;

The cost and availability of active chemical ingredients and other manufacturing components required to supply a finished product;

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

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

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

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

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

# Cash Flows

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

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

## **Operating Activities**

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

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

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

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

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

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

## **Investing** Activities

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

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

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

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

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

## **Financing** Activities

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

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

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

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

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

## **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments as of September 30, 2012 (except as noted below):

Contractual Obligations		Less than 1 Year		1 - 3 Years		3 - 5 Years		Greater than 5 Years		Total						
				( <b>\$</b> i	in t	housar	ıds)									
Secured Credit Facility <sup>(1)</sup>	\$	11,490	\$	14,491	\$		\$		\$	25,981						
Interest on Secured Credit Facility <sup>(1)</sup>		2,161		1,762						3,923						
Operating leases <sup>(2)</sup>		964		1,979		2,059		618		5,620						
Purchase obligations <sup>(3)</sup>		8,144								8,144						
Total <sup>(4)</sup>	\$	22,759	\$	18,232	\$	2,059	\$	618	\$	43,668						

(1)

Annual interest expense is currently \$2.2 million on \$26.0 million of principal outstanding currently.

(2)

Our commitments for operating leases relate to our lease of copiers and office and laboratory space as of September 30, 2012.

(3)

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

(4)

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

above.

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

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will also be obligated to pay royalties to Afecta based on net sales worldwide of our product candidates in the low-single digits. We have also entered into a purchase and sale agreement with Rune, where we obtained the exclusive worldwide rights to a product concept from Rune. There are no future milestone payments owing to Rune under this agreement. If we receive approval to market and sell any products based on the Rune product concept for SPN-809, we will be obligated to pay royalties to Rune based on net sales worldwide in the low single digits.

## **Off-Balance Sheet Arrangements**

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

## **Critical Accounting Policies and Estimates**

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

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

#### **Revenue Recognition**

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

#### Multiple Element Arrangements

For multiple element arrangements, we evaluate the components of each arrangement as separate elements based on certain criteria. Accordingly, revenues from collaboration agreements are recognized based on the performance requirements of the agreements. We recognize revenues when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed and determinable, and collection is reasonably assured.

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



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

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

## **Milestone Payments**

Milestone payments have been recognized as revenue when the collaborative partner acknowledges completion of the milestone and substantive effort was necessary to achieve the milestone. In January 2011, we adopted ASU 2010-17, *Revenue Recognition-Milestone Method*. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved only if the milestone meets all the criteria identified in the guidance to be considered substantive. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

the milestone payments are non-refundable;

achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

substantive effort is involved in achieving the milestone;

the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and

a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and recognized as revenue when services have been rendered and there are no further performance obligations. The adoption of ASU 2010-17 did not have a material impact on our consolidated results of operations, financial position, or liquidity.

#### **Royalty Revenues**

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

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

## Inventories

Inventories, which are recorded at the lower of cost or market, include materials, labor and other direct and indirect costs and are valued using the first-in, first-out method. We capitalize inventories produced in preparation for commercial launches when it becomes probable that the related product candidates will receive regulatory approval and that the related costs will be recoverable through the commercialization of the product. Following the receipt of tentative approval for Trokendi XR from the FDA on June 25, 2012, and the receipt of approval of Oxtellar XR from the FDA on October 19, 2012, we will capitalize validation batch manufacturing costs, to the extent the product is expected to be sold commercially after the product launch.

## Accrued Expenses

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

fees paid to CROs in connection with clinical trials;

fees paid to investigative sites in connection with clinical trials;

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

professional service fees.

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

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

## Stock-Based Compensation

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

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

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

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

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the input of subjective assumptions, including stock price volatility, assumed dividend yield, the expected term of stock options and a risk-free interest rate. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies, or our guideline peer group, for which historical information is available. We will continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants. The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future. We determine the average expected term of stock options according to the "simplified method" as described in Staff Accounting Bulletin 110, which is the mid-point between the vesting date and the contractual term. We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected term assumed at the date of grant. The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2009, 2010 and 2011 and the nine months ended September 30, 2011 and 2012 are set forth in our consolidated financial statements appearing at the end of this prospectus.

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

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



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

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

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

our stage of development and business strategy;

our financial condition, operating results and book value;

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

our projected operating results;

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

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

important developments relating to the results of our clinical trials;

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

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

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

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

plus accumulated unpaid dividends.

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

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

(1)

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

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

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

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

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

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

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

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

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

## Stock Option Grants on December 15, 2009

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

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

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

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



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

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

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

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

#### Stock Option Grants on October 14, 2011

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

Scenario	Probability
1. An initial public offering in late 2011	0%
2. Royalty monetization in 2011 with an initial public offering in the first half of 2012	5%
3. Preferred equity financing in 2011, royalty monetization 2011, and an initial public offering in the second half of 2012	5%
4. Preferred equity financing in 2011 with an initial public offering in the first half of 2012	60%
5. Merger or other sale transaction in late 2011	30%
83	

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

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

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

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

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

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

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

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

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



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

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

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

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

#### Lender Warrants

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

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

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

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

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

Subsequent to the completion of our initial public offering, which occurred on May 1, 2012, we have calculated the fair value of the common stock warrants using a Black-Scholes model within a Monte-Carlo framework. The Monte-Carlo simulation is a generally accepted statistical method used to estimate fair value based on the application of subjective assumptions, consistently applied for each period, including the probability, timing and magnitude of our issuance of additional common stock in future financings. This valuation is computed at the end of each fiscal quarter to reflect conditions at each valuation date until the warrants are exercised or they expire. In addition to assumptions regarding future equity financings, consideration is also given to the current stock price, anticipated stock volatility going forward, and the anti-dilution provisions embedded in the warrant agreements. In October 2012, a lender exercised both tranches of its warrants to purchase an aggregate of 101,667 shares of common stock using a cashless net share settlement. As a result of this exercise, we issued 64,309 shares of common stock to this lender.

#### **Recent Accounting Pronouncements**

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

#### Jumpstart Our Business Startups Act of 2012

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

## Quantitative and Qualitative Disclosure About Market Risk

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2012, we had unrestricted cash, cash equivalents, marketable securities and long term investments of \$62.5 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash, cash equivalents, marketable securities and long term investments, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments. We do not have any foreign currency or other derivative financial instruments.

We contract with contract research organizations and investigational sites globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements, primarily with respect to Euro denominated currencies. We do not hedge our foreign currency exchange rate risk. A hypothetical 10% appreciation in Euro exchange rates against the U.S. dollar from prevailing market rates would have increased our net loss by approximately \$540,000 for the nine months ended September 30, 2012. Conversely, a hypothetical 10% depreciation in Euro exchange market rates would have decreased our net loss by approximately \$540,000 for the nine months ended September 30, 2012. We do not believe that inflation and changing prices over the years ended December 31, 2009, 2010 and 2011 or the nine months ended September 30, 2011 and 2012 had a significant impact on our consolidated results of operations.



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### BUSINESS

#### Overview

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system, or CNS, diseases. Our extensive expertise in product development has been built over the past 20 years: initially as a stand alone development organization, then as a U.S. subsidiary of Shire plc and, upon our acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals. We are planning for the commercial launch of two neurology products in 2013 for the treatment of epilepsy and are developing multiple product candidates in psychiatry to address the large market opportunity in the treatment of attention deficit hyperactivity disorder, or ADHD, including ADHD patients with impulsive aggression. We intend to market our products in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists and to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

Our neurology portfolio consists of an approved product and a tentatively approved product. On October 19, 2012, the FDA granted final approval of Oxtellar XR (extended release oxcarbazepine), formerly known as SPN-804, as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age. On November 15, 2012, the FDA granted Oxtellar XR a three year marketing exclusivity. On June 25, 2012, the FDA granted tentative approval of Trokendi XR (extended release topiramate), formerly known as SPN-538, as initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures, and as adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures or with seizures associated with Lennox-Gastaut syndrome. The final approval for Trokendi XR may not be made effective until the expiration of the marketing exclusivity period that Topamax has regarding safety information of topiramate in a specific pediatric population. This marketing exclusivity expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. We anticipate the commercial launch of Oxtellar XR to occur during the first quarter of 2013 and the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA.

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

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

We use our proprietary technologies to enhance the therapeutic benefits of approved drugs through advanced extended release formulations. Oxtellar XR and Trokendi XR are novel oral once-daily extended release formulations of oxcarbazepine and topiramate, respectively, for the treatment of epilepsy. We believe that these will be the first extended release formulations for the treatment of these indications available in the U.S. Immediate release formulations of oxcarbazepine and topiramate are available in generic form and are marketed by Novartis and Johnson & Johnson under the brand names of Trileptal and Topamax, respectively. According to IMS Health, peak sales of Trileptal and Topamax represented an estimated 8.1% and 25.8% of the total seizure disorder market in 2006 and 2008, respectively. We pursued a Section 505(b)(2) regulatory strategy for Oxtellar XR, which allows us to rely on the existing data from the new drug application, or NDA, of Trileptal. The once-per-day dosing of each of Oxtellar XR and Trokendi XR is designed to improve patient compliance and to provide a better tolerability profile compared to the current immediate release anti-epileptic drugs, or AEDs, that are taken multiple times per day to maintain

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therapeutic drug concentrations over the dosing interval. We believe there is a significant unmet need for extended release products, such as Oxtellar XR and Trokendi XR, for the treatment of epilepsy. Extended release products have been shown to improve compliance, increase seizure control, reduce side effects and improve tolerability<sup>(1)</sup> as compared to immediate release products.<sup>(2)</sup>

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

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

Product	Indication	Status
Oxtellar XR	Adjunctive therapy for epilepsy	Final approval by FDA
Trokendi XR	Epilepsy	Tentative approval by FDA
SPN-810	Impulsive aggression in ADHD	Phase IIb completed
SPN-812	ADHD	Phase IIa completed
SPN-809	Depression	IND filed
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We have a successful track record of developing novel products by applying proprietary technologies to known drugs to improve existing therapies and enable the treatment of new indications. We have a broad portfolio of drug development technologies consisting of six platforms that include the following: Microtrol (multiparticulate delivery platform), Solutrol (matrix delivery platform) and EnSoTrol (osmotic delivery system). Our proprietary technologies have been used in the following approved products: Carbatrol (carbamazepine), Adderall XR (mixed amphetamine salts), and Intuniv (guanfacine), marketed by Shire; Equetro (carbamazepine), marketed by Validus Pharmaceuticals Inc.; Sanctura XR (trospium chloride), marketed by Allergan; and Oracea (doxycycline), marketed by Galderma. We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies and our product candidates. Throughout our 20 year history, we have continued our commitment to innovation with a focus for the past six years on successfully developing our own product candidates in neurology and psychiatry.

(1)

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

(2)

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

(3)

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

#### **Our Strategy**

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

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

*Continue to advance our product candidates in our psychiatry portfolio, including SPN-810 and SPN-812.* As part of our longer term strategy, we intend to further develop our product candidates in our psychiatry portfolio to enable further diversification of our pipeline and future growth. For example, we recently completed a Phase IIb trial of SPN-810 for impulsive aggression in patients with ADHD for which we received positive topline results in November 2012.

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

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

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

## Epilepsy

#### Overview

Epilepsy is a complex neurological disorder characterized by spontaneous recurrence of unprovoked seizures, which are sudden surges of electrical activity in the brain that impair a person's mental or physical abilities. Epilepsy, which is typically diagnosed by a neurologist, is estimated to affect 50 million people worldwide<sup>(4)</sup> and 2 million people in the United States.<sup>(5)</sup> According to IMS Health, U.S. sales of AEDs were approximately \$4.0 billion in 2011. The annual cost of epilepsy to the healthcare system is estimated to be \$12.5 billion.<sup>(6)</sup>

Epileptic seizures can cause a person to experience severe muscle jerking, to lose consciousness and fall, or to suffer from distorted vision, all potentially leading to physical injuries or hospitalization. Until reliable seizure control has been achieved, patients are forced to adjust their lifestyles to avoid activities that a seizure can significantly disrupt or render life threatening. A breakthrough seizure is a sudden, unexpected

(4)

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

(5)

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

(6)

Epilepsy Foundation, Cost Study Shows Divide in Treatment Effects, published April 2000.

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seizure experienced by a patient who previously had achieved reliable seizure control. Even when no physical injury occurs, breakthrough seizures often result in significant social, legal and developmental consequences for patients such as loss of driver's license, loss of employment, disruption of school attendance, academic underachievement, and disruption of social networks. In addition, a single breakthrough seizure can lead to permanent loss or reduction in overall seizure control. Data suggest that a significant proportion of patients who experience a breakthrough seizure have a lower chance of achieving reliable seizure control.<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>

## **Current Treatment Options**

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

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

# Dynamics of the Epilepsy Market

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

## Compliance is Critical to the Reduction in Breakthrough Seizures

Compliance with drug treatment regimens is critically important to achieving effective therapy for patients with epilepsy where the consequences of non-compliance can be life threatening. Patient non-compliance with AED therapy is a serious issue and remains one of the most common causes of breakthrough seizures. Not only is taking all prescribed doses critical for epileptic patients, but the timing of when patients take

(7)

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

(8)

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

(9)

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

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

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

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

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

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

(10)

(11)

Faught, R.E., Weiner, J.R., Guérin, A. et al., Impact of nonadherence to antiepileptic drugs on healthcare

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

utilization and costs: Findings from RANSOM study, published March 2009 Epilepsia; 50:501-9.

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

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

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

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

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

## Benefits of Extended Release Products in the Epilepsy Market

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

Achieving reliable seizure control for patients and avoiding the serious health and life dangers that can be associated with breakthrough seizures depends on patients being compliant and diligent in taking their medications. Frequent and multiple dosing, side effects and lack of tolerability of the immediate release products can significantly contribute to patients forgetting doses or skipping them. Even taking a second or

(12)

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

(13)

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

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third dose later than the scheduled time may place a patient at an increased risk of a breakthrough seizure because the drug level in the patient's blood could drop below the minimum effective therapeutic level that prevents such seizures. We believe increased patient compliance can be achieved with extended release products that offer once-daily dosing, reduced side effects and improved tolerability. We believe physicians understand that the release profiles of extended release products can produce more consistent and steadier blood levels as compared to immediate release products, resulting in fewer side effects and better tolerability that further help patients to be compliant, have fewer breakthrough seizures and, correspondingly, enjoy a better quality of life.

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

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

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

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

The enhanced safety profile of extended release products as compared to similar immediate release products has been supported by several studies. For example, in a 2004 published trial conducted by physicians at Johns Hopkins, Carbatrol, an anti-epileptic extended release carbamazepine product that uses our Microtrol technology, and Tegretol XR, another extended release carbamazepine product, demonstrated better tolerability and side effect profiles than comparable immediate release products. The trial reported

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that 49% of patients had side effects during treatment with immediate release carbamazepine such as sedation, double-vision, confusion, ataxia, dizziness or poor coordination, whereas with extended release carbamazepine treatments, only 20% of patients reported these side effects.

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

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

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

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

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

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

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\$26,000 per patient on an annual basis, is significantly greater than any cost savings per patient that may be achieved through switching to a low-cost generic AED. According to a 2009 survey, the total healthcare costs for patients using branded topiramate products were approximately 20% lower than for patients using multiple generic topiramate products.<sup>(14)</sup>

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

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

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

# Source: IMS Health

#### **Our Neurology Portfolio**

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

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

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

The FDA approved our NDA for Oxtellar XR on October 19, 2012 as adjunctive therapy for partial seizures in adults and in children 6 years to 17 years of age. The FDA granted tentative approval of Trokendi XR on June 25, 2012, as initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures, and as adjunctive therapy in patients 6 years of age and older with similar seizures associated with Lennox-Gastaut syndrome. The final approval for Trokendi XR may not be made effective until the expiration of the marketing exclusivity protection that Topamax has regarding safety information of topiramate in a specific pediatric population, which expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. We anticipate the commercial launch of Oxtellar XR to occur during the first quarter of 2013 and the commercial launch of Trokendi XR to occur during the third quarter of 2013 assuming the receipt of final approval by the FDA. If we are successful in obtaining final FDA approval, we believe that Trokendi XR could, over time, capture a significant share of the topiramate prescriptions, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market of the last 15 years.

## Oxtellar XR (extended release oxcarbazepine)

Oxtellar XR is a novel oral once-daily extended release formulation of oxcarbazepine, for which we received approval from the FDA on October 19, 2012 as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age. On November 15, 2012, the FDA granted three year marketing exclusivity to Oxtellar XR. Oxtellar XR delivers oxcarbazepine, another effective AED, which is marketed by Novartis under the brand name Trileptal and is available in a generic form. Trileptal was initially developed and approved in the United States in 2000. Trileptal is indicated for monotherapy and adjunctive therapy of epilepsy. It reached peak worldwide sales of \$721 million in 2006, before generic products entered the U.S. market in October 2007.<sup>(16)</sup> With approximately 3.4 million total oxcarbazepine prescriptions in 2011 and trending at 3.5 million prescriptions in 2012, oxcarbazepine represents a portion of prescriptions with approximately 2.8% of total prescriptions, according to data from IMS Health. Oxcarbazepine is an active voltage-dependent sodium channel blocker that, despite its effectiveness in treating epilepsy, is associated with many side effects that tend to limit its use. The side effects associated with taking oxcarbazepine include, among others, dizziness, double vision, somnolence, nausea and vomiting. Oxtellar XR has been designed to reduce side effects, resulting in improved patient compliance and tolerability.

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

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

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## Oxtellar XR Development Program

We submitted an NDA for Oxtellar XR that was accepted for filing by the FDA in February 2012 and approved on October 19, 2012. The various clinical trials conducted on Oxtellar XR and that supported the NDA were designed to select the best extended release once-per-day formulation that delivers equivalent levels of oxcarbazepine compared to immediate release twice-per-day Trileptal, as well as to test the robustness and consistency of our technology in delivering the once-per-day formulation across a full range of product strengths. We also have scaled up our production of the product candidate at our commercial contract manufacturing facility, which produced clinical supplies to conduct our Phase III trial.

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

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

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

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

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

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

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in the treatment of seizures of partial origin in subjects with refractory epilepsy on at least one and up to three other AEDs.

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

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

#### Percent Median Seizure Reduction per 28 Days: All Countries

Percent Median Seizure Reduction per 28 Days: North America

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

#### **Treatment Response and Seizure-Free Rates (ITT Population)**

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

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

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



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# Commercialization Strategy

We expect Oxtellar XR to be the only once-daily oxcarbazepine product indicated for the treatment of epilepsy as an adjunctive therapy and to compete against the existing immediate release oxcarbazepine products on the market. We believe that Oxtellar XR could, over time, capture a significant share of the oxcarbazepine prescription market, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market over the past 15 years. To support the commercial launch of Oxtellar XR, which was granted three years of market exclusivity by the FDA, we plan to build a small specialty sales force primarily targeting neurologists to promote the use of Oxtellar XR as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age in the United States. We expanded our agreement with the CMO to provide for the production of commercial quantities of Oxtellar XR to fulfill expected demand through the commercial launch of the product.

## Trokendi XR (extended release topiramate)

Trokendi XR is a novel oral once-daily extended release topiramate product for the treatment of epilepsy. The FDA issued a tentative approval of Trokendi XR in June 2012, as initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures, and as adjunctive therapy in patients 6 years of age and older with similar seizures or with seizures associated with Lennox-Gastaut syndrome. The final approval for Trokendi XR may not be made effective until the period of marketing exclusivity protection associated with safety information regarding a specific pediatric population, which expires on June 22, 2013. We are not required to complete any additional clinical trials for Trokendi XR. Topiramate is marketed by Johnson & Johnson under the brand name Topamax and is also available in a generic form. Topiramate is currently available only in immediate release form and is indicated for monotherapy and adjunctive therapy of epilepsy and for the treatment of migraine. Topamax reached peak worldwide sales of \$2.7 billion in 2008, before generic products entered the U.S. market in March 2009.<sup>(15)</sup> With approximately 10.0 million total topiramate prescriptions in 2011 and trending at 10.7 million prescriptions in 2012, topiramate continues to represent a significant portion of prescriptions with approximately 8.4% of total prescriptions, according to data from IMS Health. Topiramate is believed to work in epilepsy through various mechanisms. It enhances the inhibitory effect of the GABA (gamma-aminobutyric acid) neurotransmitter that regulates neuronal excitability throughout the nervous system, blocks the excitatory effect of the glutamate neurotransmitter, blocks the sodium channel and inhibits the carbonic anhydrase enzyme. The side effects associated with taking topiramate, which have tended to limit its use, include, among others, dizziness, fatigue, somnolence and slowing of certain cognitive functions. We believe that this creates an opportunity for us to offer patients Trokendi XR as an alternative therapy to immediate release topiramate with an improved once-per-day profile.

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

Trokendi XR was studied in a U.S. Phase II, multicenter, open-label, sequentially-designed conversion clinical trial among patients between the ages of 18 and 65 having partial-onset or primary generalized seizures. Prior to enrolling in the study, patients were taking topiramate twice-a-day immediate release products with total daily regimen that ranged from 200mg-400mg. Patients were first converted to

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

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

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

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

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

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# Trokendi XR Development Program

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

# Commercialization Strategy

If we are successful in obtaining final regulatory approval, we believe that Trokendi XR will be the first once-daily topiramate product approved, as initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures, and as adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures or with seizures associated with Lennox-Gastaut syndrome. We believe that Trokendi XR could, over time, capture a significant share of the topiramate prescriptions, consistent with the performance of similar extended release products that have been introduced in the U.S. epilepsy market over the past 15 years. We plan to expand our sales force that will commercially launch Oxtellar XR and will subsequently be used to commercially launch Trokendi XR in the third quarter of 2013. We expect to finalize the terms of the commercial manufacture and supply of Trokendi XR with the CMO as the tentatively approved product gets closer to a final approval by the FDA.

# ADHD

# Overview

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States.<sup>(17)</sup> An estimated 60% to 80% of children with ADHD continue to meet criteria for ADHD into adolescence.<sup>(18)</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>(19)</sup>

(17)

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

(18)

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

(19)

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

# **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>(20)</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 65% of total oral stimulant prescriptions based on IMS Health data, are extended release formulations that last up to twelve hours or more.

While stimulant treatments calm and improve the concentration of ADHD patients, these drugs have been shown to have various side effects including loss of appetite, insomnia and, to a lesser degree, cardiovascular effects. Stimulant treatments are controlled substances and can be associated with social stigma and the potential for abuse. Approximately 30% of patients with ADHD are non-responsive to or non-tolerant of treatment with stimulants.<sup>(21)</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.

# **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>(22)</sup> In addition, it has been estimated that approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.<sup>(23)</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.

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

(20)

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

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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*.

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

# (23)

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

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

Currently, there are no approved medications for treating impulsive aggression in patients with ADHD. The current treatment options for impulsive aggression in patients with ADHD include psychosocial interventions, such as school- or family-based behavioral therapies, which are usually not wholly effective. In the large, multisite Multimodal Treatment Study of Children with ADHD,<sup>(24)</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.

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

## **Our Psychiatry Portfolio**

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

#### SPN-810 (molindone hydrochloride)

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

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

(24)

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

## SPN-810 Development Program

We have completed five clinical trials for SPN-810, including a Phase IIa U.S. trial in which we tested the safety and tolerability of SPN-810, immediate release molindone hydrochloride, in patients with ADHD who suffer from serious persistent conduct problems. This open-label, dose-ranging trial randomized 78 children, 6-12 years of age, into one of four treatment groups, which were given four different doses of immediate release molindone hydrochloride, between 10 mg and 40 mg per day, depending on weight, three times a day over a six-week treatment period, after 2-5 weeks of titration. SPN-810 was well tolerated in the trial, with no clinically meaningful changes in standard hematology, clinical chemistry values, vital signs or electrocardiogram, or ECG, results. Besides safety and tolerability assessments, the primary outcome measure was the change in the Nisonger Child Behavior Rating Form-Typical Intelligence Quotient, or NCBRF-TIQ, conduct problem subscale scores from baseline to endpoint in the ITT population. NCBRF-TIQ is a known instrument that has been used for assessing child and adolescent behavior. Scores improved after baseline in all treatment groups. By visit 12, after 6 weeks of treatment, the mean reduction from baseline for each treatment group was 7.0, 8.7, 8.2 and 14.3, in groups 1, 2, 3, and 4, respectively, representing decreases of 34%, 34%, 32% and 55%, respectively. In addition, the difference between group 1 and group 4 was statistically significant (p≤0.041) at all time points except visit 2 and the greatest improvement in scores on the NCBRF-TIQ conduct problem subscale was seen in group 4, which was the highest-dose group (14.8 mean reduction). The below chart summarizes the mean change in NCBRF-TIQ conduct problem subscale observed in our Phase IIa trial.

# NCBRF-TIQ Conduct Problem Subscale: Mean Change from Baseline 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)

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

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

In June 2011, we initiated a Phase IIb multicenter, randomized, double-blind, placebo-controlled trial in the United States in pediatric subjects 6 to 12 years of age diagnosed with ADHD and impulsive aggression that is not controlled by optimal stimulant and behavioral therapy. The primary objective of the study was to assess the effectiveness of SPN-810, extended release, at three different doses in reducing impulsive aggression after at least three weeks of treatment. The primary endpoints were the effect in reducing impulsive aggression as measured by change in the score of the Retrospective Modified Overt Aggression Scale and the rate of remission. Secondary endpoints include measurement of the effectiveness of SPN-810 on Clinical Global Impression and ADHD scales as well as evaluation of the safety and tolerability of the drug. In addition, we will be exploring the potential added advantages of an extended-release formulation, such as greater compliance and, therefore, effectiveness in school-age children and lower unwanted side effects or interpatient variability. Patients who completed the study were offered the opportunity to continue into an open-label phase of six months duration. We received preliminary results in November 2012.

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

For patients of 30 kg or more in weight, the low and medium doses of SPN-810 showed statistical significance versus placebo on the change in R-MOAS primary endpoint with p-values of 0.024 and 0.049,

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

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

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

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

R-MOAS=Retrospective-Modified Overt Aggression Scale

R-MOAS Change=from Baseline (Visit 5) to Endpoint (Visit 10)

R-MOAS Remission=Score of ≤10 (LOCF=Last Observation Carried Forward) at Endpoint (Visit 10)

# Efficacy in Patients $\geq$ 30 kg on Low to Medium Doses

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

R-MOAS=Retrospective-Modified Overt Aggression Scale

R-MOAS Change=from Baseline (Visit 5) to Endpoint (Visit 10)

R-MOAS Remission=Score of ≤10 (LOCF=Last Observation Carried Forward) at Endpoint (Visit 10)

## Statistical Significance in Patients $\geq$ 30 kg on Low Dose

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

SNAP-IV=Swanson, Nolan and Pelham, ADHD Rating Scale

ODD=Oppositional Defiant Disorder

## Efficacy in Patients $\geq$ 30 kg on Low Doses

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

CGI=Clinical Global Impression

## SNAP-IV=Swanson, Nolan and Pelham, ADHD Rating Scale

## ODD=Oppositional Defiant Disorder

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

SPN-810 was well tolerated throughout the study across all doses. The two serious adverse events that occurred were not drug related. One patient in the low dose arm and two patients in the medium dose arm had severe adverse events that were considered either possibly or definitely related to the drug. Six patients in total discontinued the study because of adverse events in the active treatment arms: one in low dose; two in medium dose; and three in high dose. Analysis of all safety and clinical lab data has not yet been completed, though SPN-810 seemed to have a good safety and tolerability profile.

## Safe and Well Tolerated

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

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

#### Safe and Well Tolerated

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

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

## SPN-812

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

SPN-812 would provide an additional option to the few non-stimulant therapies currently available. We believe that SPN-812 could be more effective than other non-stimulant therapies due to its different pharmacological profile. Due to its demonstrated efficacy as an anti-depressant, SPN-812, if studied in that specific patient population and shown to be effective, may exhibit increased benefit in up to an estimated 40% of ADHD patients who also suffer from major depression.<sup>(25)</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.

(25)

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

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## SPN-812 Development Program

We completed a proof-of-concept Phase IIa U.S. clinical trial of SPN-812 in adults for the treatment of ADHD in 2011, in which SPN-812 was well tolerated and demonstrated a statistically significant improvement over placebo as a treatment for ADHD. The trial met the primary endpoints of safety and tolerability, and showed statistically significant median reduction versus placebo in both investigator-rated and patient-rated ADHD symptom scores. The trial was a randomized, double-blind, placebo-controlled trial in 52 adults with a current diagnosis of ADHD (26 subjects per treatment group).

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

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

## SPN-809

We are developing SPN-809 as a novel once-daily product candidate for the treatment of depression. SPN-809 is based on the same active ingredient as SPN-812. We currently have an open IND for SPN-809 as a treatment of depression, the indication for which the active ingredient in SPN-809 was approved and marketed in Europe for many years. Depression is a serious and common disease affecting approximately 121 million people worldwide.<sup>(26)</sup> Based on IMS Health data, the worldwide market for anti-depressants is approximately \$12 billion.

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

## **Other Product Candidates**

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

(26)

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



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## **Our Proprietary Technology Platforms**

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

## Microtrol (multiparticulate delivery platform)

Microtrol is based on the use of coated and uncoated multi-particulates that can be 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, or Royalty Sub, in exchange for \$63 million. We primarily reinvested the proceeds from this transaction into our research and development activities. In December 2011, we sold 100% of our equity ownership interests in Royalty Sub. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" History of our Company" for additional details regarding the sale of Royalty Sub.

## Solutrol (matrix delivery platform)

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

## EnSoTrol (osmotic delivery system)

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

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

## **Other Technologies**

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

#### Sales and Marketing

We are preparing for the build-out of our commercial infrastructure to launch both Oxtellar XR and Trokendi XR in the United States. In anticipation of the commercial launch of Oxtellar XR in the first quarter of 2013, we are hiring a small specialty sales force, initially consisting of a limited number of field sales representatives to support the launch of the product. Upon final FDA approval and commercial launch of Trokendi XR, which we anticipate to be in the third quarter of 2013, we intend to expand our sales force. 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 contractual relationships for the commercial manufacture of all our product candidates. For Trokendi XR and Oxtellar XR, 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 manufactures for the final commercial products.



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We currently employ internal resources and as needed third-party consultants to manage our manufacturing contractors.

For Oxtellar XR, we have entered into an agreement with a CMO and are presently negotiating agreements with a CMO for Trokendi XR. These are leading CMOs headquartered in North America for the manufacture of the final commercial products. They offer a comprehensive range of contract manufacturing and packaging services and have successfully handled the scale up of the two product candidates to a commercial production scale in preparation for the commercialization of both product candidates.

## Competition

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

## Epilepsy

There are currently over 15 branded products, as well as their generic counterparts, on the U.S. market indicated to treat some form of epilepsy. Several NCEs 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 final approval is received, Trokendi XR (extended release topiramate) will compete with all immediate release topiramate products including Topamax and related generic products. We are aware that Upsher-Smith 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 Trokendi XR, then Upsher-Smith could obtain three years of marketing exclusivity, which would significantly delay our entry into the U.S. market.

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

## ADHD

Competition in the U.S. ADHD market has increased with the commercial launch of several products in recent years, including the launch of generic versions of branded drugs, such as Adderall XR. Shire plc is one of the leaders in the U.S. ADHD market with three products: Adderall XR, an extended release stimulant treatment designed to provide once-daily dosing; Vyvanse, a stimulant prodrug product launched in 2007; and Intuniv, a non-stimulant treatment launched in November 2009. Other stimulant products for the treatment of ADHD in the U.S. market include the following once-daily formulations: Concerta; Metadate CD; Ritalin LA; Focalin XR; and Daytrana. Other non-stimulants are Strattera and Kapvay. We are also aware of clinical development efforts by several large pharmaceutical companies including 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 products and product candidates, including Oxtellar XR and Trokendi XR. 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 Oxtellar XR, Trokendi XR, our pipeline product candidates and technologies in the United States and abroad.

## Patent Portfolio

Our extended release oxcarbazepine patent portfolio currently includes four U.S. patents two of which cover Oxtellar XR. In addition, we have certain pending U.S. and foreign patent applications that relate to the U.S. patents, as well as additional patents in Europe, Canada and Mexico directed to various extended release formulations containing oxcarbazepine. The issued U.S. patents will expire in 2027. We own all of the issued patents and the pending applications.

In addition to the patents and patent applications relating to Oxtellar XR, we currently have two U.S. patents that cover Trokendi XR. In addition, we have certain pending U.S. and foreign patent applications in Canada and other countries that relate to the U.S. patents, as well as a patent in Europe directed to various extended release formulations containing topiramate. The two issued U.S. patents will expire in 2027 and 2029. We own all of the issued patents and pending applications.

Our patent portfolio also contains patent applications relating to our other pipeline products. We have two families of pending U.S. non-provisional and foreign counterpart patent applications relating to our SPN-810 product candidate. Patents, if issued, from the applications could have terms expiring from 2029 to 2031. With regard to our SPN-812 product candidate, we have two families of pending U.S. non-provisional and foreign counterpart patent applications. Patents, if issued, from the applications could expire from 2029 to 2031.

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

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in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, or PTA, which compensates a patentee for administrative delays by the USPTO in granting a patent. In view of a recent court decision, the USPTO is under greater scrutiny regarding its calculations where the USPTO erred in calculating the 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 our SPN-812 product candidate and issuance of a U.S. patent covering SPN-812 based on a U.S. patent application in our portfolio, we may obtain a U.S. patent that is eligible for limited patent term restoration.

