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

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

Registration No. 333-184930

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Copies to:

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

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

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

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

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

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

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

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

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

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

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

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

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

SUBJECT TO COMPLETION, DATED NOVEMBER 26, 2012

PRELIMINARY PROSPECTUS

6,000,000 Shares

Supernus Pharmaceuticals, Inc.

Common Stock

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

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

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

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

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

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

Joint Book-Running Managers

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

Co-Managers

Stifel Nicolaus Weisel **Lazard Capital Markets**

Prospectus dated , 2012

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

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SUMMARY

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

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

Supernus Pharmaceuticals, Inc.

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

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

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

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

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

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

Our Neurology Portfolio

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

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

Oxtellar XR (extended release oxcarbazepine)

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

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

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

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

(3)

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

(4)

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

(5)

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

(6)

IMS Health data.

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Trokendi XR (extended release topiramate)

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

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

Our Psychiatry Portfolio

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States.[7] An estimated 60% to 80% of children with ADHD continue to meet the criteria for ADHD into adolescence, and as many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, conduct disorder, anxiety disorder and depression.[8] In addition, approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.[9] There are currently no approved products for the treatment of impulsive aggression in individuals with ADHD.

SPN-810 (molindone hydrochloride)

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

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

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

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

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

SPN-812

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

Our Proprietary Technology Platforms

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

Our Strategy

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

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

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

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

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

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

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

Risks Associated With Our Business

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

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

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

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

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

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

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

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

Implications of being an Emerging Growth Company

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

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

Reduced disclosure about our executive compensation arrangements.

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

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

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

Corporate Information

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

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

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

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THE OFFERING

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

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

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

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

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

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

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

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

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

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

Unless otherwise indicated, all information in this prospectus:

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

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

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SUMMARY FINANCIAL DATA

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

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

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

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

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

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

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

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RISK FACTORS

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

Risks Related to Our Business and Industry

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

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

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

- establish commercial manufacturing arrangements with third-party manufacturers for Trokendi XR;
- produce, through a validated process, sufficiently large quantities and inventory of our products to permit successful commercialization;
- build and maintain a wide variety of internal sales, distribution and marketing capabilities sufficient to build commercial sales of our products;
- establish collaborations with third parties for the commercialization of our products in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- secure widespread acceptance of our products from physicians, health care payors, patients and the medical community;
- properly price and obtain adequate coverage and reimbursement of the product by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements; and
- manage our growth and spending as costs and expenses increase due to commercialization.

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

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

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

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

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

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

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing capability and strategies; and
- ability to obtain sufficient third-party coverage or reimbursement.

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

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

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

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

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

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

- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;
- establish commercial manufacturing arrangements with third-party manufacturers;
- build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;
- establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- secure acceptance of our product candidates from physicians, health care payors, patients and the medical community;
- successfully complete our clinical trials; and
- manage our spending as costs and expenses increase due to commercialization and clinical trials.

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

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

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

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

- we may not be able to attract talented and qualified personnel to build an effective marketing or sales force capability;
- the cost of establishing a marketing and sales force capability may not be justifiable in light of the revenues generated by Oxtellar XR, Trokendi XR if it receives final approval, or any of our product candidates if approved by the FDA; and
- our direct sales and marketing efforts may not be successful.

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

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

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

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of each product or product candidate as a safe and effective treatment;
- perceived advantages of our products or product candidates over alternative treatments;
- relative convenience and ease of administration of our products or product candidates compared to existing treatments;
- any labeling restrictions placed upon each product or product candidate in connection with its approval;
- the prevalence and severity of the adverse side effects of each of our products or product candidates;

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

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

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- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which each product or product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- any negative publicity related to our or our competitors' products or product candidates, including as a result of any related adverse side effects;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness; and
- the availability of adequate reimbursement by third parties.

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

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

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

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

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

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

- could determine that we cannot rely on Section 505(b)(2) for any of our product candidates;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong reference listed drug or drugs or that approval of our Section 505(b)(2) application for Trokendi XR, or any of our other product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the active pharmaceutical ingredient, or API, used in our product candidates;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

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

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

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

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

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

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

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

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

- regulatory authorities may withdraw approvals of the product candidate or otherwise require us to take the approved product off the market;
- regulatory authorities may require additional warnings, or a narrowing of the indication, on the product label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to modify the product in some way;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of approved products may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- clinical holds imposed by the FDA.

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

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

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

- unforeseen safety issues; or

- lack of adequate funding to continue the trial.

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

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

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

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

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

Further, many competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

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

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

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

issue warning letters or untitled letters;

impose civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing bioequivalence and/or clinical trials;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling Oxtellar XR, Trokendi XR, or any product candidate approved in the future, if any, unless the third party licenses its rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and
- redesigning Oxtellar XR, Trokendi XR, or any of our product candidates so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- may fail to comply with applicable regulatory requirements;

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

- may breach or terminate their arrangement with us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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impairment of our business reputation and exposure to adverse publicity;

withdrawal of bioequivalence and/or clinical trial participants;

initiation of investigations by regulators;

costs of related litigation;

distraction of management's attention from our primary business;

substantial monetary awards to patients or other claimants;

loss of revenues; and

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

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

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

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

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

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

exposure to unknown liabilities;

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

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

higher than expected acquisition and integration costs;

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

increased amortization expenses;

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

inability to motivate key employees of any acquired businesses.

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

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

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

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

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

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

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

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

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

- manage our regulatory approvals and clinical trials effectively;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities;
- commercialize our product candidates;
- improve our operational, financial and management controls, reporting systems and procedures; and
- attract and motivate sufficient numbers of talented employees.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Finances and Capital Requirements

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

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

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

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

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

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

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

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

- the rate of progress and cost of our trials and other product development programs for our product candidates;
- the costs and timing of in-licensing additional product candidates or acquiring other complementary companies;
- the timing of any regulatory approvals of our product candidates;
- our ability to successfully launch our products and to continue to increase the level of sales in the marketplace;
- the actions of our competitors and their success in selling competitive product offerings;

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

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

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

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

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

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

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

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

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

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

Our operating results may fluctuate significantly.

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

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

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

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

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

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- potential side effects of our future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- any intellectual property infringement lawsuit in which we may become involved;
- our ability to establish an effective sales and marketing infrastructure;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- competition from existing products or new products that may emerge;
- regulatory developments affecting our products and product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- the achievement and timing of milestone payments under our existing collaboration and license agreements; and
- the level of market acceptance for any approved product candidates and underlying demand for that product and wholesalers' buying patterns.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Indebtedness

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

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

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

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

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

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

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

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

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

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

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

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

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

dispose of certain assets;

change our lines of business;

engage in mergers or consolidations;

incur additional indebtedness;

create liens on assets, including our intellectual property;

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

engage in certain transactions with affiliates.

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

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

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

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Risks Related to Securities Markets and Investment in Our Stock

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

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

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

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividen