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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

COMMISSION FILE NUMBER: 001-35518

or

☐ **TRANSMISSION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware			**20-2590184**
(State or other jurisdiction of incorporation or organization)			(I.R.S. Employer Identification Number)
9715 Key West Avenue (Address of Principal Executive Offices)	**Rockville**	**MD**	**20850** (zip code)
	(301)	**838-2500** (Registrant's telephone number, including area code)	

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

TITLE OF EACH CLASS:	**Outstanding at February 13, 2020**	**Trading Symbol**	**NAME OF EACH EXCHANGE ON WHICH REGISTERED:**
Common Stock, $0.001 Par Value	52,533,973	SUPN	The NASDAQ Stock Market LLC

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **NONE**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2019, the aggregate market value of the common stock held by non-affiliates of the registrant based on the closing price of the common stock on The NASDAQ Global Market was $1,677,874,611.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2020 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's 2019 fiscal year end, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SUPERNUS PHARMACEUTICALS, INC.
FORM 10-K

For the Year Ended December 31, 2019

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

We are the owners of various U.S. federal trademark registrations(®) and registration applications(™), including the following marks referred to in this Annual Report on Form 10-K pursuant to applicable U.S. intellectual property laws: "Supernus®," "Oxtellar XR®," "Trokendi XR®," "Microtrol®," "Solutrol®," and the registered Supernus Pharmaceuticals logo.

All other trademarks or trade names referred to in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are referred to without the ® and ™ 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.

PART I

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933, that involve risks and uncertainties. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Annual Report other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "seek," "anticipate," "should," "could," "would," "potential," or the negative of those terms and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. All of these forward-looking statements are based on information available to us at this time, and we assume no obligation to update any of these statements. Actual results could differ from those projected in these forward-looking statements as a result of many factors, including those identified in the "Business," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections and elsewhere in this Annual Report on Form 10-K. We urge you to review and consider the various disclosures made by us in this report, and those detailed from time to time in our filings with the Securities and Exchange Commission, that attempt to advise you of the risks and factors that may affect our future results.

ITEM 1. BUSINESS.

Overview

Supernus Pharmaceuticals, Inc. (the Company) was incorporated in Delaware, and commenced operations in 2005. The Company became publicly traded in 2012 and is listed on The NASDAQ Stock Exchange under the ticker symbol SUPN. Our principal executive offices are located in Rockville, Maryland.

We are a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases in neurology and psychiatry. Our extensive expertise in product development has been built over the past 25 years: initially as a privately-held stand-alone development organization; then, as a United States (U.S.) subsidiary of Shire Plc (Shire, a subsidiary of Takeda Pharmaceutical Company Ltd.); and upon our acquisition of substantially all of the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals.

Products and Product Candidates

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

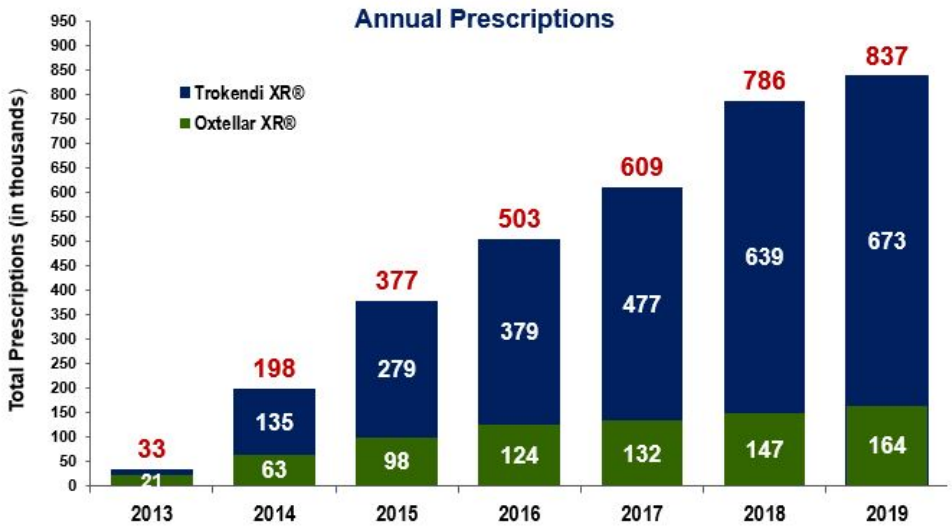
	Product	Indication	Development
Marketed	Trokendi XR® (topiramate) extended-release capsules	Epilepsy / Migraine*	
Marketed	Oxtellar XR® (oxcarbazepine) extended-release tablets	Epilepsy	
Pipeline	SPN-812	ADHD	PDUFA, November 8, 2020**
Pipeline	SPN-604	Bipolar	Phase III
Pipeline	SPN-809	Depression	IND/Phase II Ready
Pipeline	SPN-817	Severe Epilepsy	Phase I

* Prophylaxis of migraine headache in adults and adolescents.

** Prescription Drug User Fee Act (PDUFA)

We currently market two products, Oxtellar XR and Trokendi XR in the U.S. Oxtellar XR and Trokendi XR are the first once-daily extended release oxcarbazepine and topiramate products indicated for the treatment of epilepsy in the U.S. market. In April 2017, we launched Trokendi XR for the prophylaxis of migraine headache in adults and adolescents. In January 2019, we launched Oxtellar XR for monotherapy treatment of partial onset epilepsy seizures in adults and in children 6 to 17 years of age. We market our products through our own sales force in the U.S. and seek strategic collaborations with other pharmaceutical companies to commercialize our products outside of the U.S.

Our net product sales of $383.4 million in 2019 were driven by continued growth in prescriptions for Oxtellar XR and Trokendi XR, as shown in the following graph:



Source: IQVIA

As of year-end 2019, Trokendi XR represented approximately 5% of the topiramate market, and Oxtellar XR represented approximately 3% of the oxcarbazepine market. Total annual prescriptions for the topiramate and oxcarbazepine markets are approximately 13.4 million and 4.7 million, respectively.

We are also developing multiple proprietary CNS product candidates to address significant unmet medical needs and market opportunities. We are developing SPN-812 (viloxazine hydrochloride) as a novel, non-stimulant product candidate to treat children 6 to 17 years of age who have ADHD. We expect to launch SPN-812, assuming FDA approval, in the fourth quarter of 2020. Additionally, we initiated a Phase III ADHD program to study SPN-812 in adults during the third quarter of 2019.

Furthermore, we are developing SPN-604 (extended release oxcarbazepine) for the treatment of bipolar disorder. We initiated a pivotal Phase III monotherapy trial in the fourth quarter of 2019. We expect enrollment in this study to continue through 2021. If approved, SPN-604 would represent the first approval for the treatment of bipolar disorder with oxcarbazepine in the U.S.

Following our acquisition of Biscayne Neurotherapeutics, Inc. in 2018, we are currently developing SPN-817 to treat severe pediatric epilepsy disorders.

We expect to incur significant research and development expenses related to the continued development of each of our product candidates through FDA approval or until the program terminates. We incurred total research and development expenses of $69.1 million, $89.2 million and $49.6 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Assuming we obtain FDA approval for the product candidates currently in our portfolio, we anticipate creating a sales force to market our products to the relevant population of psychiatrists and primary care physicians.

We have a successful track record of developing and launching novel products by applying proprietary formulation technologies to known drugs to improve their side effect profile or to improve patient compliance. In addition, we have developed new indications for existing therapies. Our key proprietary technology platforms include: Microtrol, Solutrol and EnSoTrol. These technologies have been utilized to create ten marketed products, including: Trokendi XR and Oxtellar XR; Adderall XR (developed for Shire); Intuniv (developed for Shire); Mydayis (developed for Shire); and Orenitram (developed for United Therapeutics Corporation); as well as our product candidate SPN-812.

We continue to build our intellectual property portfolio to provide protection for our technologies, products and product candidates.

We expect to incur significant expenses as we: invest in research and development related to the continued development of each of our product candidates through FDA approval or until the program terminates; expand product indications for approved products; invest in sales and marketing resources for existing and new products; enter into agreements to purchase products or other companies; and invest in support of our business, technology, regulatory and intellectual property portfolio.

Our Strategy

Our vision is to become a leading pharmaceutical company, developing and commercializing new medicines for treatment of CNS diseases in neurology and psychiatry. Key elements of our strategy to achieve this vision include:

- *Drive growth and profitability.* We will continue to drive the prescription growth of Trokendi XR and Oxtellar XR, by continuing to dedicate sales and marketing resources in the U.S.

- *Advance our pipeline toward commercialization.* In January 2020, the FDA accepted the NDA for SPN-812 for the treatment of ADHD in pediatric patients. We initiated a Phase III trial for the treatment of ADHD in adult patients with SPN-812 in the third quarter of 2019. We also initiated a Phase III trial for SPN-604 for the treatment of bipolar disorder in adults in the fourth quarter of 2019.

- *Pursue strategic business development opportunities.* We are actively exploring a broad range of strategic opportunities that fit well with our strong presence in CNS, while also exploring other disease areas that are driven by specialty physicians, including orphan or rare diseases. These strategic options include: in-licensing products and/or entering into development collaborations leading to commercialization rights; opportunities that leverage and/or expand our sales force call points for our marketed products and product candidates; co-development partnerships outside the U.S. for our pipeline products; and growth opportunities through value-creating and transformative merger and acquisition transactions, including both commercial stage and development stage products.

- *Continue to grow our pipeline.* Through our internal research and development efforts, we plan to continue to evaluate and develop additional CNS product candidates that we believe have significant commercial potential.

Our Neurology Portfolio

Our neurology portfolio includes two commercial products and one product candidate for the treatment of neurological diseases:

- Trokendi XR, a once-daily extended release topiramate product for the prophylaxis of migraine headache and for the treatment of epilepsy;

- Oxtellar XR, a once-daily extended release oxcarbazepine product that was initially approved for adjunctive treatment of partial onset epilepsy seizures. During January 2019, we launched Oxtellar XR for the monotherapy treatment of partial onset epilepsy seizures in adults and in children 6 to 17 years of age; and

- SPN-817, a novel synthetic form of huperzine A, whose mechanism of action (MOA) includes potent acetyl cholinesterase inhibition, with pharmacological activities in CNS conditions such as epilepsy.

Epilepsy Overview

Epilepsy is a complex neurological disorder characterized by spontaneous recurrence of unprovoked seizures, which are sudden surges of electrical activity in the brain that impair a person's mental and/or physical abilities.

Compliance with drug treatment regimens is critically important to achieving effective control for patients with epilepsy. Non-compliance with anti-epileptic drug (AED) therapy is a serious issue and remains the most common cause of breakthrough seizures for patients. Not only is taking all prescribed doses critical to control breakthrough seizures, but the timing of when patients take their prescribed doses can also be crucial.

We believe extended release products, and in particular Trokendi XR and Oxtellar XR, may offer important advantages in the treatment of epilepsy. The release profiles of extended release products can produce more consistent and steadier plasma concentrations as compared to immediate release products, potentially resulting in fewer side effects, better tolerability, fewer emergency room visits, improved efficacy and fewer breakthrough seizures. Extended release products may help patients improve adherence and, consequently, help patients enjoy a better quality of life.

In addition, when considering treatment regimens for patients with epilepsy, neurologists and epileptologists take into consideration the MOA of the different anti-epileptics that are available. By combining several different MOAs, it is sometimes possible to get significantly better seizure control. We recently acquired SPN-817, an antiepileptic, which we believe has an MOA that is different from that of other products, and can therefore potentially represent a unique additional treatment alternative.

Migraine Overview

Approximately 39 million individuals in the U.S. are affected by migraine. The World Health Organization categorizes migraine as one of the most disabling medical illnesses worldwide.

Migraine is a painful complex neurological disorder, consisting of recurring, painful attacks that can significantly disrupt time with loved ones, education and careers. Migraine headaches are often characterized by throbbing pain, extreme sensitivity to light or sound and, potentially, nausea and vomiting.

As in epilepsy, we believe extended release products, and in particular Trokendi XR, may offer important advantages for treatment of migraine. The release profiles of extended release products can produce more consistent and steadier plasma concentrations as compared to immediate release products, potentially resulting in fewer side effects, better tolerability, fewer emergency room visits and improved efficacy. Extended release products may help patients improve adherence, have fewer breakthrough migraines and, consequently, help patients enjoy a better quality of life.

Commercial Products

Trokendi XR

Trokendi XR is indicated for: initial monotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic (PGTC) seizures; as add-on therapy in patients 6 years of age and older with partial onset or PGTC seizures or with seizures associated with Lennox-Gastaut syndrome; and for prophylaxis of migraine headache in adults and adolescents 12 years of age and older. Trokendi XR's once-daily dosing is designed to improve patient adherence over the current immediate release products, which must be taken multiple times per day. We believe a once-daily dosing regimen improves compliance, making it more probable that patients take their medication and maintain sufficient levels of medication in their bloodstreams. Trokendi XR's unique smooth pharmacokinetic profile results in lower peak plasma concentrations, higher trough plasma concentrations, and slower plasma uptake rates. This results in smoother and more consistent plasma concentrations than immediate release topiramate formulations. We believe that such a profile mitigates blood level fluctuations that are frequently associated with many side effects, thereby reducing the likelihood of breakthrough seizures or migraine headaches that patients can suffer when taking immediate release products. Side effects associated with immediate release products may lead patients to skip doses, which could place them at higher risk for breakthrough seizures or migraine headaches.

Oxtellar XR

Oxtellar XR is indicated as therapy of partial onset seizures in adults and in children 6 years to 17 years of age. With its novel pharmacokinetic profile showing lower peak plasma concentrations, a slower rate of plasma input, and smoother and more consistent blood levels as compared to immediate release products, we believe Oxtellar XR improves the tolerability of oxcarbazepine and thereby reduces side effects. In addition, Oxtellar XR once-per-day dosing is designed to improve patient compliance compared to the current immediate release products that must be taken multiple times per day.

Product Candidates

SPN-817 (huperzine A)

SPN-817 will have new chemical entity status (NCE) in the U.S. market. We expect to have significant intellectual property (IP) protecting this product candidate through our own research and development efforts, as well as through in-licensed IP. SPN-817 represents a novel MOA for an anticonvulsant. Development will initially focus on the drug's anticonvulsant activity, which has been shown in preclinical models for treatment of partial seizures and Dravet Syndrome. SPN-817 is in clinical development, and has received an Orphan Drug designation for Dravet Syndrome from the FDA.

SPN-817 Development Program

We plan on studying SPN-817 initially in severe pediatric epilepsy disorders. A Phase I proof-of-concept trial is currently underway in adult patients with refractory complex partial seizures, studying the safety and pharmacokinetic profile of a new extended release formulation of non-synthetic huperzine A. The Company initiated an Investigational New Drug (IND) application, enabling preclinical activities in the U.S.

We will focus on completing and optimizing the synthesis process of the synthetic drug and developing a novel dosage form. Given the potency of huperzine A, a novel extended release oral dosage form is critical to the success of this program, because initial studies with immediate release formulations of non-synthetic huperzine A have shown dose-limiting serious side effects.

Manufacturing

We currently depend on third-party commercial manufacturing organizations (CMOs) for all manufacturing operations, including production of raw materials, dosage form product and product packaging. This encompasses products for commercial use, as well as some products for preclinical and clinical research. We currently employ internal resources to manage our manufacturing contractors.

We have entered into agreements with leading CMOs headquartered in North America, including Patheon Pharmaceuticals, Inc. (a subsidiary of Thermo Fisher Scientific Inc.), Packaging Coordinators, Inc; and Catalent Pharma Solutions, for the manufacture and packaging of the commercial products Oxtellar XR and Trokendi XR, as well as for our pipeline candidate, SPN-812. These CMOs offer a comprehensive range of contract manufacturing and packaging services. Commercial products as well as our product candidates are single sourced from third-party suppliers.

We do not own or operate manufacturing facilities for the production of any of our product candidates beyond that used in Phase II clinical trials, nor do we have plans to develop our own manufacturing operations in the foreseeable future.

Sales and Marketing

We have a commercial sales and marketing organization in the U.S. to support sales of Oxtellar XR and Trokendi XR. We believe our current sales force of over 200 sales representatives is effectively targeting healthcare providers, primarily neurologists, to support and grow our epilepsy and migraine product franchise. Simultaneously promoting two neurology products allows us to leverage our commercial infrastructure and gain efficiencies in operations.

Epilepsy Competition

Trokendi XR competes with all immediate release and extended release topiramate products, including Topamax, Qudexy XR and their related generic products. Oxtellar XR competes with all immediate release oxcarbazepine products, including Trileptal and its related generic products. Both Oxtellar XR and Trokendi XR compete with other anti-epileptic products, both branded and generic.

Migraine Competition

Trokendi XR competes with all immediate release and extended release topiramate products, including Topamax, Qudexy XR and their related generic products, as well as other products used for the prevention of migraine headaches. Most notably, this includes a new class of products introduced in 2018, anti-CGRPs (calcitonin gene related peptide); Botox; beta-blockers; valproic acid; and amitriptyline.

Our Psychiatry Portfolio

Our psychiatry portfolio includes three product candidates for the treatment of psychiatric disorders:

- SPN-812, the most advanced product candidate, is a novel non-stimulant product being developed for the treatment of ADHD. In January 2020, the FDA accepted the review of the NDA for SPN-812 for the treatment of children and adolescents with ADHD and assigned a PDUFA target action date of November 8, 2020;
- SPN-809, which employs the same active ingredient as in SPN-812, is Phase II ready and is in development for the treatment of depression; and
- SPN-604 is being developed for the treatment of bipolar disorder. A Phase III clinical trial was initiated during the fourth quarter of 2019.

ADHD Overview

ADHD is a 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 an estimated 3% to 5% of adults in the U.S.[(1)] An estimated 50% of children with ADHD continue to meet criteria for ADHD into adolescence[(2)].

Diagnosis of ADHD requires a comprehensive clinical evaluation based on identifying patients who exhibit the core symptoms of inattention, hyperactivity, and impulsivity. Although many children may be inattentive, hyperactive or impulsive, the level of severity and degree of functional impairment, as well as considerations as to what may be behind the underlying symptoms, determine which children meet the diagnosis and therefore should be treated for ADHD.

Non-stimulant treatments for ADHD accounted for about 8% of the total ADHD prescriptions in the U.S. in 2018, with stimulants constituting approximately 92% of ADHD prescriptions. The ADHD market is projected to grow approximately 4% annually, from approximately 75 million prescriptions in 2019 to approximately 78 million prescriptions by 2020. According to data from IQVIA, the U.S. market for ADHD prescription drugs was $8.5 billion for the year ended December 31, 2019.

Bipolar Disorder Overview

Bipolar disorder is a mental disorder that causes unusual shifts in mood, energy, activity levels, concentration and the ability to carry out day-to-day tasks. There are three main types of bipolar disorder; bipolar I disorder, bipolar II disorder and cyclothymic disorder. 12 month prevalence of bipolar disorder in the U.S. is 2.8% and lifetime prevalence is 4.4%[(3)]. Based on our market research we believe that bipolar I to bipolar II prevalence is 7:3.

A psychiatrist or other mental health professional diagnoses bipolar disorder based on the symptoms, lifetime course, and experiences of the individual. Physicians primarily treat with combination therapies containing mood stabilizers. According to data from IQVIA, for the year ended December 31, 2019, 56 million prescriptions were written in the U.S. for bipolar disorder.

Product Candidates

SPN-812 (viloxazine hydrochloride)

SPN-812 is a serotonin norepinephrine modulating agent (SNMA), which we are developing as a novel non-stimulant for the treatment of ADHD. SPN-812 has the potential to address an $8.5 billion market opportunity in the U.S. We believe SPN-812 could be well-differentiated as compared to other non-stimulant treatments due to its different pharmacological and pharmacokinetic profile. The active ingredient in SPN-812, viloxazine hydrochloride, has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant, albeit at much higher dosage levels. Viloxazine hydrochloride is a structurally distinct, bicyclic, SNMA with NCE status in the U.S.

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

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

(4) Harvard Medical School, 2007. National Comorbidity Survey (NSC). (2017, August 21).

The FDA accepted the review of the NDA for SPN-812 for the treatment of children and adolescents with ADHD in January 2020 and assigned a PDUFA target action date of November 8, 2020. We plan to launch it, pending FDA approval, in the fourth quarter of 2020. We expect SPN-812, if approved, to have five-year market exclusivity due to its NCE status in the U.S. Furthermore, we are developing IP covering the novel synthesis process for the active ingredient in SPN-812, its novel use in ADHD and its novel extended release delivery system.

SPN-812 Development Program

The Phase III pivotal program consisted of four three-arm, placebo-controlled trials: P301 and P303 trials in patients 6 to 11 years old; and P302 and P304 trials in patients 12 to 17 years old. We announced positive topline results from the pediatric trials (P301 and P303) and the first adolescent trial (P302) in December 2018. Results of the second adolescent Phase III trial (P304) were released in March of 2019.

We initiated a Phase III program in adults in the third quarter of 2019.

Refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 for the results of the previously completed Phase IIb trials.

Results of P301 and P303 Phase III trials

Both studies were randomized, double-blind, placebo controlled, multicenter, parallel group clinical trials in children 6 to 11 years of age who are diagnosed with ADHD. After titration, each treatment was administered orally once a day over five weeks in study P301, and over seven weeks in study P302. A total of 477 patients were randomized in the P301 study, across placebo and two doses (100mg; 200mg), and a total of 313 patients were randomized in the P303 study, across placebo and two doses (200mg; 400mg). The primary objective of both studies was to assess the efficacy of SPN-812 in reducing the symptoms of ADHD in children. The primary outcome measure was the change, from baseline to the end of the study, in the ADHD Rating Scale (RS-5) total score. Safety and tolerability were assessed by monitoring: adverse events (AEs); clinical laboratory tests; vital signs; electrocardiograms (ECGs); suicidality; and physical examinations. Patients who completed the study were offered the opportunity to continue into an open-label phase, that is currently on-going.

On December 6, 2018, we announced positive topline results from the P301 and P303 Phase III studies of SPN-812, having successfully met the primary endpoint. At daily doses of 100 mg and 200 mg in study P301, and at daily doses of 200mg and 400mg in study P303, statistically significant improvement in the symptoms of ADHD, from baseline to end of study, as measured by the ADHD-RS-5, was achieved. Patients receiving SPN-812 100 mg and 200 mg had a −16.6 point change ($p=0.0004$) and a−17.7 point change ($p<0.0001$) from baseline, respectively, in the primary endpoint, vs. a −10.9 point change for placebo at week 6. This primary result, based on Mixed Model Repeated Measures (MMRM) analysis in the Intent-To-Treat (ITT) population, was confirmed by sensitivity analyses using Analysis of Covariance (ANCOVA) (100 mg, $p=0.0008$; 200 mg, $p<0.0001$). All SPN-812 doses tested in the trials were well tolerated.

The study demonstrated fast onset of action, reaching statistical significance for 100 mg and 200 mg doses as early as week 1, with p- values of 0.0004 and 0.0244, respectively. Statistical significance was maintained on a weekly basis through the end of the trial at week 6. In addition, at the end of the study, SPN-812 100 mg and 200 mg reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the ADHD-RS-5, scale with p- values ranging from <0.0001 to 0.0026. Finally, SPN-812 100 mg and 200 mg met all secondary endpoints, including the important analysis of the Clinical Global Impression Improvement (CGI-I) secondary endpoint, with p- values of 0.002 and <0.0001, respectively, compared to placebo.

At the end of the P303 Study, SPN-812 200 mg and 400 mg doses reached statistical significance, as compared to placebo, in the primary endpoint. Patients receiving 200 mg and 400 mg had a −17.6 point change ($p=0.0038$) and a −17.5 point change ($p=0.0063$) from baseline to end of study, respectively, in the primary endpoint vs. a −11.7 point change for placebo at week 8. This primary result, based on MMRM analysis in the ITT population, was confirmed by sensitivity analyses using ANCOVA (200 mg, $p=0.0058$; 400 mg, $p<0.0121$).

Onset of action for SPN-812 showed clear differences compared to placebo starting by week 1, reaching statistical significance at week 5, which was sustained through the rest of the trial.

As with the P301 study, at the end of the P303 study, SPN-812 200 mg and 400 mg reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the ADHD-RS-5, scale with p- values ranging from 0.0020 to 0.0248. In addition, 200 mg and 400 mg met the CGI-I secondary endpoint, with p- values of 0.0028 and 0.0099, respectively, compared to placebo.

Overall, both trials exhibited favorable tolerability and safety profiles, with low incidence of AEs across all doses. AEs were mild, leading to low discontinuation rates due to AEs, ranging from 2.2% to 4.8%. Treatment related AEs that reported at more than or equal to 5% included somnolence, headache, decreased appetite, fatigue and upper abdominal pain.

Results of P302 Phase III trial

On December 20, 2018, we announced positive topline results from the P302 Phase III study of SPN-812 in patients 12 to 17 years old for the treatment of ADHD. The trial was successful in meeting the primary endpoint, demonstrating that SPN-812 at daily doses of 200 mg and 400 mg achieved statistically significant improvement in the symptoms of ADHD, from baseline to end of study, as measured by the ADHD-RS-5. Each of the SPN-812 doses tested in the trials was well tolerated.

The study was a randomized, double-blind, placebo controlled, multicenter, parallel group clinical trial, in adolescents 12 to 17 years of age diagnosed with ADHD. Each treatment was administered orally once a day over six weeks, including the titration phase of the 400 mg dose group.

A total of 310 patients were randomized across placebo and two doses of SPN-812 (200 mg/400 mg). The primary objective was to assess the effect of SPN-812 in reducing the symptoms of ADHD in adolescents 12 to 17 years old. The primary outcome measure was the change, from baseline to the end of the study, in the ADHD-RS-5 total score. Safety and tolerability of SPN-812 were assessed by the monitoring of: AEs; clinical laboratory tests; vital signs; ECGs; suicidality; and physical examinations. Patients who completed the study were offered the opportunity to continue into an open-label phase, currently on-going.

At the end of the P302 Study, 200 mg and 400 mg doses reached statistical significance, as compared to placebo, for the primary endpoint. Patients receiving 200 mg and 400 mg had a −16.0 point change (p=0.0232) and a −16.5 point change (p=0.0091) from baseline, respectively, in the primary endpoint, vs. a −11.4 point change for placebo, at week 6. This primary result, based on MMRM analysis in the ITT population, was confirmed by sensitivity analyses using ANCOVA (200 mg, p=0.0163; 400 mg, p=0.0055).

The study demonstrated fast onset of action, reaching statistical significance for the 400 mg dose as early as week 1, with a p-value of 0.0085, and maintaining statistical significance on a weekly basis through the end of the trial at week 6. Onset of action for the 200 mg dose showed clear difference compared to placebo starting by week 1, reaching statistical significance at week 3. This difference was sustained through the rest of the trial.

As with the P301 and P303 studies, at the end of the P302 study, 200 mg and 400 mg doses reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the ADHD-RS-5 scale, with p-values ranging from 0.0005 to 0.0424. In addition, 200 mg and 400 mg doses met the CGI-I secondary endpoint, with p-values of 0.0042 and 0.0003, respectively, compared to placebo.

Overall, the trial exhibited favorable tolerability and safety profiles, with low incidence of AEs across all doses. AEs were mild, leading to low discontinuation rates due to AEs, ranging from 1.9% to 4.1%. Treatment related AEs that reported at more than or equal to 5% for SPN-812 included somnolence, fatigue, decreased appetite, headache and nausea.

Results of P304 Phase III trial

On March 28, 2019, we announced topline results from the P304 Phase III study of SPN-812, in patients 12 to 17 years old for the treatment of ADHD.

The study is a randomized, double-blind, placebo controlled, multicenter, parallel group clinical trial in adolescents 12 to 17 years of age, diagnosed with ADHD. Each treatment was administered orally once a day over seven weeks, including one week of titration for 400 mg and two weeks of titration for 600 mg.

A total of 297 patients were randomized across placebo and two doses of SPN-812 (400 mg/600 mg). The primary objective was to assess the efficacy of SPN-812 in reducing the symptoms of ADHD, in adolescents 12 to 17 years old. The primary outcome measure was the change, from baseline to the end of the study, in the ADHD-RS-5 total score tested on the 600 mg followed by the 400 mg in the statistical plan. Safety and tolerability of SPN-812 were assessed by the monitoring of: AEs; clinical laboratory tests; vital signs; ECGs; suicidality; and physical examinations. Patients who completed the study were offered the opportunity to continue into an open-label phase, currently on-going.

At the end of the study (EOS), SPN-812 400 mg reached statistical significance as compared to placebo, for the primary endpoint. Patients receiving 400 mg had an -18.3 Least Squares (LS) Mean change from baseline (p=0.0082) vs. LS Mean change of-13.2 from baseline for placebo at week 7. SPN-812 600 mg did not reach statistical significance with an LS Mean change of -16.7 (p=0.0712) from baseline in the primary endpoint at week 7. The result, based on MMRM analysis in the ITT population, was consistent with the results from sensitivity analyses using ANCOVA (400 mg, p=0.0191; 600 mg, p=0.1002) at week 7 (EOS), with placebo based imputation for missing data.

At the 400 mg dose, SPN-812 demonstrated statistically significant onset of action starting week 2 (p=0.0063), which continued to the end of the study at week 7 (p=0.0082). At the 600 mg dose, SPN-812 demonstrated statistically significant difference from placebo in the primary endpoint during the last week of titration (week 2, dosed at 400 mg, p=0.0456) and the first week of maintenance (week 3, dosed at 600 mg, p=0.0238).

As with the first three studies (P301, P302 and P303), at the end of the P304 study, the 400 mg dose reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the ADHD-RS-5 scale, with p-values of 0.0484 and 0.0042, respectively. In addition, the SPN-812 400 mg dose met the CGII secondary endpoint, with a p-value of 0.0051 compared to placebo.

While the 600 mg dose did not reach statistical significance, it was not required for the submission or approvability of the NDA for children and adolescents. It was included to assess a potentially higher level of efficacy, to identify the maximum effective dose and to help in designing our trials for the adult population.

Overall, the trial exhibited both favorable tolerability and a favorable safety profile, consistent with the other Phase III trials, with low incidence of AEs across all doses. AEs were mild leading to low discontinuation rates, ranging from 4.0% to 5.1%. Treatment related AEs that reported at more than or equal to 5% for SPN-812 were somnolence, fatigue, decreased appetite, headache and nausea.

With the completion of the P304 study, we now have a robust clinical data package in more than 1,000 children and adolescent patients, across all three doses of SPN-812: 100 mg, 200 mg and 400 mg. We submitted an NDA to the FDA in November 2019, and received acceptance of the filing in January 2020. The FDA has assigned a PDUFA target action date of November 8, 2020. We expect to launch SPN-812, assuming FDA approval, in the fourth quarter of 2020.

SPN-809 (viloxazine hydrochloride)

SPN-809 is a novel once-daily product candidate for the treatment of depression. SPN-809 incorporates the same active ingredient as SPN-812. We currently have an open investigational IND for SPN-809 as a treatment for depression, the indication for which the active ingredient in SPN-809 was approved and marketed in Europe for many years. The active ingredient was never approved in the U.S. for this indication.

Because SPN-809 contains the same active ingredient as SPN-812, we expect that many of our activities related to the development of SPN-812 will also benefit the development of SPN-809.

SPN-604 (extended release oxcarbazepine for bipolar)

SPN-604 is a novel once-daily product candidate for the treatment of bipolar. It includes the active ingredient oxcarbazepine which has the well-known MOA of a sodium channel blocker. This MOA has been proven to treat bipolar through several products that are currently approved by the FDA and are on the market for such use. In addition, a significant portion of the current oxcarbazepine market is to treat psychiatric disorders such as bipolar despite the fact that the drug has never been approved by the FDA for such use.

We initiated a Phase III program for the treatment of bipolar disorder in the fourth quarter of 2019. This program will likely include a monotherapy trial and an adjunctive trial. The monotherapy Phase III clinical trial was initiated during the fourth quarter of 2019.

If approved, SPN-604 would represent the first approval for the treatment of bipolar disorder with oxcarbazepine in the U.S.

ADHD Competition

Competition in the U.S. ADHD market has increased with the commercial launch of several branded products in recent years, as well as the launch of generic versions of branded drugs, such as Adderall XR, Intuniv and Strattera.

Treatment options for ADHD in the U.S. market can be broadly classified as either stimulant or as non-stimulant products. Shire Plc, one of the leaders in the U.S. ADHD market, has four marketed products: Vyvanse, a stimulant drug product launched in 2007; Intuniv, a non-stimulant product launched in November 2009; Adderall XR, an extended release stimulant product providing once-daily dosing, launched in October 2001; and Mydayis, a stimulant product launched in August 2017. Other marketed stimulant products for the treatment of ADHD in the U.S. include the following once-daily formulations: Concerta; Metadate CD; Ritalin LA; Focalin XR; Daytrana; Adzenys XR-ODT; Cotempla XR ODT; and Aptensio XR. Other marketed non-stimulants in the U.S. include Strattera and Kapvay.

We are also aware of clinical development efforts by several companies, including Sunovion, Ironshore/Highland and Otsuka, to develop additional treatment options for ADHD. Sunovion filed its non-stimulant product, Dasotraline, with the FDA in September of 2017 for treatment of adults, children and adolescents with ADHD. Sunovion received a non-approvable letter. In 2019, Ironshore/Highland launched Jornay PM, a new stimulant product. In 2017, Otsuka Pharmaceutical Co., Ltd. announced an agreement with Neurovance, Inc. to acquire Neurovance, a privately held, venture-funded, clinical stage pharmaceutical company, focused on ADHD and related disorders. Otsuka is currently conducting Phase III clinical trials to evaluate the efficacy, safety, and tolerability of non-stimulant Centanafadine sustained-release tablets in adults with ADHD.

Bipolar Competition

Treatment options for bipolar disorder include mood stabilizers, atypical antipsychotics and antidepressants. The majority of patients are on mood stabilizers, commonly with atypical antipsychotics in bipolar I disorder or as monotherapy in bipolar II disorder. Within the mood stabilizer category, Lithium and Depakote are used most in bipolar I disorder treatment, followed by Lamictal and Trileptal, while Lamictal is preferred in treating bipolar II disorder, followed by Lithium, Trileptal and Depakote. Trileptal is used off-label for treating bipolar disorder. Based on our market research, we believe that SPN-604 is expected to compete within the mood stabilizer category as a second line therapy.

Our Proprietary Technology Platforms

We have a successful track record of developing novel products by applying proprietary formulation technologies to known drugs to improve their side effect profile or to improve patient compliance. In addition, we have developed new indication for existing therapies. Our key proprietary technology platforms include Microtrol, Solutrol and EnSoTrol. These technologies create novel, customized product profiles, designed to enhance efficacy, reduce the frequency of dosing so as to improve patient compliance and improve tolerability. We have employed our technologies in the development of a total of ten products that are currently on the market, including our products Trokendi XR and Oxtellar XR, along with eight products being marketed by our partners. Trokendi XR uses the Microtrol multiparticulate delivery platform, while Oxtellar XR uses the Solutrol matrix delivery platform. EnSoTrol was utilized to develop Orenitram, an oral formulation of treprostinil diethanolamine, or treprostinil, which was launched by United Therapeutics Corporation (UTC) in 2014. Microtrol was also utilized to develop Mydayis, which was launched by Shire in 2017.

Our Research and Development group is also engaged in generating and assessing NCEs. These NCEs were generated by leveraging our expertise in structure function relationships in active molecules. Our NCEs are currently being assessed in preclinical pharmacology models for CNS activity, and are advancing through IND enabling toxicology studies to support future clinical investigation.

Intellectual Property and Exclusivity

Overview

We have been building and continue to build our IP portfolio relating to our products and product candidates, including Oxtellar XR, Trokendi XR and SPN-812. We seek patent protection, where appropriate, both in the U.S. and internationally for products and product candidates. We have established and continue to build proprietary positions for Oxtellar XR, Trokendi XR, our pipeline product candidates and our technologies in the U.S. and abroad.

Our policy is to protect our innovations and proprietary products by, among other things, filing patent applications in the U.S. and abroad, including Europe, Canada and other countries when appropriate. We also rely on trade secrets, know-how, proprietary knowledge, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology. We cannot be sure that any patents, if granted, will sustain legal challenge.

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

On Oxtellar XR, the Company prevailed in litigation against third parties, and, therefore, we expect that Oxtellar XR will have patent protection through the expiry of its patents in 2027. On Trokendi XR, the Company entered into settlement agreements that allow third parties to enter the market by selling a generic version of Trokendi XR by January 1, 2023, or earlier under certain circumstances. For more information, please see Part I, Item 3—*Legal Proceedings* contained in this Annual Report on Form 10-K.

Patent Portfolio

We currently have ten U.S. patents that cover Trokendi XR. We own all of the issued patents. We have one patent issued for extended release topiramate in each of the following countries: Mexico; Australia; Japan; and Canada. We have two patents issued in Europe. The ten issued U.S. patents covering Trokendi XR will expire no earlier than 2027.

The Company has entered into settlement agreements with third parties, permitting sale of a generic version of Trokendi XR by January 1, 2023, or earlier under certain circumstances.

Our extended release oxcarbazepine patent portfolio currently includes twelve U.S. patents, nine of which cover Oxtellar XR. The nine issued U.S. patents covering Oxtellar XR will expire no earlier than 2027. We own all of the issued patents and the pending U.S. patent applications. We have two issued patents for extended release oxcarbazepine in both Europe and Australia, and one patent issued in each of the following countries: Canada; Japan; China and Mexico. In addition, we have a pending U.S. patent application that covers various extended release formulations containing oxcarbazepine.

Our patent portfolio contains patent applications relating to our pipeline products. Specifically, with regard to SPN-810, we are developing an IP position covering the novel synthesis process of the active ingredient, its novel use in IA and its novel formulation. We have four families of pending U.S. non-provisional and foreign counterpart patent applications relating to SPN-810. Patents, if issued, could have terms expiring from 2029 to 2033. We have two patents issued each in the U.S. and Europe, three patents issued in Japan, and one patent issued each in Canada, Mexico, and Australia, covering modified release formulations of molindone hydrochloride. In another patent family, covering the novel synthesis process of the active ingredient, we have four patents issued in the U.S., two patents issued in Japan and Australia, and one patent issued each in Europe and Mexico. The third patent family, covering use of molindone hydrochloride in treating aggression, includes three patents issued each in the U.S. and Japan, two patents issued each in Mexico and Australia, and one patent issued in Canada. We own all of the issued patents and the pending patent applications.

With regard to SPN-812, we have three families of pending U.S. non-provisional and foreign counterpart patent applications. Patents, if issued, could expire from 2029 to 2033. We have one patent issued each in Europe and Canada, covering a method of treating ADHD using viloxazine hydrochloride. In another family, covering the novel synthesis process of active ingredient, we have four patents issued in the U.S., five patents issued in Mexico, and one patent issued each in Europe, Japan, Canada and Australia. We have four patents issued in the U.S. covering modified release formulations of viloxazine hydrochloride, two patents issued in Japan and Australia and one patent issued in Mexico. We own all of the issued patents and the pending patent applications.

U.S. Patent Application Process

The U.S. patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is submitted to the United States Patent and Trademark Office (USPTO), and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the U.S., a patent's term may be lengthened via a patent term adjustment (PTA), which compensates a patentee for administrative delays by the USPTO in granting a patent. Because of a recent court decision, in which the USPTO erred in calculating the PTA by denying the patentee a portion of the patent term to which it was entitled, the USPTO is under greater scrutiny regarding its calculations of PTAs.

Alternatively, a patent's term may be shortened if a patent is terminally disclaimed over another patent.

In evaluating the patentability of a claimed invention, the filing date of a non-provisional patent application is used by the USPTO to determine what information constitutes prior art. If certain requirements are satisfied, a non-provisional patent application can claim the benefit of the filing date of a previously filed provisional patent application. In such an instance, the filing date accorded to the provisional patent application may supersede information that otherwise could preclude the patentability of an invention.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension (PTE). This permits the patent term to be extended as compensation for that portion of a patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a PTE of up to five years beyond the expiry date of the patent. The length of the PTE is related to the length of time the drug is under FDA review. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent for an approved drug may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other foreign jurisdictions.

In the future, if and when our pharmaceutical products receive FDA or other regulatory approval, we may be able to apply for PTEs on patents covering those products. Depending upon the timing, duration and specifics of FDA approval and the issuance of a U.S. patent, we may obtain limited patent term restoration.

Other Intellectual Property Rights

We seek trademark protection in the U.S. and internationally, where available and when appropriate. We have filed for trademark protection for several marks, which we use in connection with our pharmaceutical research and development collaborations as well as with our products. We are the owner of various U.S. federal trademark registrations (®) and registration applications (™), including the following marks referred to in this Annual Report on Form 10-K, pursuant to applicable U.S. intellectual property laws: "Supernus®," "Microtrol®," "Solutrol®," "Trokendi XR®," "Oxtellar XR®," and the registered Supernus Pharmaceuticals logo.

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

To protect our competitive position, it may be necessary to enforce our patent rights through litigation against infringing third parties. We presently have no pending lawsuits. See Part I, Item 3—*Legal Proceedings*. Litigation to enforce our own patent rights is subject to uncertainties that cannot be quantified in advance. In the event of an adverse outcome in litigation, we could be prevented from commercializing a product or precluded from using certain aspects of our technology platforms. This could have a material adverse effect on our business. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part; on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize products or use technologies that are similar to ours, and then compete directly with us, without compensation to us. See Part I, Item 1A—*Risk Factors*: "If we are sued for infringing intellectual property rights of third parties, it could be costly and time consuming to defend such a suit. An unfavorable outcome in that litigation could have a material adverse effect on our business."

In-Licensing Arrangements

Rune HealthCare Limited

We have a purchase and sale agreement with Rune HealthCare Limited (Rune), where we obtained the exclusive worldwide rights to a product concept from Rune for SPN-809. If we receive approval to market and sell any products covered by the agreement, we will be obligated to pay royalties on worldwide net product sales, at a rate in the low-single digits.

SPN-817

We obtained worldwide rights, excluding certain markets in Asia where rights have been previously out-licensed, to SPN-817. SPN-817 has received Orphan Drug designation from the FDA for the treatment of Dravet Syndrome, a severe form of childhood epilepsy. These rights were obtained through our acquisition of Biscayne Neurotherapeutics, Inc. We may be obligated to pay up to $73 million if certain development milestones are achieved. In addition, we may be obligated to pay up to $95 million if certain sales milestones are achieved. In addition, we will be obligated to pay a low single digit royalty on net sales to Biscayne, and any applicable royalties to third parties for the use of in-licensed IP. The maximum combined royalty we will pay to all parties on net product sales is approximately 12%, depending on the IP covering the marketed product and the applicable tiered sales levels.

Confidential Information and Inventions Assignment Agreements

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

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

Government Regulation

U.S. Drug Development Process

The research and development process generally begins with discovery research, which focuses on the identification of a molecule that has the desired effect against a given disease. The FDA requires submission of an IND, which must become effective before human clinical trial testing may commence. The results of pre-clinical testing, along with other information, including information about product chemistry, product manufacturing and controls, and a proposed clinical trial protocol are submitted to the FDA as part of the IND. Until the IND is approved, or becomes effective following a waiting period, we may not start the clinical trials. This is typically followed by additional preclinical laboratory and animal testing, as well as adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use. Satisfaction of FDA approval requirements typically takes many years. The actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation, as well as animal studies, to assess the characteristics and potential pharmacology, pharmacokinetics, and toxicity of the product. The conduct of the preclinical tests must comply with FDA regulations and requirements, including good laboratory practices.

If preclinical testing of an identified compound proves successful, the compound moves into clinical development. While these are generally conducted in three sequential phases, the phases may overlap or be combined.

- Phase I - Involves the first human tests of the drug, in a small number of healthy volunteers or in patients, to assess safety, tolerability, potential dosing, and if possible, early evidence on effectiveness.

- Phase II - Involves trials in a relatively small group of patients, to determine the effectiveness of the drug for a particular indication(s); dosage tolerance and optimum dosage; and to identify common adverse effects and safety risks.

- Phase III - Tests confirming favorable results in earlier phases, in a significantly larger patient population, and to further demonstrate efficacy and safety.

Clinical trials must be conducted in compliance with applicable regulations and consistent with good clinical practices, as well as protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the parameters to determine effectiveness. Each protocol involving testing on patients, and subsequent protocol amendments, must be submitted to the FDA as part of the IND. The FDA may order the temporary halt or permanent discontinuation of a clinical trial at any time, or to impose other sanctions if they believe that the clinical trial is not being conducted in accordance with the applicable requirements, or if continuing the trial presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) or ethics committee, for approval. The IRB/ethics committee may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB/ethics committee requirements, or they may impose other sanctions.

Concurrent with clinical trials, companies usually complete additional animal studies, and must develop additional information about the chemistry and physical characteristics of the product candidate. They must finalize a process for manufacturing the product in commercial quantities, in accordance with current good manufacturing practice (cGMP) requirements. Moreover, product used in late stage clinical trials must be manufactured under the proposed commercial process, and at the same scale as will be used commercially. The manufacturing process must be capable of consistently producing quality batches of the product candidate. The manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested. Stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

The research and development process, from discovery through a new drug launch, requires substantial time, effort, skill, and financial resources. The research and development of any product candidate has a significant amount of inherent uncertainty. Often, substantial resources must be committed even though success is far from assured. There is no guarantee when, or if, a product candidate will receive the regulatory approval required to launch a new drug or new indication of an existing drug.

In addition to the development of new products and new formulations, research and development projects also may include Phase IV trials, sometimes called post-marketing studies. For such projects, clinical trials are designed and conducted to collect additional data regarding, among other parameters, the benefits and risks of an approved drug. Alternatively, these trials may be conducted to assess the effectiveness of a product candidate in a new patient population.

U.S. FDA Review and Approval Processes

After the completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing, along with a description of the manufacturing process, validation of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information. The NDA requests approval to market the product. Each NDA is subject to a substantial user fee at the time of submission, unless a waiver is granted by the FDA. A holder of an approved NDA may also be subject to annual product and establishment user fees. These fees typically increase annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing, which is based on the agency’s threshold determination that the NDA is sufficiently complete to permit substantive review. Additional information may be requested, rather than accepting an application for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. Review status could be either standard or priority. The review period for standard review applications is typically ten months and, for priority review applications, it is typically six months post acceptance. The review process may be extended by the FDA for three additional months, to consider new information submitted during the review for clarification purposes.

The FDA may also refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, which is typically a panel that includes clinicians and other experts. The advisory committee reviews and evaluates information, and prepares a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. After the FDA evaluates the information provided in the NDA, it issues either an approval letter or a complete response letter. A complete response letter outlines the deficiencies in the submission, and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed, the FDA will re-initiate review. If it is satisfied that the deficiencies have been addressed, the FDA will issue an approval letter.

During the review period, the FDA will typically inspect one or more clinical sites to assure compliance with good clinical practice regulations. The FDA will inspect the facility(ies) at which the drug is manufactured, to ensure compliance with cGMP regulations. The FDA may also undertake an audit of nonclinical and clinical sites. The FDA will not approve the product unless compliance is satisfactory, and unless the application contains the data that provide substantial evidence that the drug is safe and effective in the indication studied.

A marketing approval authorizes commercial marketing of the drug, with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigating strategy (REMS), to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, such restricted distribution methods, patient registries and other risk minimization tools. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug’s safety or efficacy in commercial use, and may impose other conditions, including distribution and labeling restrictions, which can materially affect the potential addressable market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, if problems are identified following initial marketing, or if post-marketing commitments are not met.

The approval process is lengthy and difficult. The FDA may refuse to approve the NDA if the applicable regulatory criteria are not satisfied. Further, data obtained from clinical trials are not always conclusive, or the FDA may interpret data differently than us. In addition, if a product receives regulatory approval, the approval may be significantly limited to specific diseases, dosages, or indications. This could restrict the commercial value of the product. Also, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling as well as requiring Phase IV testing.

New Drug Application

Our activities encompass two types of NDAs: the Section 505(b)(1) NDA (Full NDA) and the Section 505(b)(2) NDA.

A Section 505(b)(1), which is a Full NDA, must contain all pertinent information and full reports of investigations conducted by the applicant to demonstrate the safety and effectiveness of the drug, as well as complete preclinical, clinical and manufacturing information.

Section 505(b)(2) NDAs often provide an alternative path to FDA approval for new or improved formulations, or for new uses of previously approved products. For a Section 505(b)(2) application, the FDA 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 permits the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The Section 505(b)(2) regulatory approval process is designed to allow for potentially expedited, lower cost and lower risk regulatory approval, based on previously established safety, efficacy and manufacturing information on a drug which has been already approved by the FDA for the same or a different indication.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted on previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that either: (1) the required patent information has not been filed; or (2) the listed patent has expired; or (3) the listed patent has not expired, but will expire on a particular date, and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent, or that such patent is invalid or unenforceable, is known as a Paragraph IV certification.

If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product have expired. Further, the FDA also will not approve, as applicable, a Section 505(b)(2) NDA application until any non-patent exclusivity has expired, such as for example: five-year exclusivity period for obtaining approval of an NCE; or three year exclusivity period for an approval based on new clinical trials; or pediatric exclusivity, listed in the Orange Book for the referenced product.

A section 505(b)(2) NDA applicant must send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. If the relevant patent holder elects to initiate litigation, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product, only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

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

We have filed a Section 505(b)(1) NDA for SPN-812 and will need to file a 505(b)(1) NDA for certain products in the future. Of its very nature, the Section 505(b)(1) NDA for SPN-812 carries a higher degree of regulatory approval risk than a Section 505(b)(2) NDA. In addition, a requirement for more extensive testing and development can adversely impact our ability to compete with alternative products that arrive on the market sooner than our product candidate. Further, the time and financial resources required to obtain FDA approval for SPN-812 could substantially and materially increase. After we gain approval for SPN-812 for one indication, additional indications may be submitted using the Section 505(b)(2) regulatory pathway. The FDA may not approve our filing under Section 505(b)(2) for SPN-812 for other indication(s), and therefore would require a full NDA filing. In such case, the time and financial resources required to obtain approval could also significantly increase.

Pediatric Information

Under the Pediatric Research Equity Act of 2007 (PREA), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indication(s) in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data, full waivers, or partial waivers of the data requirements. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which an orphan drug designation has been granted.

Orphan Drug Designation

Orphan drug designation is granted by the FDA to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey an advantage in or shorten the duration of the regulatory review and approval process. However, if an orphan drug later receives approval for the indication for which it has orphan designation, the FDA may not approve any other applications to market the same drug for the same indication. Exceptions to this policy include showing clinical superiority to the product with the orphan drug exclusivity, or if the license holder cannot supply sufficient quantities of the product. Orphan drug exclusivity in the U.S., which is seven years, does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition, provided the sponsor has conducted appropriate clinical trials required for approval. Among the other benefits of orphan drug designation are tax credits for certain research expenses and waiver of the NDA application user fee for the orphan indication.

Priority Review

Under FDA policies, a drug candidate is eligible for priority review, or review within six months from filing, for a new molecular entity (NME). In addition, a six month review period may pertain to a non-NME, if the drug candidate provides a significant improvement as compared to marketed drugs in the treatment, diagnosis, or prevention of a disease. A fast track designated drug candidate would ordinarily meet the FDA’s criteria for priority review. The FDA makes its determination of priority or standard review during the 60-day filing period post the initial NDA submission.

Fast Track Designation

The FDA is required to facilitate the development and expedite the review of drugs, that are intended for the treatment of a serious or life-threatening condition and for which there is currently no effective treatment. These products must demonstrate the potential to address unmet medical needs for the condition. The FDA must determine if the drug candidate qualifies for the fast track designation within 60 days of receipt of the sponsor's request. Once the FDA designates a drug as a fast track candidate, it is required to facilitate the development, and expedite the review of that drug, by providing more frequent communication with, and guidance to, the sponsor. In addition to other benefits such as greater interaction with the FDA, the FDA may initiate a review of the sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information, and if the applicant pays the applicable user fees. However, the FDA's review period for filing and reviewing an application does not begin until the last section of the NDA has been submitted. Additionally, a fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Post-approval Regulatory Requirements

Any drugs for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things: record-keeping requirements; reporting of AE's with the product; providing the FDA with updated safety and efficacy information; product sampling and distribution requirements; complying with certain electronic records and signature requirements; and complying with FDA promotion and advertising requirements.

Drugs may be promoted only for the approved indication and in accordance with the provisions of the approved label. Changes to some of the conditions established in an approved application, including changes in indications, labelling, or manufacturing processes or facilities, may require submission to further review, and approval by the FDA before the change can be implemented.

Adverse event reporting and submission of periodic reports is required following marketing approval. The FDA may also require post-marketing testing, known as Phase IV testing, REMS, and surveillance to monitor the effects of an approved product, or to place conditions on an approval that could restrict the distribution and use of the product.

Pursuant to the FDA's approval of Oxtellar XR, we committed to conducting four pediatric post-marketing studies; however, the FDA granted a waiver for the pediatric study requirements for ages from birth to one month, and a deferral for submission of post-marketing assessments for children one month to six years of age.

Pursuant to the FDA's approval of Trokendi XR, the FDA granted a deferral for submission of post-marketing pediatric studies in the following categories: (1) adjunctive therapy in partial onset seizures (POS) for children one month to less than six years of age; (2) initial monotherapy in POS and PGTC for children two years to less than ten years of age; and (3) adjunctive therapy in PGTC and adjunctive therapy in Lennox-Gastaut Syndrome from two years to less than six years of age.

Since our product approvals, we have created formulations and successfully executed programs that would enable us to meet our deferred pediatric commitments. As a result of this additional information, we have identified a need to renegotiate the commitments made at the time of our NDA approvals for both Oxtellar XR and Trokendi XR. Supernus plans to interface with the FDA on these programs and these commitments.

In addition, quality control as well as the manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and by certain state agencies for compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory agencies may withdraw product approval or request product recalls if a company fails to comply with regulatory standards, or if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, prescription drug manufacturers in the U.S. must comply with applicable provisions of the Drug Supply Chain Security Act, and: provide and receive product tracing information; maintain appropriate licenses; ensure they only work with other properly licensed entities; and have procedures in place to identify and properly handle suspect and illegitimate products.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited PTE under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term restoration of up to five years as compensation for patent term lost during product development and during the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally 50% the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the drug. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The Federal Food, Drug, and Cosmetic Act (FDCA) provides a five-year period of non-patent marketing exclusivity within the U.S., to the first applicant to gain approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active pharmaceutical ingredient (API) or active moiety, which is the molecule or ion responsible for the therapeutic action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a Section 505(b)(2) NDA submitted by another company for another version of such drug, where the applicant does not own or have a legal right of reference to all the data required for approval. As an alternative to submission via 505(b)(2) approval, an applicant may choose to submit a full Section 505(b)(1) NDA, wherein the applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. They may not reference to other clinical trials or data.

The FDCA also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA, or supplement to an existing NDA, if new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support: new indications; dosages; routes of administration; or strengths of an existing drug. Alternatively, these trials may be for a new use, if the 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, sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a Section 505(b)(2) product that did not incorporate the exclusivity-protected changes of the approved drug product. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug, to facilitate the approval of an ANDA or other application for generic substitutes.

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

Other Regulatory Requirements

The U.S. has enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the U.S., the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (as amended), is a sweeping measure intended to improve quality of care, constrain healthcare spending, and expand healthcare coverage within the U.S. This is accomplished primarily through imposition of health insurance mandates on employers, and individuals and expansion of the Medicaid program.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain business and marketing practices in the pharmaceutical industry in recent years. These laws include: anti-kickback; false claims; patient data privacy; and security and transparency statutes and regulations.

The U.S. Foreign Corrupt Practices Act (FCPA), to which we are also subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business, or to influence a person working in an official capacity. Under FCPA, it is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate, in an attempt to obtain or retain business, or to otherwise influence a person working in an official capacity. Historically, pharmaceutical companies have been the target of FCPA and other anti-corruption investigations and penalties.

In addition to regulations in the U.S., we are subject to a variety of foreign regulations governing clinical trials, commercial sales, as well as distribution of our product candidates, to the extent we choose to clinically evaluate or sell products outside of the U.S. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the appropriate regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The requirements, approval process and time frame varies from each jurisdiction. As in the U.S., post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the U.S. We generally market our products outside of the U.S. through licensing arrangements.

Refer to Part 1, Item 1A—*Risk Factors*, for discussion of risks associated with government regulations.

Customers

The majority of our product sales are to pharmaceutical wholesalers and distributors who, in turn, sell our products to pharmacies, hospitals and other customers, including federal and state entities. Each of the three customers, AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation, accounted for more than 30% of our total product revenue in 2019, and collectively accounted for more than 90% of our total product revenue in 2019.

Employees

As of December 31, 2019, we employed 464 full-time employees. We consider relations with our employees to be good. None of our employees is represented by a labor union.

Internet Information

Our website is *www.supernus.com*. Through a link on the Investor Relations portion of our website, you can access our filings with the Securities and Exchange Commission (SEC). Information contained on our website is not a part of this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below, with all of the other information we include in this report, and the additional information in the other reports we file with the Securities and Exchange Commission (the "SEC" or the "Commission"). These risks may result in material harm to our business, our financial condition, and results of our operations. In this eventuality, the market price of our common stock may decline and you could lose part or all of your investment.

Risks Related to Our Industry and Business

We are dependent on the commercial success of Oxtellar XR and Trokendi XR.

Our financial performance, including our ability to replace revenue and income lost to generic and other competition as well as to grow our business, depends heavily on the commercial success of our products. A substantial amount of our resources are focused on maintaining and/or expanding the revenue generated by our approved products in the U.S., Oxtellar XR and Trokendi XR. If any of our major products were to become subject to problems, such as changes in prescription growth rates, unexpected side effects, loss of intellectual property protection, supply chain or product supply shortages, regulatory proceedings, changes in labeling, publicity adversely affecting doctor or patient confidence in our product, material product liability litigation, pressure from new or existing competitive products, or adverse changes in coverage under managed care programs, the adverse impact on our revenue and profit could be significant. In addition, our revenue and profit could be significantly impacted by the timing and rate of commercial acceptance of key new products.

Our ability to generate significant product revenue from sales of Oxtellar XR and Trokendi XR in the near term will depend on, among other things, our ability to:

- Defend our patents, intellectual property and products from competition, both branded and generic;
- Maintain commercial manufacturing arrangements with third-party manufacturers;
- Produce, through a validated process, sufficiently large quantities of our products to meet demand;
- Continue to maintain a wide variety of internal sales, distribution and marketing capabilities, sufficient to sustain and grow revenue;

- Continue to maintain and grow widespread acceptance of our products from physicians, health care payors, patients, pharmacists and the medical community;
- Properly price and obtain adequate reimbursement coverage of these products 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;
- Obtain approval from the FDA to expand the labeling of our approved products, for additional indications;
- Adequately protect against and effectively respond to any claims by holders of patents and other IP rights alleging that our products infringe their rights; and
- Adequately protect against and effectively respond to any unanticipated adverse effects or unfavorable publicity that develops with respect to our products, as well as respond to the emergence of new or existing competitive products, which may be proven to be more clinically effective and cost-effective.

There are no guarantees that we will be successful in completing these tasks. We will need to continue investing substantial financial and management resources to maintain our commercial sales and marketing infrastructure and to recruit and train qualified marketing, sales and other personnel.

Sales of Oxtellar XR or Trokendi XR may slow for a variety of reasons, including competing products or safety issues. Any increase in sales of Oxtellar XR and Trokendi XR will be dependent on several factors, including our ability to educate physicians, to increase physician awareness and physician acceptance of the benefits and cost-effectiveness of our products relative to competing products.

Our ability to increase market acceptance of any of our products or to gain market acceptance of 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;
- Prevalence, nature, and severity of any adverse side effects;
- Availability of alternative treatments, including branded and generic products; and
- Pricing and cost effectiveness.

Further, Oxtellar XR and Trokendi XR are subject to continual review by the FDA. We cannot provide assurance that newly discovered or reported safety issues will not arise. With the use of any marketed drug by a wider patient population, serious AEs may occur from time to time that initially do not appear to be related to the drug itself. Any safety issues could cause us to suspend or to 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.

In addition, we have expressed certain long term revenue expectations. If we are not successful in broadening and/or maintaining the current commercial acceptance of either Oxtellar XR or Trokendi XR, such that we cannot achieve those revenue expectations with respect to Oxtellar XR and Trokendi XR, this could result in a material adverse impact on our anticipated revenue, earnings and liquidity.

If other versions of extended or controlled release oxcarbazepine or topiramate are approved and successfully commercialized, our business could be materially harmed.

Third parties have and in the future may receive approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate in the U.S. For example, Upsher-Smith launched Qudexy XR (extended release topiramate) and a branded generic version of Qudexy XR in in 2014. Upsher Smith also entered into settlement with a generic company to launch a generic to Qudexy XR in 2020, and a separate settlement with another generic company to enter the market at a date that is unknown to us. Entry of new generic products could adversely impact the sales or prescriptions for Trokendi XR, or could result in an earlier than anticipated entry of generics to compete with Trokendi XR. We have the right to defend our products against third parties who may infringe or are infringing our patents.

In addition, we are aware of companies who are marketing modified-release oxcarbazepine products outside of the U.S., such as Apydan, which was developed by Desitin Arzneimittel GmbH and which requires twice-daily administration. If companies with modified-release oxcarbazepine products outside of the U.S. pursue or obtain approval of their products within the U.S., such competing products may limit the potential success of Oxtellar XR in the U.S. Our business and growth prospects could be materially impaired.

Accordingly, if any third party is successful in obtaining approval to manufacture and market its own version of extended release oxcarbazepine or topiramate in the U.S., we may not be able to prospectively realize revenues from Oxtellar XR or Trokendi XR.

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 business is operating in an ever more challenging environment, with significant pressures by federal and state governments, insurers and other payors on the pricing of our products, affecting on our ability to obtain and maintain satisfactory rates of reimbursement for our products. The U.S. federal and state governments and payors are under intense pressure to control healthcare spending even more tightly than in the past. These pressures are further compounded by consolidation among distributors, retailers, private insurers, managed care organizations and other private payors, resulting in an increase their negotiating power, particularly with respect to our products. In addition, these pressures are augmented by significant controversies and intense publicity about pricing for pharmaceuticals, which are viewed by some as excessive, as well as government investigations and legal proceedings regarding pharmaceutical pricing practices.

Our ability or our collaborators' ability to successfully commercialize our products, including Oxtellar XR, Trokendi XR, and our product candidates, including SPN-812, 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 be approved for marketing by the FDA. Third-party payors are increasingly challenging the effectiveness of and prices charged for medical products and services. Government authorities and third-party payors have attempted to control costs, in some instances, by limiting coverage, by limiting the amount of reimbursement for particular medications, or by encouraging the use of lower-cost generic products. 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. Moreover, that level of reimbursement may change over time, as a result of decisions made by payors. Reduced or partial payment, or reduced 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 significant discount, which would adversely affect our ability to realize an appropriate return on our investment in our products or product candidates or to maintain profitability.

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 to what extent they will provide reimbursement. Moreover, they will consider the efficacy and cost effectiveness of comparable or competitive products, including generic products, in making reimbursement decisions for our products. Because each third-party payor individually approves payment or reimbursement, obtaining these approvals can be a time consuming and expensive process, requiring 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 months or years before a particular private insurer or managed care organization reviews a particular product. We may ultimately be unsuccessful in obtaining coverage. In addition, our competitors may have more extensive existing business relationships with third-party payors that could have an impact on the coverage for our 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.

In some foreign jurisdictions, particularly Canada and Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take 6 to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or to obtain 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, if approved, 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, and could be unprofitable.

In addition, many managed care organizations negotiate the reimbursement price of products through the use of formularies, which establish reimbursement levels. Exclusion of a product from a formulary can lead to 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 managed care formularies or reimbursed at adequate levels, or if those policies increasingly favor generic products, our market share and gross margins could be negatively affected. This would have a material adverse effect on our overall business and financial condition.

We expect these challenges to continue and potentially to intensify in 2020 and following years, as political pressures mount, and healthcare payors, including government-controlled health authorities, insurance companies and managed care organizations, step up initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generic products and to impose overall price cuts. Such pressures could have a material adverse impact on our business, financial condition, or results of operations, as well as on our reputation.

We depend on wholesalers and distributors for retail distribution of Oxtellar XR and Trokendi XR. If we lose any of our significant wholesalers or distributors, our business could be harmed.

The majority of our sales of Oxtellar XR and Trokendi XR are made to wholesalers and distributors who, in turn, sell our products to pharmacies, hospitals and other customers. For the year ended December 31, 2019, three wholesale pharmaceutical distributors, AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation, each individually accounted for more than 30% of our total revenue in 2019, and collectively accounted for more than 90% of our total revenue in 2019. The loss of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases, could have a material adverse effect on our business, results of operations, financial condition, and prospects.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased. This may result in increased competitive and pricing pressures on pharmaceutical products. We cannot assure you that we can manage these pricing pressures, or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our sales of Oxtellar XR and Trokendi XR can be greatly affected by the inventory levels our respective wholesalers and distributors carry. We monitor wholesaler and distributor inventory of Oxtellar XR and Trokendi XR using a combination of methods. Pursuant to distribution service agreements with our three largest wholesale customers, we receive product inventory reports. For other wholesalers where we do not receive inventory reports, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive production, resulting in our holding substantial quantities of unsold inventory, or alternatively inadequate supplies of product in distribution channels, resulting in inability to support sales at the retail level. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations, the expectations of securities analysts and/or investors.

At times, wholesalers and distributors may increase inventory levels in response to anticipated price increases, resulting in greater wholesaler purchases prior to the anticipated price increase, and reduced wholesaler purchases in later quarters. This may cause substantial fluctuations in our results of operations from period to period. If our financial results are below expectations for a particular period, the market price of our common stock may drop significantly.

We may not be able to effectively market and sell our product candidates, if approved, in the U.S.

We plan on building our sales and marketing capabilities in the U.S. to commercialize our product candidates, if approved. We will build such capabilities by investing significant amounts of financial and management resources. Furthermore, the cost of establishing and maintaining marketing and sales capabilities may not be economically justifiable, in light of the revenues generated by any of our product candidates.

If we are unable to establish and maintain adequate sales and marketing capabilities for our product candidates; if we are unable to do so in a timely manner, we may not be able to generate sufficient product revenues from our product candidates to be profitable.

Final marketing approval of any of our product candidates, or approval of additional indications for existing products by the FDA or by 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 obtaining regulatory approval of our product candidates and approval for additional indications for existing products. Our business depends on the successful clinical development; i.e., successful completion of clinical trials and commercialization of our product candidates. We are not permitted to market any of our product candidates in the U.S. until we receive approval of an NDA from the FDA, or in any foreign jurisdiction, from the requisite authority. 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. We cannot, therefore, predict the timing of any future revenues from these product candidates.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate or deny a prior approval supplement [(1)] for many reasons. For example, the FDA:

- Could reject or delay the marketing application for an NCE;
- Could determine that we cannot rely on Section 505(b)(2) for any approval 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 a specific 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 U.S., including any findings that the clinical and other benefits of our product candidates do not 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; the outcome and measurement scale used in the trials; or the clinical protocols whether with or without a special protocol assessment process;
- May determine that we have identified the wrong reference listed drug or drugs, or that approval of our Section 505(b)(2) application of our product candidate 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 raw materials, including the API or formulated product used in our product candidates, wherein those deficiencies may result in interruption in the ability to supply product;
- 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;
- May not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates, or may approve them with warnings and precautions that could limit the acceptance of our product candidates and their commercial success; or
- May not approve the addition of new indications to the label of our existing products.

[(1)] Changes that have a substantial potential to have an adverse effect on product quality, identify strength, purity or potency (i.e., major change) require submission of a "prior approval supplement" and approval by FDA prior to distribution of the drug product made using the change.

Notwithstanding the approval of many products by the FDA pursuant to Sections 505(b)(1) and 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 eliminate our ability to generate revenues for that candidate. Any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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, or be required to withdraw our products from the market.

We do not currently own or operate manufacturing facilities for the production of any of our products or for the commercial production of our product candidates, nor do we have plans to develop our own manufacturing operations at commercial scale in the foreseeable future. We currently depend on third-party CMOs in various countries for the supply of API for our products and product candidates, including drug substance for our preclinical research and clinical trials. For Oxtellar XR and Trokendi XR, we currently rely on single source suppliers for raw materials, including API, as well as single source suppliers to produce and package final dosage forms. With respect to product candidates, we currently rely on Bachem Americas, Inc. and Bachem AG (collectively Bachem), a company based in Switzerland, as the sole supplier and manufacturer for viloxazine hydrochloride raw material, the API in SPN-812.

There is a risk that supplies of our products or product candidates may be significantly delayed by or may become unavailable as a result of manufacturing, equipment, process, or business-related issues affecting our suppliers. Any future curtailment in the availability of raw materials could result in production or other delays, with consequent adverse business effects. 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. Accordingly, as it relates to SPN-812, for example, we may encounter additional manufacturing and supply-chain risks due to the regulatory and political structure of Switzerland, or as a result of the international relationship between Switzerland and the U.S.

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 can adversely affect production costs and yields, quality control, stability of the product and quality assurance testing, as well as compliance with federal, state and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain or maintain FDA approval and to market our products and product candidates, respectively, would be jeopardized. In addition, any delay or interruption in producing clinical trial supplies could delay or prohibit the completion of our clinical trials, increase the costs associated with conducting our 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 and other requirements as enforced by the FDA, including electronic tracking and submission. These requirements include 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 similar foreign regulatory requirements. 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 to successfully commercialize such products. We may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical development, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs, or result in our being unable to effectively commercialize our product candidates. Furthermore, if we fail to obtain the required commercial quantities on a timely basis from our suppliers and at commercially reasonable prices, we may be unable to meet demand for our approved products, or may not be able to sell our products profitably.

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 sNDAs, including Section 505(b)(2) applications, for, among other things, new indications, dosage forms, routes of administration, strengths, or for a new use of an existing drug. If the clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application, the FDA may grant exclusivity for the product, sometimes referred to as clinical investigation exclusivity. This prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use for new clinical investigations prior to 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 full NDA, and has conducted its own adequate, well-controlled clinical trials, demonstrating safety and efficacy. It would not 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. This would be the case if the FDA had not previously approved any other drug containing the same 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 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, it did not grant a similar marketing exclusivity period for Trokendi XR.

In November 2019, we submitted the NDA for SPN-812 to the FDA. We expect SPN-812, if approved, to have a five year market exclusivity, given its NCE status in the U.S. If we are unable to obtain marketing exclusivity for our subsequent product candidates, then our competitors may obtain approval for competing products more easily than if we had such marketing exclusivity. In such an event, our future revenues could be reduced, possibly materially.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the sales of those products or 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 be cited by potential competitors in support of approval of an ANDA. 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 or product candidate and that the generic product is bioequivalent to our product. Bioequivalence implies that a product is absorbed in the body at the same rate and to the same extent as our product or 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. Companies that produce generic equivalents are generally able to offer their products at significantly lower prices. Thus, regardless of the regulatory approval pathway, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product, through both price and volume erosion. Accordingly, competition from generic equivalents would adversely, materially, and permanently impact our revenues, profitability and cash flows from those products. In this eventuality, it would substantially limit our ability to obtain a return on the investments we have made in our products and product candidates.

If our competitors develop or market alternatives for treatment of our target indications, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense product-driven 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. These include large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. The availability of new products or the approval of new indications for existing products may limit the demand for and the price we are able to charge for any of our products. We may be unable to differentiate our products from competitive offerings.

In addition to competition for our currently marketed products, we anticipate that we will face intense competition when our pipeline product candidates are approved by regulatory authorities, and we begin their commercialization process. In particular, we are aware of several companies that have various product candidates under development to treat ADHD. These may compete with our SPN-812 product candidate. These companies include Sunovion, Ironshore/Highland and Otsuka.

New developments, including the development of other drug technologies, may render our products or product candidates obsolete or noncompetitive. As a result, our products and product candidates may become obsolete before we recover expenses incurred in connection with their development, or we realize revenues from their commercialization. Moreover, 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, including personnel and technology;
- 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, have faster onset to action, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted, or less costly than ours. They 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 approved product candidates, our business, results of operations, financial condition and prospects may be materially and adversely affected. Mergers and acquisitions in the pharmaceutical industry may result in even higher level of resources being concentrated at competitors. Competition may intensify as a result of advances made in the commercial applicability of technologies, and as a result of greater availability of capital for investment.

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

Even though U.S. regulatory approval has been obtained for Trokendi XR and Oxtellar XR, the FDA may impose significant restrictions on their indicated uses, or may impose restrictions on marketing, or may impose requirements for costly post-approval studies. For example, both Trokendi XR and Oxtellar XR were approved on the basis of post-approval commitments, including the development of additional age-appropriate formulations of the drugs, and the conduct of post-approval clinical studies in accordance with timelines laid out in the approval letters. The post-approval commitments required the creation of new drug product formulations, which we have not been able to accomplish. Despite significant efforts, in certain cases we have been unable to meet the FDA's timelines. Refer to Part I, Item 1—*Post-approval Regulatory Requirement*s for more information. To date, the only consequence of our failure to meet our PREA commitment deadlines has been a notation on FDA websites, making the status of PREA publicly known.

We are also required to conduct an additional post-approval study with respect to Trokendi XR for the treatment of prophylaxis of migraine. If we do not meet our post-marketing commitments, and are unable to show good cause for our inability to adhere to the timetables laid out in the approval letters, the FDA could take enforcement action against us, including withdrawal of approval. While we believe that we can show good cause for our inability to meet the timelines for our post-approval study requirements, the FDA may disagree. Refer to Part I, Item 1—*Post-approval Regulatory Requirement*s for more information.

Our products, product candidates 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 information. In addition, manufacturers of drug products and their facilities are subject to continual review and to periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice (cGMP) regulations. If we, our collaborators, or a regulatory authority discovers previously unknown problems with a product, including side effects that are unanticipated in severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product or on the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing.

If we or our collaborators, or our products, product candidates, or our collaborators' products, or the manufacturing facilities for our products, product candidates or our collaborators' products 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 suspend production for a sustained period of time; or
- Seize or detain products or require us to initiate a product recall.

In addition, our product labeling, advertising, and promotion of our approved products 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. Notwithstanding, physicians may nevertheless prescribe products to their patients in a manner that is inconsistent with the approved label, which is known as "off label use". 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 promoted off-label use 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 companies from engaging in off-label promotion. If we are found to have promoted off-label use, we may be enjoined from such off-label promotion and become subject to significant liability. This could have an adverse effect on our reputation, business and revenues.

Further, the FDA's policies may prospectively change. Additional government regulations may be enacted that could affect our products or prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements, or to adopt new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we have obtained, adversely affecting our business, prospects and ability to achieve or sustain profitability.

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 to use one of our proprietary technologies in an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension, and other indications. United Therapeutics Corporation launched Orenitram (treprostinil) in 2014, which triggered payment of a milestone payment to us of $2.0 million. In the third quarter of 2014, we received a cash payment of $30.0 million from HealthCare Royalty Partners III, L.P.'s (HC Royalty), for the purchase of certain of our rights under our license agreement with United Therapeutics Corporation related to the commercialization of Orenitram. Ownership of the royalty rights will return to us if/when a certain cumulative threshold payment to HC Royalty is reached. We are entitled to receive milestones and royalties for use of this formulation in indications other than arterial hypertension. If we materially breach any of our obligations under the license agreement, we could lose the right to receive any future royalty payments thereunder, which could be financially significant to us.

We intend to rely on third-party collaborators to market and commercialize our products and product candidates outside the U.S. We utilize strategic partners outside the U.S., where appropriate, to assist in the commercialization of our products and product candidates. We currently possess limited resources, and may not be successful in establishing collaborations or licensing arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and licensing partners. By entering into strategic collaborations or similar arrangements, we rely on third parties to financially support their local operations, including support required for development, commercialization, sales, marketing and regulatory activities, as well as expertise in each of those subject areas.

Our future collaboration agreements may limit 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 certain development milestones, and royalties payable on product sales. The milestones 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, 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. The ability of some of our product candidates to reach their potential could be limited if our future collaborators fail to apply sufficient development or commercialization efforts related to those product candidates;

- Decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources, or in the belief that other internal drug development programs may have a higher likelihood of obtaining marketing approval, or may potentially generate a greater return on investment;
- 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 collaboration with us;
- Not have necessary and sufficient resources to develop the product candidate through clinical development, marketing approval and commercialization;
- Fail to comply with applicable regulatory requirements;
- Are unable to obtain the necessary marketing approvals; or
- Breach or terminate their arrangement with us.

If collaboration partners fail to develop or fail to effectively commercialize our products for any of these reasons, we may not be able to replace the collaboration partner with another partner to develop and commercialize the product under the terms of the collaboration, if at all. 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, impaired, or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on our own. Failure of our third-party collaborators to successfully market and commercialize our products or product candidates within and outside the U.S. could materially diminish our revenues and harm our results of operations.

Even if our product candidates receive regulatory approval in the U.S., we or our collaborators may not receive approval to commercialize our product candidates outside of the U.S.

To market any product outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other regulatory 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 U.S. 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 U.S., as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FDCA in the U.S., 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 are not freely available, we may not have the ability to commercialize our products without first negotiating with third parties to obtain their permission to refer to their clinical data in our regulatory applications. This process could require the expenditure of significant additional funds and time.

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

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

We are a party to and rely on several arrangements with third parties. These arrangements give us rights to IP that are necessary for the development of certain of our product candidates. In addition, we may enter into similar arrangements in the future for other product candidates. Our current arrangements impose various development, financial and other obligations on us. If we materially breach these obligations, or if third parties fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which could result in our inability to develop, manufacture, market and sell products that are covered by such IP.

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

As part of our growth strategy, we intend to develop and market additional product candidates. We may spend substantial resources and several years completing the development of a particular current or future internal product candidate, during which process we can experience failure at any stage, and for many reasons. The product candidates to which we allocate our resources, even if approved, may not be commercially 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 technologies to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and approved products, and to manage our spending as expenses related to undertaking clinical trials can be substantial.

We may be unable to acquire product candidates or products.

The process of proposing, negotiating and implementing a license, or acquiring a product candidate or an 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, the product candidate, or approved product. We have limited resources, including financial resources, to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies, and to integrate them into our current infrastructure. Moreover, we may devote significant resources to potential acquisitions or to in-licensing opportunities wherein those transactions are never consummated, 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;
- Incur substantial debt, or dilutive issuances of securities, or depletion of cash to pay for acquisitions;
- Incur higher than expected acquisition, integration, and operating costs;
- Experience difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- Impair relationships with key suppliers or customers of any acquired businesses, due to changes in management and ownership; and
- Unable to retain and/or motivate key employees of any acquired businesses.

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

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

- Non-compliance by third parties with regulatory and quality control standards;
- Sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third party supplier or manufacturer fail to comply with applicable regulatory standards;
- Possible breach of the agreements by the CROs or CMOs because of factors beyond our control, insolvency or other financial difficulties of any of these third parties; labor unrest; natural disasters; or other factors adversely affecting their ability to conduct their business; and
- Termination or non-renewal of an agreement by a third party, at a time that is inconvenient for us, and for reasons not entirely under our control.

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 in the foreseeable future to develop our own manufacturing operations to support Phase III clinical trials or support commercial production. We currently depend on third-party CMOs for all of our required raw materials and drug substances for our preclinical research and clinical trials. For Oxtellar XR and Trokendi XR, we currently rely on single source suppliers for raw materials, including API, and rely on third-party manufacturers for the production and packaging of final commercial products. If any of these vendors are unable to perform their obligations to us, including due to violations of the FDA's requirements, our ability to meet regulatory requirements, projected timelines, and necessary quality standards for the development or commercialization of products would be adversely affected. Further, if we were required to change vendors, it could result in substantial delays in our regulatory approval efforts, significantly increase our costs, and delay generation of revenues. 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 business prospects.

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

We may be unable to sufficiently demonstrate the safety and efficacy of our product candidates in obtaining regulatory approval. We must demonstrate, with substantial evidence gathered in well-controlled studies and to the satisfaction of the relevant regulatory authorities, that each product candidate is safe and effective for use in the target indication. We may be required to conduct additional studies or trials to adequately demonstrate safety and efficacy, which could prevent or significantly delay our receipt of regulatory approval, increase clinical costs, and ultimately delay or otherwise impair the commercialization of that product candidate.

Any product candidate that we in-license or acquire may require additional development prior to commercial sale, including formulation development, extensive clinical testing, and approval by the FDA or applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical to 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.

In addition, the results from the trials that we have completed for our product candidates may not be replicated in future trials. 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, these clinical development programs might be terminated.

Delays or failures in the completion of clinical development of our product candidates would increase our costs, 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 in obtaining regulatory approval to commence a clinical trial, or in complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- Difficulties obtaining Investigational Research Board (IRB) or ethics committee approval to conduct a trial at a prospective site;
- Delays in reaching or failure to reach agreement on acceptable terms with prospective trial sites and investigators, the contractual terms of which can be subject to extensive negotiation and may vary significantly from site to site;
- Insufficient or inadequate supply of or quantity of a product candidate for use in trials;
- Challenges recruiting and enrolling patients to participate in clinical trials, for any and all 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 enrolled in a clinical trial, but who may be prone to withdraw due to side effects from the therapy, lack of efficacy, or personal issues;
- Temporary cessation of clinical trials (clinical holds); or
- Delays due to ambiguous or negative interim results in clinical trials.

Clinical trials may be suspended or terminated by us; or at a trial site by the site's Data Safety Monitoring Board (DSMB) or ethics committee overseeing the clinical trial; or by the FDA; or by 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 which ultimately result in the imposition of a delay or clinical hold;
- Unforeseen safety issues; or
- Lack of adequate funding to continue the trial.

Failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols may result in the inability to use the trial data to support product approval. 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 IRBs or ethics committees for reexamination, which may adversely impact the cost, timing and/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, or if we terminate any of our clinical trials, our ability to obtain regulatory approval of our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues diminished.

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

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt development. This could result in the denial of regulatory approval by the FDA or other regulatory authorities, and result in potential product liability claims. Undesirable side effects caused by any of our products could cause regulatory authorities to temporarily or permanently halt product sales, which could have a material adverse effect on our business.

Immediate release oxcarbazepine and topiramate products, which use the same APIs (Active Product Ingredient) as Oxtellar XR and Trokendi XR, are known to cause various side effects, including but not limited to dizziness, paresthesia, headaches, cognitive deficiencies such as memory loss and speech impediment, digestive problems, somnolence, double vision, gingival enlargement, nausea, weight gain, oral malformation birth defects, visual field defects, infants small for gestational age, 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.

Products that were or are currently on the market and use the same API as our product candidates, including SPN-812, SPN-810 (drug products), SPN-817 (dietary supplements), and SPN-604, were known to cause various side effects, including but not limited to drowsiness, depression, hyperactivity, euphoria, extrapyramidal reactions, nausea, headache, diarrhea, vomiting, sleep difficulties, agitation, exacerbation of anxiety, sleepiness, mouth dryness, tachycardia, constipation and urinary difficulties. The labels for those products also included precautions and warnings about; among other things; tardive dyskinesia; neuroleptic malignant syndrome; elevation of prolactin levels; convulsive events in patients that are treated for or have a prior history of epilepsy; inhibition of hepatic metabolism of certain drugs; risk of suicide before antidepressant clinical improvement; need for monitoring patients with cardiac, hepatic or renal insufficiency; or patients at risk for angle-closure glaucoma. The use of SPN-812, SPN-810, SPN-817 and SPN-604 may cause similar side effects as compared to these reference products, or may cause additional or different side effects.

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

- Regulatory authorities may withdraw approval 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 proper use of the medication and the risks of side effects, for distribution to patients;
- We may be required to modify the product in some way;
- Regulatory authorities 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 be held liable for harm caused to patients; or
- 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.

We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.

Regulatory authorities in the United States may designate drugs for relatively small patient populations as orphan drugs. The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals annually in the U.S. Orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research, and user fee waivers under certain circumstances. In addition, if a drug receives its first FDA approval in an indication for which it has orphan drug designation, that drug is entitled to seven years of market exclusivity. This implies that the FDA may not approve any other firm's application for the same drug for that same indication for a period of seven years. Exceptions are limited, such as showing clinical superiority over the drug with orphan drug exclusivity.

Although we have been granted FDA orphan drug designation for SPN-817 for the treatment of Dravet Syndrome, and we intend to expand our designation for alternative uses where applicable, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or it may result from a competing product reaching the market with an orphan designation for the same disease indication. Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the U.S. for seven years. Even if we obtain exclusivity, the FDA could subsequently approve an alternative drug for the same condition, if the FDA concludes that the second to reach the market is clinically superior in that it is safer, more effective or makes a major contribution to patient care. In addition, a competitor may receive approval of different products for the same indication for which our orphan product has exclusivity, or may obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In August 2017, the FDA Reauthorization Act of 2017 (FDARA) was enacted. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period, regardless of showing clinical superiority.

The FDA may further reevaluate the Orphan Drug Act, including the FDARA amendment, its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future. It is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Healthcare reform measures could hinder or prevent the commercial success of our products or product candidates.

The U.S., certain states, and certain foreign governments have shown significant, increased interest in pursuing healthcare reform and changes to the healthcare delivery system. Government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally, adversely impacting the level of reimbursement available from governmental agencies and/or commercial third-party payors. The continuing efforts of third-party payors, including U.S. federal and state agencies, foreign governments, insurance companies, managed care organizations, employers, and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices at launch or to increase prices once launched. These initiatives could adversely impact our ability to generate revenues, to achieve profitability, or to and maintain profitability. There have been a number of legislative and regulatory proposals and initiatives to change the healthcare system in ways that could adversely affect our ability to profitably sell any approved product. Some of these proposed reforms would result in reduced reimbursement rates for our products, which would adversely affect our business strategy, operations and financial results.