## Other Intellectual Property Rights

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

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



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

#### **In-Licensing Arrangements**

#### Afecta Pharmaceuticals, Inc.

We have entered into two license agreements with Afecta Pharmaceuticals, Inc., or Afecta, pursuant to which we obtained an exclusive option to evaluate Afecta's CNS pipeline and to obtain exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. Under the terms of the license agreements, we have paid Afecta \$550,000 in license fees and milestone payments and may pay up to an additional \$300,000 upon the achievement of certain milestones. If a product candidate is successfully developed and commercialized, we will be obligated to pay royalties to Afecta based on net sales worldwide in the low-single digits. Unless terminated by us or Afecta for material breach or bankruptcy, by Afecta for our discontinuation of development and commercialization activities, or by us for convenience, the license agreements will continue in full force and effect on a country-by-country basis until six months from the discontinuation of the commercial sale and collection of revenues for the Afecta product.

## Rune Healthcare Limited

In June 2006, we entered into a purchase and sale agreement with Rune Healthcare Limited, or Rune, where we obtained the exclusive worldwide rights to a product concept from Rune for SPN-809. Under the terms of the agreement, we have paid Rune a £25,000 up-front fee. If we receive approval to market and sell any products based on the Rune product concept, we will be obligated to pay royalties to Rune based on net sales worldwide in the low-single digits. Unless terminated by us or Rune for material breach, by Rune for our discontinuation of development or commercialization activities relating to a product based on the Rune product concept, we will be obligated to pay royalties to Rune product concept, we will be obligated to pay royalties to Rune product concept, we will be obligated to pay royalties to Rune for 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 tentatively approved products and product candidates, including Trokendi XR, must receive final approval from 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 requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, product detention, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

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

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

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

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

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

FDA review and approval of the NDA.

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

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

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects

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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.

During the development of a new drug, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase III clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. An SPA is intended to provide assurance that if the agreed upon clinical trial protocol is followed, the clinical trial endpoints are achieved, and there is a favorable risk-benefit profile, the data may serve as the primary basis for an efficacy claim in support of an NDA. However, SPA agreements are not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. In particular, SPAs are not binding on the FDA if previously unrecognized public health concerns arise during the performance of the clinical trial, other new scientific

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concerns regarding product candidate's safety or efficacy arise, or if the sponsoring company fails to comply with the agreed upon clinical trial protocol.

## U.S. Review and Approval Processes

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

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the 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 Safety and Innovation Act of 2012, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. Pursuant to the FDA's approval of Oxtellar XR, we must conduct four pediatric studies as post-marketing studies; however, the FDA granted a waiver for the pediatric study requirements for ages birth to one month and a deferral for submission of post-marketing assessments for children 1 month to 6 years of age.

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



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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.

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

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

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

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

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information.



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Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter 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,



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

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

#### **Post-Approval Requirements**

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

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

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in

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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. For example, in July 2012, the Food and Drug Administration Safety and Innovation Act was enacted, expanding drug supply chain requirements and strengthening FDA's response to drug shortages, among other things. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our 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 Care Reform Law, a



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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 government reimbursement programs that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

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

the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

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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, 2012, we employed 80 full-time employees. 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 operations. We are currently reviewing our growth plans, primarily related to the commercialization of Oxtellar XR and Trokendi XR to determine whether we need to secure a modest increase in office space to support our future operations.



## 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.

Name	Age	<b>Position</b> (s)
Jack A. Khattar	51	President & Chief Executive Officer, Director
Gregory S. Patrick	61	Vice President, Chief Financial Officer
Jones W. Bryan, Ph.D.	48	Vice President of Business Development
Padmanabh P. Bhatt, Ph.D.	55	Senior Vice President, Intellectual Property, Chief Scientific Officer
Stefan K.F. Schwabe, M.D., Ph.D.	60	Executive Vice President of Research and Development, Chief Medical Officer
Tami T. Martin, R.N., Esq.	57	Vice President of Regulatory Affairs
M. James Barrett, Ph.D. <sup>(2)</sup>	70	Director and Chairman of the Board
Michael Bigham <sup>(2)(3)</sup>	55	Director
Frederick M. Hudson <sup>(1)</sup>	67	Director
Charles W. Newhall, III <sup>(3)</sup>	68	Director
William A. Nuerge <sup>(1)(2)</sup>	60	Director
John M. Siebert, Ph.D. <sup>(1)</sup>	72	Director

(1)

Member of Audit Committee

(2)

Member of Compensation Committee

(3)

## Member of Governance Committee

*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.

*Gregory S. Patrick* has served as our Chief Financial Officer since November 2011. Previously, he served as Chief Financial Officer for three privately held life sciences companies; R012 (2010-2011); Bionor Immuno (2008-2010); and Sopherion Therapeutics (2004-2008). From 2001 through 2004, he served as Chief Financial Officer for Medimmune, and from 1999 to 2001, as Chief Financial Officer of Ventiv Health. Mr. Patrick served in a variety of positions at Merck & Co. from 1985 through 1999, including Vice President and Controller of Merck's Manufacturing Division, Executive Director of Corporate Planning and Reporting, and Executive Director of Financial Evaluation. He started his career with Exxon Chemical Company in engineering, and subsequently joined Booz, Allen Hamilton as a management consultant. He

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holds BS and ME degrees from Rensselaer Polytechnic Institute in Environmental Engineering, and an MBA in Finance from New York University.

*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 Pharmaceutics and Clinical Supply Manufacturing for AAI. He began his career with Schering Plough in Pharmaceutics and Formulation 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 Senior Vice President of Intellectual Property and Chief Scientific Officer since March 2012. Prior to that, he 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.

*Stefan K. F. Schwabe, M.D., Ph.D.*, has served as our Executive Vice President of Research and Development and Chief Medical Officer since July 2012. Prior to that, Dr. Schwabe served as Chief Operating Officer at DemeRx, a privately-held biotech company, working in the area of addiction. From 2006 through 2010, Dr. Schwabe was the Vice-President for Project Direction for Neurology Projects at Sanofi-Aventis, and from 2004 through 2006, he served as the Executive Director, US Clinical Development and Medical Affairs, Neuroscience for Novartis. From 1998 through 2004, Dr. Schwabe served as the Global Project Leader Topamax for Johnson & Johnson. Prior to that time, Dr. Schwabe held positions of Medical Director, Gabitril & Seroxat in the Health Care Strategy Unit, International Operations for Novo Nordisk, and both International Project Team Leader and International Clinical Team Leader Trileptal and Scientific Investigator for Ciba-Geigy. Dr. Schwabe received his Bachelor Science in Chemistry from Florida International University, his M.D. from the Ludwig-Maximilians University in Munich, Germany and his Ph.D./Doctorate from the Department of Toxicology at the Technical University of Munich, Germany. Dr. Schwabe also served as Chief Resident, Department of Neurology for the Medical College of Wisconsin in Milwaukee, Wisconsin.

*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.

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*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. and Targacept, Inc., within the past five years, he served on the board of directors of each of the publicly-traded companies Inhibitex (acquired by Bristol-Myers Squibb Co.), 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 received a Ph.D. in Biochemistry at the University of Tennessee, his MBA from the University of Santa Clara, and a BS in Chemistry from Boston College. Dr. Barrett's substantial experience with public and private companies in the healthcare sector 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 currently chairs the compensation committee of the board of directors of Avila Therapeutics, Inc. and he previously chaired the audit committee of the board of directors of Valeritas, Inc. He is also a director of Secure EDI Holdings, Inc. He has previously served as a director of Hydra Biosciences, Inc., Magellan 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 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 Educate, Inc. and GBMC Healthcare, Inc. and its affiliate, Greater Baltimore Medical Center. He is also a director of Maxim Health Care Services, Inc. Mr. Hudson received a B.S. in Accounting from Loyola University, Maryland. 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

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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 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. Mr. Nuerge's significant operational and business experience with life science companies 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 2011, Dr. Siebert has been Chief Operating Officer of New Rhein Healthcare Investors, LLC, a healthcare-based private equity group. 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 committee of the board of directors of Aradigm, Inc. He is a member of the Board of Directors of Accu-Break Pharmaceuticals, 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**

Our common stock is 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. The composition and functioning of our board of directors and each of our board committees complies with all applicable rules and regulations of the Securities and Exchange



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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, compensation committee and governance committee charters, under which the respective committees will operate.

#### **Compensation Committee**

The current members of our compensation committee are Dr. Barrett, who is the chair of the committee, Mr. Bigham and Mr. Nuerge. Each of the members of our compensation committee are 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 include:

reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers;

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

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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 Mr. Hudson, who is the chair of the committee, Dr. Siebert and Mr. Nuerge. All members of our audit committee 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 Mr. Hudson 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. Mr. Hudson, Dr. Siebert and Mr. Nuerge are independent directors as defined under the applicable rules and regulations of the SEC and The NASDAQ Global Market. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and The NASDAQ Global Market. Our audit committee's responsibilities 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, if any; and

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

#### **Governance** Committee

The current members of our governance committee are Mr. Newhall, who is the chair of the committee, and Mr. Bigham. Each of the members of our governance committee are independent under the applicable rules and regulations of the SEC and The NASDAQ Global Market. The governance committee's responsibilities 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.

## **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.

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## 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, 2011 are listed in the table below.

Jack A. KhattarChief Executive Officer, PresidentGregory S. Patrick <sup>(1)</sup> Vice President, Chief Financial OfficerPeter L. Buzy <sup>(2)</sup> Former Vice President, Chief Financial OfficerRussell P. Wilson <sup>(3)</sup> Former Vice President, Chief Financial Officer
Peter L. Buzy <sup>(2)</sup> Former Vice President, Chief Financial Officer
Russell P. Wilson <sup>(3)</sup> Former Vice President, Chief Financial Officer
Paolo Baroldi, M.D., Ph.D. <sup>(4)</sup> Senior Vice President, Chief Medical Officer
Padmanabh Bhatt, Ph.D. Senior Vice President, Intellectual Property, Chief Scientific Officer
Jones W. Bryan, Ph.D. Vice President, Business Development

(1)

Mr. Patrick joined as the Vice President, Chief Financial Officer in November 2011.

## (2)

Mr. Buzy served as the Vice President, Chief Financial Officer from October 2011 through November 2011.

## (3)

Mr. Wilson resigned as the Vice President, Chief Financial Officer in October 2011.

## (4)

Dr. Baroldi resigned as the Senior Vice President, Chief Medical Officer in March 2012. He served as a consultant to the Company from March 2012 until September 2012.

Stefan K.F. Schwabe, M.D., Ph.D. joined as the Executive Vice President of Research and Development, Chief Medical Officer in July 2012. Accordingly, for purposes of this Compensation Discussion and Analysis, he is not considered an NEO for the year ended December 31, 2011.

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.

Following the completion of our initial public offering in May 2012, our Compensation Committee has undertaken a substantial review of our existing compensation programs, objectives and philosophy to determine whether such programs, objectives, and philosophy are appropriate. 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.

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**

Following the completion of our initial public offering in May 2012, our Compensation Committee has reviewed compensation elements and amounts for NEOs, and will review these compensation elements and amounts 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 have used Compensia, Inc., a third party consultant, to assist us in compiling a report of benchmark data for 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 made a final determination of the companies that we will benchmark our compensation packages against in our annual reviews, 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.

The CEO provides 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. The Compensation Committee recommends 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 then discusses these recommendations with the CEO and will make a recommendation to the board, which the board will consider and approve, if appropriate.

The Compensation Committee considers input from our CEO and CFO when setting performance objectives for our incentive plans. The Compensation Committee considers input from our CEO and CFO, regarding benchmarking and recommendations for base salary, annual incentive targets and other compensation awards. The Compensation Committee generally gives 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. The Compensation Committee seeks 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 2010 and 2011 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 base salaries for our NEOs were increased in 2012 as a result of the Compensation Committee's review subsequent to completion of our recent initial public offering in May 2012 to ensure that the base salaries of our NEOs are in line with the base salaries of executive officers of other public companies operating in its industry. These increases in annual base salary became effective on September 1, 2012. All other terms and conditions of our compensatory arrangements with these NEOs remained unchanged at the time of these salary increases.

The annual base salaries in effect in 2010, 2011 and 2012 for each of our NEOs employed by us during fiscal year 2010 or fiscal year 2011, are as follows (the 2012 base salary reflects the pro rata effect of the increases that became effective as of September 1, 2012).

<b>Base Salary</b>					
	2010		2011		2012
\$	407,942	\$	420,180	\$	438,524
			29,767		276,667
			31,644		
	265,172		219,250		
	293,292		302,091		61,378
	266,200		274,186		295,923
	210,542		216,858		232,242
		265,172 293,292 266,200	2010 \$ 407,942 \$ 265,172 293,292 266,200	2010         2011           \$         407,942         \$         420,180           29,767         31,644           265,172         219,250           293,292         302,091           266,200         274,186	2010         2011           \$         407,942         \$         420,180         \$           29,767         29,767           31,644         265,172         219,250           293,292         302,091         266,200         274,186

(1)

Reflects the pro rated salary for 2011 for Mr. Patrick, who joined as the Chief Financial Officer on November 21, 2011.

(2)

Reflects the pro rated salary for 2011 for Mr. Buzy, who served as Chief Financial Officer from October 17, 2011 through November 28, 2011.

(3)

Reflects the pro rated salary for 2011 for Mr. Wilson, who resigned his employment with the Company effective October 21, 2011.

(4)

Reflects the pro rated salary for 2012 for Dr. Baroldi, who resigned as an executive officer of the Company effective March 13, 2012.

Dr. Schwabe's pro rated salary for 2012 is \$154,000.

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; provided, however, that the 2010 base salaries for Mr. Wilson and Dr. Baroldi were prorated because they only joined us in 2009. In setting the 2011 and 2012 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 salaries of our NEOs by 3.0% over their prior year base salaries; provided, however, that

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the 2012 base salary for Mr. Patrick was not increased because he only joined us in November 2011 and the 2012 base salary for Dr. Schwabe was prorated because he only joined us in 2012. Subsequent to our IPO in May 2012, the Compensation Committee undertook a study to re-evaluate the 2012 and 2013 base salaries of our NEO's, and as a result, the Compensation Committee decided to increase the base salaries of our NEOs effective September 1, 2012 to ensure that the base salaries of our NEOs are in line with the base salaries of executive officers of other public companies operating in its industry.

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.

#### 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 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 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 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. 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. For fiscal year 2011, the personal performance goals were as follows:

Gregory S. Patrick: Supporting our CEO in financing activities, improving financial controls, financial management budgeting and forecasting, and management of information technology;

Paolo Baroldi: Completion of all clinical activities required to support and file our NDAs, the initiation of a Phase IIb study on SPN-810, planning and initiation of preclinical activities as applicable on SPN-810 and SPN-812;



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Padmanabh Bhatt: Completion of all pharmaceutical sciences activities in support of our NDA filings, planning and preparation for the validation activities for our lead product candidates, and managing our intellectual property portfolio and supporting our licensees; and

Jones W. Bryan: Identifying and negotiating partnerships with third parties regarding rights on our product candidates in areas that are outside our focus, identifying in-licensing opportunities for product candidates that complement our portfolio, and executing supply agreements as related to our lead product candidates with contract manufacturing organizations.

For fiscal year 2011, our Compensation Committee determined that Mr. Patrick, Dr. Baroldi, Dr. Bhatt and Dr. Bryan achieved approximately 100%, 94%, 95% and 95%, respectively, of their individual performance objectives.

After our fiscal year 2011, our board reviewed the Company goals that were attained and determined that the Company performance component of our annual cash incentive plan was 100% achieved. This decision was primarily due to submission of our NDA for Oxtellar XR, the submission and acceptance for filing of our NDA for SPN-538, initiation of a Phase IIb clinical study for SPN-810 and securing financing for our Company. Concurrently, each of our NEOs prepared an assessment of his performance against his personal performance goals and discussed them with our CEO, who then made a recommendation to our board. Our board reviewed these recommendations 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 60% for corporate objectives and 40% for individual performance objectives for each NEO, other than our CEO, we paid each NEO the following 2011 annual performance bonus in 2012:

	2011 Annual Performa Target Target Bonus Bonus Percent Amount		nce Bonus Actual Bonus	
Name	(%)	(\$)	Payout (\$)	
Jack A. Khattar	40%	\$ 168,072	\$ 168,072	
Gregory S. Patrick <sup>(1)</sup>	25	7,442	7,442	
Peter L. Buzy <sup>(2)</sup>				
Russell P. Wilson <sup>(3)</sup>				
Paolo Baroldi, M.D., Ph.D.	25	75,523	73,559	
Padmanabh Bhatt, Ph.D.	25	68,547	67,176	
Jones W. Bryan, Ph.D.	25	54,215	53,130	
Russell P. Wilson <sup>(3)</sup> Paolo Baroldi, M.D., Ph.D. Padmanabh Bhatt, Ph.D.	25	68,547	67,176	

(1)

Mr. Patrick joined as the Chief Financial Officer in November 2011, so his target annual performance bonus amount for 2011 was prorated.

(2)

Mr. Buzy resigned as the Chief Financial Officer in November 2011 and he was not entitled to a bonus for 2011.

## (3)

Mr. Wilson resigned as the Chief Financial Officer in October 2011 and he was not entitled to a bonus for 2011.

Subsequent to our initial public offering in May 2012, 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 2012 were initially the same as under the annual cash incentive plan for 2011. The target bonus percentages for our NEOs were increased as a result of the Compensation Committee's review in October 2012 to ensure that the target bonus percentages of our NEOs are in line with the target bonus percentages of other

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public companies operating in its industry. Because the components of our performance goals contain highly sensitive data, such as regulatory, strategic partnering and other nonfinancial 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 or the 2012 Plan, which is described below, in the form of restricted stock and/or stock options. To date, we have primarily used 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 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.

Historically, 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. Following completion of our initial public offering in May 2012, 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 the 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.



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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;

long-term disability;

a 401(k) plan; and

an employee stock purchase 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, otherwise eligible performance-based rights or awards granted under such a plan will not qualify for the "performance-based compensation" exception under Section 162(m) unless the relevant material terms of such plan are approved by our stockholders and the awards are granted and administered in accordance with the regulations prescribed under Section 162(m).

In determining awards as part of our compensation program, we expect to consider the availability of a tax deduction as one element in designing compensation programs that are intended to reward our executive officers for their contribution to the success of the Company, but the tax impact is not the only element we will consider. We may grant awards that do not qualify for an exemption from the deduction limitations under Section 162(m) or that may otherwise be limited as to tax deductibility.

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

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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**

Unless otherwise specified, the following tables provide information regarding the compensation earned during our most recently completed fiscal year by our NEOs.

### Summary compensation table

The following table shows the compensation earned by our NEOs during the fiscal years ended December 31, 2011, December 31, 2010 and December 31, 2009.

				Non-Equity Incentive		
N	V	Salary		-	All Other	
<b>Name and Principal Position</b> Jack A. Khattar <i>Chief Executive Officer, President</i>	Year 2011 2010 2009	(\$) \$ 420,180 407,942 395,737	(\$)(1) \$	(\$)(2) \$ 168,072 159,913 158,424	(\$)(3) \$ 11,439 12,185 11,931	( <b>\$</b> ) \$ 599,691 580,040 566,092
Gregory S. Patrick <sup>(4)</sup> Vice President, Chief Financial Officer	2011 2010 2009	29,767	386,736	7,442	599	424,544
Peter L. Buzy <sup>(5)</sup> Former Vice President, Chief Financial Officer	2011 2010 2009	31,644				31,644
Russell P. Wilson <sup>(6)</sup> Former Vice President, Chief Financial Officer	2011 2010 2009	219,250 265,172 161,667	88,235 262,650	64,172 41,600	11,037 12,821 7,225	230,287 430,400 473,142
Paolo Baroldi, M.D., Ph.D <sup>(7)</sup> . Senior Vice President, Chief Medical Officer	2011 2010 2009	302,091 293,292 265,635	98,014 51,750	73,559 68,044 69,825	14,342 18,303 15,001	389,992 477,653 402,211
Padmanabh Bhatt, Ph.D. Senior Vice President, Intellectual Property, Chief Scientific Officer	2011 2010 2009	274,186 266,200 258,237	66,450	67,176 64,154 64,353	12,654 14,036 13,334	354,016 410,841 335,924
Jones W. Bryan, Ph.D. Vice President, Business Development	2011 2010 2009	216,858 210,542 204,243	66,450	53,130 47,793 49,876	8,262 10,499 11,195	278,250 335,284 265,314

(1)

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 10 to our consolidated financial statements appearing at the end of this prospectus.

# (2)

Amounts represent annual performance bonus compensation earned for the years ended December 31, 2010 and 2011 based on pre-established performance objectives. Annual performance bonus compensation for 2010 and 2011 was paid in

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early 2011 and early 2012, respectively. Our annual performance bonus program is described in more detail under " Compensation Discussion and Analysis Performance-Based Cash Incentives."

## (3)

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.

## (4)

Mr. Patrick became our Vice President, Chief Financial Officer in November 2011, 2011 base salary amount represents salary paid to Mr. Patrick in 2011.

## (5)

Mr. Buzy served as our Vice President, Chief Financial Officer from October 2011 through November 2011. 2011 base salary amount represents salary paid to Mr. Buzy in 2011.

## (6)

Mr. Wilson resigned as our Vice President, Chief Financial Officer in October 2011. 2011 base salary amount represents salary paid to Mr. Wilson in 2011.

## (7)

Dr. Baroldi resigned as the Senior Vice President, Chief Medical Officer in March 2012. He agreed to serve as a consultant to the Company until September 2012.

## Grants of Plan-Based Awards

During fiscal year ended December 31, 2011, 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, 2011. Equity awards made to our NEOs are described in more detail under "Compensation Discussion and Analysis Equity Incentives."

		Pay Under N Ince	ed Future youts on-Equity entive Awards	Awards:	Exercise or Base Price	Grant Date Fair Value of Stock
	<b>G</b> (	TT (		of Securities	-	and Options
NT	Grant	0		nUnderlying	· · · ·	. ,
Name	Date	(\$)	(\$)	<b>Options</b> (#)	(\$/sh)	(\$)
Jack A. Khattar		\$ 168,072	\$ 168,072	2		
Gregory S. Patrick <sup>(3)</sup>	12/30/2011	7,442	7,442	2 105,000	\$ 5.88	386,736
Peter L. Buzy						
Russell P. Wilson						
Paolo Baroldi, M.D.,						
Ph.D.		75,523	75,52	3		
		68,547	68,54	7		

Jones W. Bryan, Ph.D. 54,215 54,215	Padmanabh Bhatt, Ph.D.		
Ph.D. 54,215 54,215	Jones W. Bryan,		
	Ph.D.	54,215	54,215

(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)

Mr. Patrick joined as the Chief Financial Officer in November 2011, so his target annual performance bonus amount for 2011 was prorated.