In March 2010, then President Obama signed into law a comprehensive change to the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010. These laws and their regulations, which we refer to collectively as the HealthCare Reform Law, have far reaching consequences for pharmaceutical companies like us. Possible revisions to the HealthCare Reform Law are the subject of ongoing legislative debates and litigation.

The HealthCare Reform Law has continued to exert downward pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and has increased the industry's regulatory burden and operating costs. Among the provisions of the HealthCare Reform Law of importance to our products and product candidates are the following:

- An annual, nondeductible fee payable to the U.S. federal government, by any entity that manufactures or imports specified branded prescription drugs or biologic agents. This fee is based on each company's market share of prior year total sales of branded products to certain federal healthcare programs;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- Rebates owed by manufacturers under the Medicaid Drug Rebate Program for drugs that are inhaled, infused, instilled, implanted or injected;
- A Medicare Part D coverage gap discount program, in which manufacturers must agree to offer a substantial point-of-sale discount off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- Extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- Expansion of the eligibility criteria for Medicaid programs in certain states;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- A requirement to annually report the amount of drug samples that manufacturers and distributors provide to physicians; and
- A Patient-Centered Outcomes Research Institute to oversee, identify priorities for, and to conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been adopted since the Affordable Care Act was enacted. These changes include aggregate reductions in Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013. Due to subsequent legislative amendments to the statute, it will remain in effect through 2025 unless additional Congressional action is taken.

The FDA statutes, regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. It is impossible to predict whether additional legislative changes will be enacted or whether FDA regulations, guidance or interpretations will be changed, and what the impact of such changes, if any, may be. Future regulatory changes could make it more difficult for us to maintain or attain approval to develop and commercialize our products and technologies.

The FDA has enhanced its post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, or to require compliance with risk evaluation and mitigation strategies. Further, the 2012 Food and Drug Administration Safety and Innovation Act expanded drug supply chain reporting requirements and strengthened the FDA's response to drug shortages. The FDA's exercise of its authority could result in delays, or could increase costs during product development, and regulatory review. It could also result in increased costs to assure compliance with post-approval regulatory requirements, and could result in potential restrictions on the sale and/or distribution of any approved product.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. The Trump Administration and U.S. Congress have attempted, and will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders as well as other directives designed to delay, circumvent or loosen the implementation of certain provisions mandated by the Affordable Care Act that would otherwise impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals. Concurrently, Congress has considered legislation that would repeal or replace all or part of the Affordable Care Act. While Congress has not passed repeal legislation, on December 22, 2017, President Trump signed the Tax Cuts and Jobs Act (Tax Act), which included a provision that repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year. This is commonly referred to as the "individual mandate." Additionally, in January 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including: the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans; the annual fee imposed on certain health insurance providers based on market share; and the medical device excise tax on non-exempt medical devices. In addition, in December 2018, a Texas Federal District Court struck down the entire Affordable Care Act as unconstitutional, holding that following the elimination of the tax penalty under the Affordable Care Act, the remaining individual mandate portion of the Affordable Care Act could not be justified as a proper and legitimate use of Congress' taxing power. Because the Court deemed the individual mandate as inseverable from the rest of the Affordable Care Act, the entire Affordable

Care Act was rendered unconstitutional. This case will be appealed to the Fifth Circuit Court of Appeals and could ultimately end up before the U.S. Supreme Court.

Congress may consider other legislation to repeal or replace elements of the Affordable Care Act. It is difficult to predict the extent to which any of these changes to the Affordable Care Act, or additional changes, if made, may impact our business or any financial condition.

The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three years to five years. In 2019, the Trump Administration put forth a proposal to eliminate certain rebates pharmaceutical companies pay insurance companies under Medicare. The proposal would allow pharmaceutical companies and pharmacy benefit managers to negotiate rebates as long as the savings are passed directly to consumers at the pharmacy. More recently, there have been several Congressional inquiries and proposed bills designed to, among other things, bring: more transparency to drug pricing; reduce the cost of prescription drugs under Medicare; review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs.

Several of the Democratic presidential candidates running in the 2020 election are proposing a single-payer national health insurance system, often dubbed "Medicare for All". "Medicare for All" would likely establish a single public or quasi-public agency that organizes healthcare financing, but healthcare delivery would remain private. While expanding Medicare would increase the demand for prescription drugs, there is a likelihood that Medicare will be required to negotiate drug prices with manufactures, which could adversely affect our future prospects.

Certain U.S. states have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, and restrictions on access to certain products. Marketing cost disclosure and transparency measures have been designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products, and which suppliers, will be included in their prescription drug formularies. Legally mandated price controls on payment amounts by third-party payors, or other similar restrictions, could harm our business, results of operations, financial condition and prospects. Alternatively, these could prevent us from being able to commercialize our products, or to generate an acceptable return on our investment.

The availability of generic products may also substantially increase pricing pressures on, and reduce reimbursement for our future products. We expect to experience continued pricing pressures in connection with the sale of any of our products, due to the increasing influence of health maintenance organizations, their increasing leverage in pricing negotiations, and additional legislative changes.

The Drug Quality and Security Act (DQSA) became law in 2013. DQSA creates the requirement for companies to trace, verify and identify all products through the entire supply chain, from manufacturer to dispenser.

In 2016, the 21st Century Cures Act (Cures Act) was signed into law. The Cures Act was designed to modernize and personalize healthcare, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. It authorized increased funding for the FDA to spend on innovation projects. The law also amended the Public Health Service Act (PHSA) to reauthorize and expand funding for the National Institutes of Health (NIH). The Cures Act established the NIH Innovation Fund, to pay for the cost of development and implementation of a strategic plan, early stage investigations and research. It also charged the NIH with leading and coordinating expanded pediatric research. Further, the Cures Act directed the Centers for Disease Control and Prevention to expand surveillance of neurological diseases.

In August 2017, President Trump signed FDARA into law. FDARA reauthorized the various user fees to facilitate the FDA's review and oversight relating to prescription drugs, generic drugs, medical devices and biosimilars. The legislation also included several policy riders that will impact an array of issues within the FDA's authority, including, among others, pediatric study requirements, orphan drug exclusivity, and the approval process for generic drugs. With amendments to the FDCA and the PHSA, Title III of the Cures Act sought to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act reauthorized the existing priority review voucher program through 2020, for certain drugs intended to treat rare pediatric diseases; created a new priority review voucher program for drug applications, which are determined to be material national security threat medical countermeasure applications; revised the FDCA to streamline review of combination product applications; required the FDA to evaluate the potential use of "real world evidence" to help support approval of new indications for approved drugs; provided a new "limited population" approval pathway for antibiotic and antifungal drugs intended to treat serious or life-threatening infections; and authorized the FDA to designate a drug as a "regenerative advanced therapy," thereby making it eligible for certain expedited review and approval designations.

On September 19, 2019, the U.S. House Speaker Nancy Pelosi unveiled a plan to lower the cost of prescription drugs by allowing the federal government to negotiate prices annually for the most expensive drugs on the market. On December 6, 2019, House Republican leaders released a bipartisan alternative to Speaker Pelosi's plan. On December 12, 2019, the House passed H.R.3. known as the Lower Drug Costs Now Act and sent it to the Senate for consideration. Any prescription drug pricing legislation that is ultimately adopted may affect the success of our products, product candidates, and profitability.

Future healthcare reforms in the U.S. and in other countries could limit the prices that can be charged for our products and product candidates, or may otherwise limit our commercial opportunities.

Implementation of any change in healthcare laws could cause us to incur significant compliance expenses or could subject us to substantial penalties and fines if our business is found to violate these requirements.

The assessment of the financial impact of the HealthCare Reform Law on our business is on-going. There can be no assurance that our business will not be materially harmed by future implementation of or changes to the HealthCare Reform Law. If we are not in full compliance with the HealthCare Reform Law, we could face enforcement action, fines and other penalties. We could receive adverse publicity.

The HealthCare Reform Law includes various provisions designed to strengthen fraud and abuse enforcement. These include increasing funding for enforcement efforts, and lowering the intent requirement of the federal anti-kickback statute and criminal healthcare fraud statute, such that a person or entity no longer needs to have actual knowledge or specific intent to violate the statute.

If our past or present operations are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to penalties, both civil and criminal, damages, fines, exclusion from federal healthcare programs and/or the curtailment or restructuring of our operations.

The risk of our being found in violation of the HealthCare Reform Law, its underlying regulations, or other laws impacted by its implementation is made more complex by the fact that many have not been fully interpreted by the regulatory authorities or the courts. Their provisions are subject to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against these assertions, could cause us to incur significant legal expenses, and divert our management's attention from the operation of our business.

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

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

- Federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully 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. A person or entity does not need to have actual knowledge or specific intent to violate the statute in order to have committed a violation. Further, the government may assert that a claim, including items and services resulting from a violation of the federal Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below. On October 19, 2019, additional Anti-Kickback regulations were proposed which, if adopted, would create new and change existing safe harbors. Safe harbors protect certain arrangements from prosecution, if each of the elements of the safe harbor is satisfied;
- Federal civil and criminal false claims laws and civil monetary penalty 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; knowingly making a false statement material to an obligation to pay or transmit money to the federal government; or knowingly concealing or improperly avoiding or decreasing an obligation to pay money to the federal government. This may apply to entities like us, which provide coding and billing advice to customers;
- Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibits executing a scheme to defraud any healthcare benefit program, or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge or specific intent to violate the statute in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- Federal physician payment transparency requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments, and to report other transfers of value, physician ownership and investment interests;
- Federal price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our commercial products;
- 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 state anti-kickback laws, physician payment and drug pricing transparency laws, and false claims laws which may apply to our business practices, including, but not limited to: research, distribution, sales and marketing arrangements; claims for items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and the applicable compliance guidance promulgated by the federal government; otherwise restrict payments that may be made to healthcare providers; and state laws governing the privacy and security of health information in certain circumstances. Many of these state laws differ from one another 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 in violation of 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 could impair our financial results.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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, wherein those regulations or guidelines could affect the use of our products. 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 provider and patient communities. Recommendations from 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 the use of competitive or alternative products which are subsequently followed by patients and health care providers, could result in decreased use of our products.

We could be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming, distracting, and ultimately 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 were involved in several matters related to Paragraph IV Certification Notice Letters that we received in connection with our products and our collaborators' products. In connection with an ANDA (Abbreviated New Drug Application), a Paragraph IV Certification Notice Letter notifies the FDA that one or more patents listed in the FDA's Orange Book is alleged to be invalid, unenforceable, or will not be infringed by the competitive ANDA product.

In any infringement proceeding, a court may decide that a patent of ours is not valid or enforceable, or the court 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 USPTO (U.S. Patent and Trademark Office) may be necessary to determine the priority of inventions with respect to our patents and patent applications, or the patents 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, or offer terms at all. Litigation or interference proceedings may fail. Even if successful, litigation may result in substantial costs, and distract 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 they are protected in the U.S.

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, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the price of our common stock.

There can be no assurance that our product candidates will not be subject to the same risks.

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

To a significant degree, our success will depend on our ability to obtain and maintain patent protection for: our proprietary technologies; for both our products and product candidates; to preserve our trade secrets; to prevent third parties from infringing upon our proprietary rights; and to operate without infringing upon the proprietary rights of others. To that end, we seek patent protection in the U.S. and internationally for our products and product candidates. Our policy is to actively seek to protect our proprietary positions by, among other things, filing patent applications in the U.S. 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 have uncertain results. Patent applications in the U.S. and most other countries are confidential for a period of time until they are published. 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, with our collaborators, and with our 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. We could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or could be independently discovered by our competitors. Any failure to adequately prevent disclosure of our trade secrets and other proprietary information could have a material, adverse impact on our business.

In addition, the laws of certain foreign countries do not protect proprietary rights to the same extent, or in the same manner as the U.S.. 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 could be costly and time consuming to defend such a suit. An unfavorable outcome in such litigation could 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 our approved products and our product candidates, and to use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, 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, or our product candidates, may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties that we are currently unaware of, and that may be infringed by our collaborators' approved products, or Oxtellar XR, or Trokendi XR. These patents could prevent us from being able to maximize revenue generated by our products, or our product candidates. Because patent applications can take many years to issue, there may be pending patent applications which may later result in issued patents. Our collaborators' approved products, our products, or our product candidates may infringe those issued patents.

We may be exposed to, or threatened with, future litigation by third parties alleging that our collaborators' approved products, our products, or product candidates infringe their intellectual property rights. If one of our collaborators' approved products, our products, or our product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages. In such an event, we could be prevented from commercializing the applicable approved products or 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 prior to a trial. Such a trial may not occur for several years.

There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry. 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 which 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. If the court finds that the infringement was willful, we could be ordered to pay treble damages, and pay the patent owner's legal fees;
- Court rulings prohibiting us from selling our products or product candidates, unless the third party licenses its rights to us, which it is not required to do;
- If a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and
- Redesigning our products or product candidates, so they do not infringe. This may not be possible or may require substantial monetary expenditures and time.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies. 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 in 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, causing damage to our business.

We face potential litigation and product liability exposures. If successful claims are brought against us, we may incur substantial liabilities.

In recent years, the volume of claims and the amount of damages claimed in litigation against the pharmaceutical industry has increased. While we strive to conduct our business in accordance with the highest standards, we nevertheless remain exposed to litigation risk. We could be sued by many different parties, including, for example, consumers, healthcare providers, or others selling or otherwise coming into contact with our products and product candidates. Lawsuits or investigations that we may become involved in could be very expensive. These claims may be highly damaging to our reputation, even if the underlying claims are without merit, thereby adversely affecting our business.

The use of our product candidates in clinical trials, and the commercial sale of any of our products expose us to the risk of product liability claims. 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 a commercial product;
- Impairment of our business reputation and exposure to adverse publicity;
- Withdrawal of bioequivalence and/or clinical trial participants;
- Initiation of investigations by regulators;
- Costs related to litigation;
- Distraction of management's attention from our primary business;
- Substantial monetary awards to patients or other claimants;
- Loss of revenues; and

- Our inability to commercialize products for which we are obtaining marketing approval.

Our product liability insurance coverage for our clinical trials is limited to $15 million per claim, and $15 million in the aggregate. Insurance covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. On occasion, large judgments have been awarded in class action lawsuits for drugs that had unanticipated side effects. In the future, potential inability to obtain sufficient product liability insurance at an acceptable cost, or at all, to protect against potential product liability claims could prevent, or inhibit, the development and commercialization of the pharmaceutical products we develop.