## 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, 2011.

			Ol	Option Awards					
Name		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Ex F	ption ercise Price \$)(5)	Option Expiration Date			
Jack A. Khattar									
Gregory S. Patrick	(1)		105,000	\$	5.88	12/30/2021			
Peter L. Buzy									
Russell P. Wilson	(2)	14,375		\$	2.56	12/15/2019			
Paolo Baroldi, M.D., Ph.D.	(1)	25,000	25,000	\$	1.60	1/19/2019			
	(1)	1,250	3,750	\$	3.36	02/10/2020			
	(1)	13,438	40,312	\$	2.56	11/02/2020			
Padmanabh Bhatt, Ph.D.	(1)	50,000		\$	0.40	1/17/2016			
	(3)	6,250		\$	0.40	1/17/2016			
	(4)	6,250		\$	0.40	1/17/2016			
	(1)	3,000		\$	0.40	2/13/2017			
	(1)	625	1,875	\$	3.36	02/10/2020			
	(1)	9,375	28,125	\$	2.56	11/02/2020			
Jones W. Bryan, Ph.D.	(1)	625	1,875	\$	3.36	02/10/2020			
•	(1)	9,375	28,125	\$	2.56	11/02/2020			

(1)

These stock options vest over four years in four equal installments of 25% each on the first four anniversaries from the date of grant.

(2)

On November 2, 2010, this option was repriced from \$7.04 to \$2.56 per share.

(3)

These stock options vested upon the completion of our first clinical trial in humans and was satisfied in 2006.

(4)

These stock options vested upon the commercial launch of a partnered product which was satisfied in 2006.

(5)

The market value of each equity award is based on the fair market value of per share of our common stock as of the date of grant, as determined in good faith by our board.

## **Option Exercises and Stock Vested**

The table below sets forth certain information regarding options to purchase our common stock that were exercised by our NEOs during 2011.

Number of SharesValue RealizedAcquiredOn ExerciseNameOn Exercise (#)
NameOn Exercise (#)(\$)(1)
Jack A. Khattar
Gregory S. Patrick
Peter L. Buzy
Russell P. Wilson
Paolo Baroldi, M.D., Ph.D.
Padmanabh Bhatt, Ph.D.
Jones W. Bryan, Ph.D. 65,500 \$ 251,520

## (1)

Amount based on the difference between the exercise price of the options and the most recent fair market value of our common stock as determined in good faith by our board at the time of exercise.

## **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's annual bonus was originally set at up to 40% of his annual base salary, and recently increased to 50% for 2012, 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) an amount equal to the most recent annual bonus paid to him which shall be payable over 18 months, 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

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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.

On February 29, 2012, we entered into an amended and restated employment agreement with Mr. Khattar effective January 1, 2012. Mr. Khattar's salary for fiscal year 2012 is \$432,786, which will remain subject to review and increases from time to time by our board of directors based on Mr. Khattar's and the Company's performance. Mr. Khattar's amended and restated employment agreement contains other terms that are identical in all material respects to the terms of Mr. Khattar's previous employment agreement. Effective September 1, 2012, the Compensation Committee approved an increase in Mr. Khattar's annual salary to \$450,000.

## 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 employment agreement, on December 31, 2011, 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 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, 2011. No other NEOs are contractually entitled to payments upon termination or a change of control.

	Benefit	U	nination pon a ucturing	V C Re	rmination Without Cause or signation for Good Reason	I Z Cl	signation for Good Reason After a hange of Control
Jack A. Khattar	Base salary continuation Bonus <sup>(1)</sup> Continuation of benefits <sup>(2)</sup>			\$	630,270 159,913 20,058	\$	630,270 159,913 20,058
	Total			\$	810,241	\$	810,241
Padmanabh Bhatt, Ph.D.	Severance	\$	137,093				
Jones W. Bryan, Ph.D.	Severance	\$	108,429				

(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 2011, in accordance with his employment agreement. The amount set forth in the table reflects the most recent bonus paid to Mr. Khattar under our annual cash incentive plan as of December 31, 2011.

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.

## **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 directors in 2011.

	Fees	
	Earned	
	or Paid	
	in Cash	Total
Name	(\$)	(\$)
William A. Nuerge	20,000	20,000
Frederick M. Hudson	20,000	20,000
John M. Siebert	20,000	20,000

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.

### **Equity-Based Plans**

We maintain or propose to establish various benefit plans, as described below, for our officers, employees, non-employee directors and other key persons (including consultants and prospective employees). Our outstanding equity awards, which primarily consist of stock options, have been granted under our 2005 Stock Plan. Our board of directors adopted the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan, or the 2012 Plan, under which equity awards will be granted, and the Supernus Pharmaceuticals, Inc. 2012 Employee Stock Purchase Plan, or the ESPP, under which employees may purchase discounted shares of our common stock. We no longer make awards under the 2005 Stock Plan and instead make awards under the 2012 Plan. The summaries below describe the material terms of the 2012 Plan and the ESPP.

#### 2005 Stock Plan

#### Introduction

Our 2005 Stock Plan was adopted by our board and approved by our stockholders on December 21, 2005.

## Share Reserve

2,000,000 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.

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### Eligibility

All officers, employees, directors and other key persons (including consultants and advisors) are eligible to participate in the 2005 Stock Plan, but only such eligible persons as are selected by the administrator will become participants.

### 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 100% of the fair market value of our common stock on the date of the option grant and the term of awards may not exceed ten years. The administrator determines 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.

#### Transferability

Our 2005 Stock Plan does not allow for the transfer of incentive stock options, or of options (whether incentive stock options or non-qualified stock options) granted to persons required to file reports under Section 16(a) of the Exchange Act, 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.

#### 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. 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.

#### 2012 Plan

#### Introduction

Our board of directors adopted the 2012 Plan, subject to approval by our shareholders. The 2012 Plan authorizes grants of stock options (both incentive stock options and non-qualified stock options) and certain other awards.

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### Share Reserve

2,500,000 shares of common stock are reserved for delivery under awards granted pursuant to our 2012 Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. Under the 2012 Plan, the number of shares available for grant is determined net of shares of common stock withheld by the Company in payment of the exercise price of the award or in satisfaction of tax withholding requirements with respect to the award, and without reduction for any shares of common stock underlying awards that are settled in cash, that expire or become unexercisable without having been exercised, or that are forfeited to or repurchased by the Company for cash.

#### Administration

The 2012 Plan is administered by either our board of directors or a committee of our board of directors.

### Eligibility

Key employees and directors of, and consultants and advisors to, the Company and its affiliates are eligible to participate in the 2012 Plan, but only such persons as selected by the administrator become participants.

### Types of Awards

The types of awards that are available for grant under the 2012 Plan are:

stock options (incentive stock options and non-qualified stock options);

stock appreciation rights;

restricted stock;

unrestricted stock;

stock units, including restricted stock units;

performance awards;

cash awards; and

other awards that are convertible into or otherwise based on stock.

## Transferability

Under the 2012 Plan, neither incentive stock options nor, except as the administrator otherwise expressly provides, other awards are permitted to be transferred other than by will or by the laws of descent and distribution. The administrator may permit awards other than incentive stock options to be transferred by gift, subject to such limitations as the administrator may impose.

Performance Criteria

The 2012 Plan provides that grants of performance awards will be made subject to the achievement of "performance criteria" over a performance period, which may be one or more periods as established by the administrator. For purposes of awards that are intended to qualify for the performance-based compensation exception under Section 162(m) of the Code, a performance criterion means an objectively determinable measure of performance relating to any or any combination of the following (measured either absolutely or by reference to an index or indices and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; stock price;

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stockholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; or recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings. A performance criterion and any targets with respect thereto determined by the administrator need not be based upon an increase, a positive or improved result or avoidance of loss. To the extent consistent with the requirements for satisfying the performance-based compensation exception under Section 162(m) of the Code, the administrator may provide in the case of any award intended to qualify for such exception that one or more of the performance criteria applicable to such award will be adjusted in an objectively determinable manner to reflect events (for example, but without limitation, acquisitions or dispositions) occurring during the performance period that affect the applicable performance criteria.

## Corporate Transactions

In the event of a consolidation, merger or similar transaction, a sale or transfer of all or substantially all of the Company's assets or a dissolution or liquidation of the Company, the administrator may, among other things, provide for continuation or assumption of outstanding awards, for new grants in substitution of outstanding awards, for the cash-out of awards for an amount equal to the difference between their fair market value and their exercise price (if any) or for the accelerated vesting or delivery of shares under awards, in each case on such terms and with such restrictions as it deems appropriate. Except as otherwise provided in an award agreement, awards not assumed will terminate upon the consummation of such corporate transaction.

#### Adjustment

In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in the Company's capital structure, the administrator will make appropriate adjustments to the maximum number of shares that may be delivered under the 2012 Plan and the individual limits included in the 2012 Plan, and will also make appropriate adjustments to the number and kind of shares of stock or securities subject to awards, the exercise prices of such awards or any other terms of awards affected by such change. The administrator may also make the types of adjustments described above to take into account events other than those listed above if it determines that such adjustments are appropriate to avoid distortion in the operation of the 2012 Plan and to preserve the value of awards.

### Term

No awards will be made after the 10<sup>th</sup> anniversary of the 2012 Plan's adoption, but previously granted awards will be permitted to continue beyond that date in accordance with their terms. The term of each award may not exceed 10 years.

#### Amendment or Termination

The administrator may at any time or times amend the 2012 Plan or any outstanding award for any purpose, subject to stockholder approval where such approval is required by applicable law, and may at any time terminate the 2012 Plan as to any future grants of awards, except that, unless otherwise expressly provided in the 2012 Plan, the administrator may not, without the participant's consent, alter the terms of an award so as to affect materially and adversely the participant's rights under the award, unless the administrator expressly reserved the right to do so at the time the award was granted.

## ESPP

### Introduction

Our board of directors has adopted the ESPP, subject to approval by our shareholders. The ESPP, which will take effect as described below, permits our eligible employees to purchase discounted shares of our common stock, subject to certain conditions.

### Share Reserve

Up to 250,000 shares of common stock are reserved for sale under the ESPP. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

### Administration

The ESPP is administered by the board of directors or a committee of our board of directors.

## Eligibility

Each employee of the Company and its designated subsidiaries that is employed on an applicable enrollment deadline are entitled to participate, other than an employee that owns or is deemed to own 5% or more of the total combined voting power or value of all classes of stock of the Company or its subsidiaries. In addition, no employee will be granted an option under the ESPP that would permit his or her rights to purchase shares of stock under all employee stock purchase plans of the Company and its subsidiaries to accrue at a rate that exceeds \$25,000 (or such other maximum as may be prescribed from time to time by the Code) in fair market value of such stock (determined at the time the option is granted) for any calendar year during which any such option granted to such employee is outstanding at any time.

## Method of Participation

The periods of January 1 to June 30 and July 1 to December 31 of each year will generally be the "option periods" under the ESPP. However, the first option period will commence on such date, on or after an effective Form S-8 registration statement has been filed for the ESPP, as the board of directors may specify, and will end on the first June 30 or December 31 to follow such commencement by not less than six months. Generally, each eligible employee that has elected to participate in the ESPP not later than the enrollment deadline (as prescribed by the board of directors) prior to the beginning of an applicable option period will become a participant in the ESPP. Each participating employee will authorize the Company to make after-tax payroll deductions equal to a whole percentage between 2% and 20% of his or her compensation, and such deduction rate will not be permitted to be changed during an option period unless the participant cancels his or her option entirely. The aggregate amount of a participant's payroll deductions during the option period will be credited to a non-interest bearing bookkeeping account.

## Grant and Exercise of Options

Only options to purchase common stock of the Company will be issuable under the ESPP. On the first day of each option period, each participant will be granted an option to purchase the whole number (disregarding any fractional share amount) of shares of common stock equal to (i) the balance credited to the participant's withholding account (but generally subject to a limit of \$12,500 or such other amount as the board of directors imposes) on the last day of the option period divided by (ii) 85% of the lesser of the fair market value of a share stock on (a) the first day of the option period or (b) the last day of the option period. If an employee is a participant in the ESPP on the last day of an option period, he or she will be deemed to have exercised the option granted to him or her for that option period, and the number of shares of common stock described in the preceding sentence will generally be delivered to him or her as soon as practicable thereafter.

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### Termination of Employment

Upon the termination of a participant's employment with the Company for any reason, he or she will cease to be a participant, any option held by him or her under the ESPP will be deemed canceled, the balance of his or her withholding account will be returned to the participant (or his or her estate or designated beneficiary in the event of the participant's death), and he or she will have no further rights under the ESPP.

### Transfer

Each participant's rights and privileges under any option granted under the ESPP will be exercisable during the participant's lifetime only by him or her and may not be sold, pledged, assigned, or transferred in any manner.

### Corporate Transactions

In the event of a sale of all or substantially all of the Company's common stock or a sale of all or substantially all of the assets of the Company, or a merger or similar transaction in which the Company is not the surviving corporation or which results in the acquisition of the Company by another person, the board of directors in its sole discretion may (but need not) provide that each outstanding option will be assumed or a substitute option granted by the acquiror or successor corporation or a parent or subsidiary of the acquiror or successor corporation; cancel each option and return the balances in participants' withholding accounts to the participants; or end the option period on or before the date of the proposed sale or merger.

#### Adjustment

In the event of any change in the outstanding common stock of the Company by reason of a stock dividend, split-up, recapitalization, merger, consolidation, reorganization, or other capital change, the aggregate number and type of shares available under the ESPP, the number and type of shares under options granted but not exercised, the maximum number and type of shares purchasable under an option, and the option price will generally be appropriately adjusted.

#### Amendment or Termination

The Company will generally be permitted to suspend or terminate the ESPP at any time, or at any time or times to amend the ESPP to any extent and in any manner it may deem advisable, in each case by vote of the board of directors. In connection therewith, the board of directors may either cancel outstanding options or continue them and provide that they will be exercisable either at the end of the applicable option period or on such earlier date as the board of directors may specify.

#### Limitation of Liability and Indemnification Arrangements

As permitted by the Delaware General Corporation Law, we adopted provisions in our amended and restated certificate of incorporation and amended and restated bylaws 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 provides 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 have entered into indemnification agreements with each of our executive officers and directors. These agreements 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 90 days after the date of this prospectus.

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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, 2009, 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.

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

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.

In December 2011, we entered into a Unit Purchase Agreement with Royalty Opportunities S.àr.l, or ROS, which transaction is hereafter referred to as the "Purchase Transaction". Pursuant to the Unit Purchase Agreement, we sold 100% of our equity ownership interests in Royalty Sub to ROS for a payment of \$27.0 million on the closing date of the Purchase Transaction and a potential milestone payment of \$3.0 million payable upon occurrence of certain conditions. OrbiMed Advisors LLC, or OrbiMed, which acts as investment manager for ROS, 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, which, together with affiliated entities, hold more than 5% of our common stock. Investment professionals employed by OrbiMed manage the investment portfolio of UBS Juniper Crossover Fund, L.L.C., a holder of our common stock, on behalf of UBS Juniper Management, L.L.C. under the oversight of UBS Alternative and Quantitative Investments LLC. Michael Sheffery, a director on our board of directors until October 2012, is a member of OrbiMed.

#### **Indemnification Agreements**

We have entered 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 90-day period following the completion of this offering, certain of our directors and 5% stockholders have 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

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."

## **Procedures for Related Party Transactions**

Our audit committee is 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.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of September 30, 2012, before and after the completion 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, or SEC. 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, 2012 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 o Beneficiall Before Offering		Percentage Beneficial Before Offering	
5% Stockholders:	8	8	- 8	- 8
New Enterprise Associates 11, Limited Partnership and its affiliates <sup>(1)</sup>				
c/o New Enterprise Associates	10.650.000	10,650,000	43.5	35.0
1954 Greenspring Drive Suite 600	- , ,	- , ,		
Timonium, MD 21093				
OrbiMed Private Investments II, LP and its affiliates <sup>(2)</sup>	3,599,998	3,599,998	14.7	11.8
c/o OrbiMed Advisors LLC				
767 Third Avenue, 30th Floor				
New York, NY 10017				
Abingworth Bioventures IV LP and its affiliates <sup>(3)</sup>	3,600,000	3,600,000	14.7	11.8
c/o Abingworth Management Inc				
890 Winter Street, Suite 150				
Waltham, MA 02451				
T. Rowe Price Associates, Inc. and its affiliates <sup>(4)</sup>	3,001,500	3,001,500	12.3	9.9
c/o T. Rowe Price Associates, Inc.				
100 E. Pratt Street				
Baltimore, MD 21202				
Executive Officers and Directors:				
Jack A. Khattar <sup>(5)</sup>	1,527,058	1,527,058	6.2	5.0
Gregory S. Patrick	3,000	3,000	*	*
Stefan K.F. Schwabe, M.D., Ph.D.				
Padmanabh P. Bhatt, Ph.D. <sup>(6)</sup>	85,500	85,500	*	*
Jones W. Bryan, Ph.D. <sup>(7)</sup>	85,500	85,500	*	*
Tami T. Martin, R.N., Esq. <sup>(8)</sup>	60,000	60,000	*	*
M. James Barrett, Ph.D. <sup>(9)</sup>	10,650,000	10,650,000	43.5	35.0
Michael Bigham <sup>(10)</sup>	3,600,000	3,600,000	14.7	11.8
Frederick M. Hudson <sup>(11)</sup>	9,375	9,375	*	*
Charles W. Newhall, III <sup>(12)</sup>	10,650,000	10,650,000	43.5	35.0
William A. Nuerge	23,750	23,750	*	*
John M. Siebert, Ph.D. <sup>(13)</sup>	5,188	5,188	*	*
All executive officers and directors as a group (12 persons)	22,650,869	22,650,869	92.0	74.0

\*

Less than one percent.

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(1)

The number of shares beneficially owned consists of (a) 10,641,250 shares of common stock held by New Enterprise Associates 11, Limited Partnership, or NEA 11; and (b) 8,750 shares of common 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 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)

The number of shares beneficially owned consists of (a) 2,402,600 shares of common stock held by OrbiMed Private Investments II, LP; (b) 899,583 shares of common stock held by OrbiMed Private Investments II (QP), LP; and (c) 297,815 shares of common 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 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 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)

The number of shares beneficially owned consists of (a) 3,569,400 shares of common stock held by Abingworth Bioventures IV LP, or ABV IV; and (b) 30,600 shares of common stock held by Abingworth Bioventures IV Executives LP, or ABV IV Executives. Abingworth Bioventures IV, LP. 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)

The number of shares is based on information provided in a Schedule 13G filed by T. Rowe Price Associates, Inc. with the SEC on June 8, 2012. T. Rowe Price Associates, Inc. has sole voting power with respect to 490,400 shares and sole dispositive power with respect to all of the shares. T. Rowe Price Health Sciences Fund, Inc. has sole voting power with respect to 1,259,000 shares.

## (5)

Includes 1,125,000 shares of common stock held by KBT Trust and 402,058 common shares held by Mr. Khattar.

(6)

Includes 60,500 shares of common stock issuable to Dr. Bhatt upon the exercise of options within 60 days of September 30, 2012.

(7)

Includes 20,000 shares of common stock issuable to Dr. Bryan upon the exercise of options within 60 days of September 30, 2012.

## (8)

Includes 57,500 shares of common stock issuable to Ms. Martin upon the exercise of options within 60 days of September 30, 2012.

## (9)

The number of shares beneficially owned consists of 10,650,000 shares of common stock 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)

The number of shares beneficially owned consists of 3,600,000 shares of common stock 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)

Includes 4,375 shares of common stock issuable to Mr. Hudson upon the exercise of options within 60 days of September 30, 2012.

# (12)

The number of shares beneficially owned consists of 10,650,000 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)

Includes 2,188 shares of common stock issuable to Dr. Siebert upon the exercise of options within 60 days of September 30, 2012.

## DESCRIPTION OF CAPITAL STOCK

## General

Our Amended and Restated Certificate of Incorporation authorizes the issuance of up to 130,000,000 shares of common stock, par value \$0.001 per share, and 65,000,000 shares of preferred stock, par value \$0.001 per share. As of September 30, 2012, there were 24,466,049 shares of common stock outstanding. As of September 30, 2012, we had approximately 42 record holders of our capital stock. After the closing of this offering, we will have 30,466,049 shares of common stock, based on the number of outstanding shares of common stock as of September 30, 2012, and no shares of preferred stock outstanding.

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

#### **Common Stock**

We are 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**

Our board of directors is authorized, without action by the stockholders, to designate and issue up to an aggregate of 65,000,000 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. We 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 secured credit facility, the lenders received from us ten-year warrants that are exercisable for an aggregate of 93,750 shares of our common stock at an exercise price of \$4.00 per share. The warrants expire on January 26, 2021. In December 2011, in connection with the amendment of the secured credit facility, we issued to the lenders warrants that are exercisable for an aggregate of 49,999 shares of our common stock at \$5.00 per share. The warrants expire on December 30, 2021. In October 2012, one of the lenders exercised both tranches of its warrants for an aggregate of 101,667 shares using a cashless net share method. As a result of this exercise, we issued 64,309 shares of common stock to this lender.

## **Registration Rights**

#### **Demand Registration Rights**

After the expiration of the 90-day period following the completion of this offering, the holders of approximately 12,249,998 shares of our common stock will be entitled to certain demand registration rights. If holders of at least 35% of the registrable securities (or a lesser percentage if the aggregate offering price to the public would exceed \$5,000,000) request a registration, we may be required to register their shares. 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 90-day period following the completion of this offering, in the event that we propose to register any of our securities under the Securities Act of 1933, as amended, either for our own account or for the account of other stockholders, the holders of approximately 12,314,307 shares of our common stock and holders of warrants to purchase 42,082 shares of 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 under employee benefit plans and in certain circumstances, the holders of these shares of our common stock and warrants 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 90-day period following the completion of this offering, the holders of approximately 12,249,998 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, holders owning a certain percentage of our capital stock and certain other identified 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.

#### 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;

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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  $66^{2}/_{3}\%$  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 became effective upon the closing of our initial public offering in May 2012, 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 Computershare Trust Company, N.A.

#### Listing

Our shares of common stock trade on The NASDAQ Global Market under the symbol "SUPN."

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## SHARES ELIGIBLE FOR FUTURE SALE

Prior to our initial public offering in May 2012, there had 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 at any time after this public offering. Future sales of substantial amounts of our common stock, including shares issued upon this public offering or shares issued upon the exercise of outstanding options or warrants, in the public market 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 30,466,049 shares of common stock outstanding, assuming (1) no exercise of any options outstanding as of September 30, 2012, (2) no exercise of any warrants to purchase shares outstanding as of September 30, 2012 and (3) no exercise of the underwriters' option to purchase additional shares from us. All 6,000,000 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 or purchased by existing stockholders and their affiliated entities who are subject to lock-up agreements. A total of 23,506,306 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 meet the safe harbor qualifications under Rule 144 under the Securities Act as summarized below.

The holders of 15,904,808 shares of outstanding common stock as of the closing of this offering and the holders of 415,500 shares of common stock underlying options 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 dispose of or hedge any shares of common stock or securities convertible into or exchangeable or exercisable for shares of common stock for a period of 90 days from the date of this prospectus without the prior written consent of Jefferies & Company, Inc. Jefferies & Company, Inc., in its sole discretion, may release some or all of the securities from these lock-up agreements at any time, which, in the case of officers and directors, shall be with notice. 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 304,660 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.

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

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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 qualify for resale under Rule 144, 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 prior to our initial public offering in May 2012 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 below.

### Lock-up Agreements

Our officers and directors, and certain of our significant stockholders holding an aggregate of approximately 15,904,828 shares have agreed, subject to certain exceptions, that, for a period of 90 days from the date of this prospectus, they will not, without the prior written consent of Jefferies & Company, Inc. dispose of or hedge any shares of common stock or securities convertible into or exchangeable or exercisable for our common stock. Jefferies & Company, Inc. in its sole discretion, may release any of the securities subject to these lock-up agreements at any time, which, in the case of officers and directors, shall be with notice. In addition, we have agreed, subject to certain exceptions, that, for a period of 90 days from the date of this prospectus, we will not, without the prior written consent of Jefferies & Company, Inc., Piper Jaffray & Co. and Cowen and Company, LLC, dispose of any shares of common stock or securities convertible into or exchangeable or exercisable for our common stock. Jefferies & Company, Inc., Piper Jaffray & Co. and Cowen and Company, LLC, in their sole discretion, together may release any of the securities subject to this lock-up agreement at any time.

#### **Stock Options**

As of October 31, 2012, we had outstanding options to purchase 581,445 shares of common stock, of which 190,907 shares were vested. We have registered the shares of our common stock subject to the options outstanding or reserved for issuance under our stock plans on one or more registration statements on Form S-8 under the Securities Act. See "Management Equity-Based Plans" for additional information about these plans. Subject to the lock-up agreements and the restrictions imposed under our stock plans, shares of common stock issued pursuant to our stock plans after the effective date of the registration statements 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

We have outstanding warrants to purchase (i) 18,750 shares of common stock at an exercise price of \$4.00 per share and (ii) 23,332 shares of common stock at an exercise price of \$5.00 per share.

## 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 (as defined below), but does not purport to be a complete analysis of all the potential tax considerations that may be relevant to such holders. 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 for U.S. federal income tax purposes.

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 its partners will generally depend upon the status of the partners and the activities of the partnership. Accordingly, we urge partnerships (and other entities or arrangements treated as partnerships for U.S. federal income tax purposes) that hold our common stock and partners in such partnerships to consult their tax advisors.

This summary deals only with shares of our common stock that are purchased in this offering and held as "capital assets" within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the "Code"). 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 its particular 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 unearned income Medicare contribution tax, or considerations under the tax laws of any state, local or non-U.S. jurisdiction.

This summary is based on 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 or differing interpretations at any time, possibly with retroactive effect. 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 make a distribution of cash or property with respect to our common stock, such distribution 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 the relevant agent, as the case may be, with a properly executed IRS Form W-8, such as:

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. federal income 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**

Subject to the discussion below under the sections entitled "Recently Enacted Legislation Affecting Taxation of Our Common Stock Held by or Through Foreign Entities" and "Information Reporting and Backup Withholding," 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 certain U.S. source capital losses.

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 and real property 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 is imposed at an applicable rate (currently 28% and scheduled to increase to 31% in 2013) on dividends and certain other types of payments to certain U.S. persons. Backup withholding 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.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should



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consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

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 by timely filing an appropriate claim for refund with the IRS.

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 (commonly referred to as "FATCA") generally will impose a U.S. federal withholding tax of 30% on payments to certain non-U.S. entities (including certain intermediaries), including dividends on, and the gross proceeds from dispositions of, our common stock, unless such persons comply with a complicated U.S. information reporting, disclosure, and certification regime. This new regime requires, among other things, a broad class of persons to enter into agreements with the IRS to obtain, disclose, and report information about their investors and account holders. This new regime and its requirements are different from, and in addition to, the certification requirements described elsewhere in this discussion. As currently proposed, the FATCA withholding rules would apply to payments of dividends on our common stock generally beginning January 1, 2014, and to gross proceeds from dispositions of our common stock beginning January 1, 2017. Under certain circumstances, a Non-U.S. Holder may be eligible for refunds of, or credits for, such taxes.

Although administrative guidance and proposed regulations have been issued, regulations implementing the new FATCA regime have not yet been finalized and the exact scope of this new regime remains unclear and potentially subject to material changes. Prospective investors should consult with their own tax advisors regarding the possible impact of the FATCA rules on their investment in our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax under FATCA.

## **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 AND ESTATE 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.

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### UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement to be dated on or about November 29, 2012, between us and Jefferies & Company, Inc., Piper Jaffray & Co., and Cowen and Company, LLC, as representatives of the underwriters, we have agreed to sell to the underwriters and the underwriters have severally agreed to purchase from us the number of shares of common stock indicated in the table below:

	Number of Shares of Common
Underwriter	Stock
Jefferies & Company, Inc.	1,800,000
Piper Jaffray & Co.	1,320,000
Cowen and Company, LLC	1,320,000
Stifel, Nicolaus & Company, Incorporated	960,000
Lazard Capital Markets LLC	600,000

Total

6,000,000

Jefferies & Company, Inc., Piper Jaffray & Co. and Cowen and Company, LLC are acting as joint book-running managers of this offering and as representatives of the underwriters named above.

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that they currently intend to make a market in our common stock. However, the underwriters are not obligated to do so and may discontinue any market-making activities at any time without notice. No assurance can be given as to the liquidity of the trading market for the shares of common stock.

The underwriters are offering the shares of our common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

### **Commission and Expenses**

The underwriters have advised us that they propose to offer the shares of our common stock to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$0.252 per share. After the offering, the public offering price and concession to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such

amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Wi	Per thout	Share			То	otal	
	Op	otion to chase	Opti Pur	'ith ion to chase	(	Without Option to Purchase	]	With Option to Purchase
		Additional Shares		Additional Shares		dditional Shares	Additional Shares	
Public offering price	\$	8.00	\$	8.00	\$	48,000,000	\$	55,200,000
Underwriting discounts and commissions paid by us	\$	0.48	\$	0.48	\$	2,880,000	\$	3,312,000
Proceeds to us, before expenses	\$	7.52	\$	7.52	\$	45,120,000	\$	51,888,000

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$765,000.

We have agreed to reimburse up to \$20,000 of the legal fees and expenses incurred by the underwriters in connection with determining their compliance with the rules and regulations of FINRA in connection with this offering.

The underwriters have agreed to reimburse us for our expenses incurred in the offering of \$360,000, and if the underwriters' option to purchase additional shares is exercised, \$414,000.

### Listing

Our common stock is listed on The NASDAQ Global Market under the trading symbol "SUPN".

### **Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of 900,000 additional shares of our common stock from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth in the table above.

## No Sales of Similar Securities

We and our officers, directors and certain of our significant stockholders holding an aggregate of approximately 15,904,808 shares of our outstanding common stock have agreed, subject to specified exceptions, not to directly or indirectly:

sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended, or

otherwise dispose of any shares of our common stock, options or warrants to acquire our common stock, or securities exchangeable or exercisable for or convertible into our common stock currently or hereafter owned either of record or beneficially, or

publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus without the prior written consent of Jefferies & Company, Inc., Piper Jaffray & Co. and Cowen and Company, LLC with respect to us and Jefferies & Company, Inc. with respect to our officers, directors and certain significant stockholders.

The restrictions set forth above will not apply to the establishment of a trading plan that complies with Rule 10b5-1 under the Exchange Act *provided however*, that the restrictions shall apply in full force to sales pursuant to the trading plan during the 90-day restricted period.

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Jefferies & Company, Inc., Piper Jaffray & Co. and Cowen and Company, LLC with respect to us and Jefferies & Company, Inc. with respect to our officers, directors and certain significant stockholders may, in their sole discretion and at any time or from time to time before the termination of the 90-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

### Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of our common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out 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 option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. 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 of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the shares of our common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The NASDAQ Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

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## **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of our common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

### Affiliations

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for the issuer, for which they received or will receive customary fees and expenses. Healthcare Royalty Partners, an affiliate of Cowen Group, Inc., holds certain of the Non-recourse Notes issued by our former subsidiary, Royalty Sub.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer. The underwriters and certain of their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Lazard Frères & Co. LLC referred this transaction to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith.

#### **Disclaimers About Non-U.S. Jurisdictions**

#### Canada

The securities have not been and will not be qualified under the securities laws of any province or territory of Canada. The securities are not being offered or sold, directly or indirectly, in Canada or to or for the account of any resident of Canada in contravention of the securities laws of any province or territory thereof.

## European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), an offer to the public of any shares of common stock which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any shares of common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

## (a)

to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;

(b)

to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as

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defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or

(c)

in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares of common stock shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression "offer shares of common stock to the public" in relation to the shares of common stock 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 shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe to the shares of common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

## Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA ("FINMA"), and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

## 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, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (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.

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### LEGAL MATTERS

Our counsel, Saul Ewing LLP, Washington, DC, 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, 2011 and 2010, and for each of the three years in the period ended December 31, 2011, 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 (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 2 to the consolidated financial statements) 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.

We are subject to the reporting and information requirements of the Exchange Act and, as a result, file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the SEC's public reference room and the web site of the SEC referred to above. We also maintain a website at https://www.supernus.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus. The reference to our web address does not constitute incorporation by reference of the information contained at or accessible through such site.

## Supernus Pharmaceuticals, Inc.

**Consolidated Financial Statements** 

Years ended December 31, 2009, 2010 and 2011 and the unaudited nine months ended September 30, 2011 and 2012

Report of Independent Registered Public Accounting Firm

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Consolidated Statements of Operations for the Years Ended December 31, 2009, 2010, and 2011, and the Nine Months Ended	
September 30, 2011 (unaudited) and 2012 (unaudited)	<u>F-4</u>
Unaudited Consolidated Statements of Comprehensive Income (Loss) for the Years Ended December 31, 2009, 2010, and 2011, and the	
Nine Months Ended September 30, 2011 and 2012	<u>F-5</u>
Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2009, 2010, and 2011, and the	
Nine Months Ended September 30, 2012 (unaudited)	<u>F-6</u>
Consolidated Statements of Cash Flows for the Years Ended December 31, 2009, 2010, and 2011, and the Nine Months Ended	
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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, 2010 and 2011, 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, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Supernus Pharmaceuticals, Inc. at December 31, 2010 and 2011, and the consolidated results of its operations and its cash flows for the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that Supernus Pharmaceuticals, Inc. will continue as a going concern. As more fully described in Note 2, the Company has incurred recurring operating losses and negative cash flows from operations and will require additional capital to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The 2011 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

McLean, Virginia March 15, 2012 except for Note 16, as to which the date is April 9, 2012

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## Supernus Pharmaceuticals, Inc.

## **Consolidated Balance Sheets**

	2010	ber 31, 2011	Septemb 2012 (unaudi	2 ited)
	(in thous	sands, exce	pt share d	ata)
Assets				
Current assets:				
Cash and cash equivalents	\$ 23,740	\$ 48,544	\$ 2	23,412
Marketable securities	8,964		3	37,256
Marketable securities restricted	261	245		275
Accounts receivable	44	128		500
Interest receivable	114			341
Inventory				26
Prepaid expenses and other	197	338		935
Deferred financing costs, current	53	144		144