Our insurance coverage may not be sufficient to cover our legal claims, or other losses that we may incur in the future.

We seek to minimize any losses we may incur through various insurance contracts from third-party insurance carriers. However, our insurance coverage is subject to large individual claim deductibles, individual claim and aggregate policy limits, and other terms and conditions. We cannot assure that our insurance will be sufficient to cover our losses. Further, due to rising insurance costs and changes in the insurance markets, we cannot provide assurance that insurance coverage will continue to be available on terms similar to those presently available to us, or available at all. Any such losses not covered by insurance could have a material adverse effect on our financial condition, results of operations, and cash flows.

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. As such, we may be subject to claims that we or these employees have used or disclosed trade secrets, or disclosed 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.

As we continue to increase the size of our organization, we may experience difficulties in managing growth.

Our personnel, systems and facilities currently in place may not be adequate to support future growth. Our future financial performance and our ability to compete effectively will depend, in significant degree, on our ability to effectively manage our recent and any future growth. In 2019, we increased employee headcount from 448 employees to 464 employees. Revenues in 2019 were $392.8 million, compared to $408.9 million in 2018. Our need to effectively execute our growth strategy requires that we:

- Manage regulatory approvals and clinical trials effectively;
- Manage our internal development efforts effectively and in a cost effective manner, while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- Commercialize our product candidates;
- Improve our operational, financial and management controls, financial reporting systems and procedures; and
- Attract, retain and motivate sufficient numbers of talented employees, with the requisite skills and experience.

This 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 to recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure; give rise to operational mistakes; loss of business opportunities; loss of employees; and reduced productivity.

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. In addition, our growth will cause us to comply with an increasing number of regulations and statutory requirements. 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 impaired; and we may not be able to implement our business strategy.

We face significant competition in attracting and retaining talented employees. Further, managing succession for, and retention of key executives is critical to our success. Our failure to do so could have an adverse impact on our future performance.

We are highly dependent upon skilled personnel in key parts of our organization, and we invest heavily in recruiting, training and retaining qualified individuals, which includes significant efforts to enhance the diversity of our workforce. The loss of the service of key members of our organization, including senior members of our scientific and management teams, high-quality researchers, development specialists, and skilled personnel, could delay or prevent the achievement of major business objectives. Our future growth will demand talented employees and leaders, yet the market for such talent has become increasingly competitive. In addition, our ability to hire qualified personnel also depends on our flexibility to reward superior performance, and to pay competitive compensation.

We may not be able to attract or motivate qualified management, 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 key personnel to accomplish our business objectives, we may experience constraints that may significantly impede the achievement of our objectives.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transition involving key employees and members of our management team could hinder our strategic planning and business execution. In addition, our failure to adequately plan for succession of senior management and for other key management roles, or the failure of key employees to successfully transition into new roles, could have a material adverse effect on our business and results of operations.

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. Mr. Khattar has an employment agreement. Other members of the senior management team have executive retention agreements, but these agreements do not guarantee the services of these executives will continue to be available to us. 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, or will not generate concern among employees and those with whom we do business.

In addition to competition for personnel, our corporate offices 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. As a result, despite significant efforts on our part, we may be unable to attract and retain qualified individuals in sufficient numbers, which could have an adverse effect on our business, financial condition and results of operations.

We may enter into significant, complex and unusual transactions, which may require us to engage outside consultants and financial professionals in order to comply with complex accounting and reporting requirements.

From time to time, the Company may be presented with, and may choose to enter into, significant, complex and unusual business or financial transactions, either to raise capital or in the context of entering into a business arrangement with a third party. These transactions may entail complex accounting or financial reporting requirements, with which we may not be familiar. Accordingly, we may need to hire additional personnel, or retain the services of outside accounting, financial reporting, and legal experts, to guide both the transaction and to assist management in becoming compliant with the attendant financial reporting requirements. Acquiring such additional resources could increase our legal and financial compliance costs, divert management's attention from other matters, and/or make certain activities more time consuming.

Given the complexity of such transactions, there is inherent risk regarding compliance with financial reporting requirements. Because the relevant regulations and standards are subject to varying interpretation, in many cases due to their lack of specificity, their application in practice may evolve over time, as new guidance is provided by regulatory and governing bodies, and as the market gains familiarity with these requirements. This could result in continuing uncertainty regarding compliance matters, and on-going financial reporting requirements.

If our efforts to comply with new laws, regulations and accounting standards differ from the intentions of regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected.

Our operations rely on sophisticated information technology, systems and infrastructure, a disruption of which could harm our operations.

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. In addition, we rely on various information technology, and systems, some of which are dependent on services provided by third parties, to manage our technology platform and operations.

These systems provide critical data and services for internal and external users, including procurement, inventory management, transaction processing, financial, commercial and operational data, human resources management, legal and tax compliance, financial reporting and other information necessary to operate and manage our business. These systems are complex, and are frequently updated as technology improves. This includes software and hardware that is licensed, leased or purchased from third parties. If our information technology, equipment or systems fail to function properly due to internal errors or defects, implementation or integration issues, catastrophic events or power outages, we may experience a material disruption in our ability to manage our business operations. Failure or disruption of these systems could have an adverse effect on our operating results and financial condition. In addition, 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. Any failure to manage, expand, or update our information technology infrastructure, or any failure in the operation of this infrastructure, could harm our business.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we or our vendors collect and store sensitive data in our or their data centers and on our networks, including: intellectual property; proprietary business information; proprietary information of our customers, suppliers and business partners; and personally identifiable information of our employees and patients in our clinical trials. In addition, hardware, software, or applications we procure from third parties, or through open source solutions, may contain defects in design or other problems that could unexpectedly compromise information security. The continued occurrence of high-profile data breaches provides evidence of an external environment which is increasingly hostile to information security, and to the secure processing, maintenance and transmission of information critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers, or breached due to employee error, malfeasance or other disruptions. Despite our efforts to improve our information security controls, it is possible that the security controls we have implemented to safeguard personal data and our networks, train our employees and vendors on data security, and implement security requirements and other practices, we may not prevent the compromise of our networks or the improper disclosure of data that we or our vendors store and manage. Unauthorized parties may also attempt to gain access to our systems or facilities, or those of third parties with whom we do business, through fraud, trickery, or other forms of deceiving our employees, contractors, and vendors. If we, our vendors, or other third parties with whom we do business experience significant data security breaches, or fail to detect and appropriately respond to significant data security breaches, we could be exposed to government enforcement actions. Improper disclosure could also harm our reputation, create risks for customers, or subject us to liability under laws that protect personal information. This could adversely affect our business, revenues and competitive position.

We recently completed a move to our new headquarters and we may face disruption and additional costs as we complete the move-in process.

We have entered into a lease to relocate our corporate headquarters in 2019. In connection with the relocation, we incurred additional expenses, including those related to moving and costs to leave our existing facilities, tenant improvements and associated expenses not covered by the landlord, as well as furniture and equipment purchases for the new corporate headquarters. As we complete the move-in process, the relocation could result in additional business disruption, and could have a negative impact on our operating results. In addition, we may incur charges related to exiting our current lease if we are not able to exit or release on favorable terms.

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

Our activities and the activities conducted by our third-party manufacturers and suppliers involve the controlled storage, use and disposal of hazardous materials. 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 applicable 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 may interrupt our business operations, including our commercialization, 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 applicable laws and regulations, we have no direct control over our third-party manufacturers, and therefore cannot guarantee that this is the case. We can eliminate the risk of accidental contamination, or that such safety procedures will prevent injury from these materials. In such an event, we may be held liable for any resulting damages. Such liability could exceed our resources.

We do not currently maintain biological or hazardous materials insurance coverage. While we have implemented processes and procedures to ensure that the suppliers we use are complying with all applicable regulations, there can be no assurances that such suppliers in all instances will comply with such processes and procedures, or otherwise comply with applicable regulations. Noncompliance could result in our marketing and distribution of contaminated, defective or dangerous products, which could subject us to liabilities. This could result in the imposition by governmental authorities of procedures or penalties that could restrict or eliminate our ability to sell products. Any or all of these effects could adversely affect our business, financial condition and results of operations.

Provisions in our agreement with Shire, or its successor, 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., the predecessor of Supernus Pharmaceuticals. Under the purchase agreement, we agreed to refrain perpetually from engaging in any research, formulation development, analytical testing, manufacture, technology assessment, or oral bioavailability screening that relate to five specific drug compounds (i.e., amphetamine, carbamazepine, guanfacine, lanthanum and mesalamine), and any derivative thereof. Although these various restrictions and covenants on us do not currently impact our products, 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.

Risks Related to Our Finances and Capital Requirements

Although we have been profitable from operations since the fourth quarter of 2014, there is no assurance that we will continue to generate net income in the future. We may not be able to maintain or increase profitability.

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 our product candidates. We have financed our operations through revenue generated from operations and various transactions including the following:

- The completion of our $52.3 million initial public offering in May 2012;
- The completion of our follow-on $49.9 million equity offering in November 2012;
- The completion of our $90.0 million private placement offering of 7.50% Convertible Senior Secured Notes (2019 Notes) in May 2013;
- The $30.0 million monetization of certain future royalty streams in 2014, under our existing license for Orenitram; and
- The completion of our $402.5 million private placement of 0.625% Convertible Senior Notes (2023 Notes) in March 2018.

Our ability to remain profitable depends upon our ability to generate the same or increasing levels of revenue from sales of our products, Oxtellar XR and Trokendi XR, while simultaneously funding the requisite research expenditures to gain FDA approval for our product candidates. Since 2013, the first year in which we generated revenue from our first commercial products, we have demonstrated the ability to become and remain profitable. Future revenues will highly depend on our ability to maintain or grow demand for our products and defend against potential generic competition, and successfully develop and commercialize our product candidates.

As of December 31, 2019, we had retained earnings of approximately $199.5 million. However, prior to 2018, we had incurred significant operating losses since inception through 2014, substantially as a consequence of costs incurred in connection with our development programs, expenses associated with launching our products, and from selling, general and administrative costs associated with our operations. We expect our research and development costs to continue to be substantial and to increase with respect to our product candidates, as we advance those product candidates through preclinical studies, clinical trials, manufacturing scale-up and other pre-approval activities. We expect our selling, general and administrative costs to continue to increase as we continue to support the ongoing commercialization of our products, and to further increase in anticipation of launching our product candidates.

While we anticipate maintaining profitability in 2020 and beyond, we cannot be certain that we will do so. Any potential future losses, if and when they occur, could have an adverse impact on our stockholders' equity and working capital.

Our operating results may fluctuate significantly.

We expect that any revenue we generate will fluctuate from quarter to quarter and year to year, as a result of revenue generated from approved products, our license agreements, the amount and timing of development milestones, and product revenue received under our collaboration license agreements.

Our net earnings and other operating results will be affected by numerous factors, including:

- The level of market acceptance for any approved product candidate, underlying demand for that product and wholesalers' buying patterns;
- Variations in the level of expenses related to our development programs;
- The success of our product development and clinical trial activities through all phases of clinical development;
- Our execution of any collaborative, licensing or similar commercial arrangements, and the timing of payments we may make or receive under these arrangements;
- Any delays in regulatory review and approval of product candidates in clinical development;
- The timing of any regulatory approvals, if received, of additional indications for our existing products;
- Potential side effects of our products and our future products that could delay or prevent commercialization, cause an approved drug to be taken off the market, or result in litigation;
- Any intellectual property infringement lawsuit in which we may become involved;
- Our ability to maintain an effective sales and marketing infrastructure;
- Our dependency on third-party manufacturers to supply or manufacture our products and product candidates;
- Competition from existing products, new products, or potential generics to our products or to competitive products that may emerge;
- Regulatory developments affecting our products and product candidates; and
- Changes in reimbursement environment and regulatory changes.

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.

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, commercialization or business development efforts.

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

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 raise additional funds. 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:

- Our ability to successfully support our products in the marketplace and the rate of increase in the level of sales in the marketplace;
- The rate of progress, clinical success, and cost of our trials and other product development programs for our product candidates;
- The costs and timing of in-licensing product candidates or acquiring other complementary companies;
- The timing of any regulatory approvals of our product candidates;
- The actions of our competitors and their success in selling competitive product offerings, including generics; and
- The status, terms and timing of any collaborative, licensing, co-promotion or other arrangement.

Additional financing may not be available in the amount we require or may not be available on terms that are favorable to us, or at all. 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, our commercialization efforts or strategic initiatives.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited, or may expire prior to utilization.

Our ability to utilize our U.S. federal and state net operating losses or U.S. federal tax credits is currently limited, and may be limited further, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders change their aggregate ownership position by more than 50 percentage points over their lowest ownership percentage in a testing period, which is typically three years, or since the last ownership change. We are already subject to Section 382 limitations due to cumulative ownership changes that, as of November 15, 2013, totaled more than 50%. As of December 31, 2019, we had U.S. federal net operating loss carryforwards of approximately $10.8 million and research and development tax credit carryforwards of approximately $4.2 million. Future changes in stock ownership may also trigger an additional ownership change and, consequently, another Section 382 or Section 383 limitation.

Any limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization, which would reduce our gross deferred income tax assets. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and tax credit carryforwards to reduce U.S. federal and state income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

Complying with increased financial reporting and securities laws reporting requirements has increased our costs and requires additional management resources. We may fail to meet these obligations.

We face increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 (SOX), 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 reporting costs. As of the beginning of 2017, we transitioned from "accelerated filer" to "large accelerated filer" status, which led to further increases in our legal, audit, NASDAQ listing fees and financial compliance costs. The Securities Exchange Act of 1934, as amended (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 outside advisors 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 and increasing costs to maintain the same or similar coverage.

As a public company, we are subject to Section 404 of SOX relating to internal controls over financial reporting. We have and expect to continue to incur significant expense and to devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit group. We have hired additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We expect that we will have to compete in the market place for qualified accounting and financial staff and we may have difficulties identifying and attracting qualified persons.

Implementing any necessary changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify or replace 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. 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 give assurance that our internal controls over financial reporting will prove to be effective.

We may identify material weaknesses in our internal controls over financial reporting or otherwise fail to maintain an effective system of internal controls, which might cause stockholders to lose confidence in our financial and other public reporting, which in turn would harm our business and the trading price of our common stock.

Effective internal control over financial reporting and adequate disclosure controls and procedures are necessary for us to provide reliable financial reports. These 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 conducted by us in connection with Section 404(a) of SOX, or the subsequent testing by our independent registered public accounting firm in connection with Section 404(b) of SOX, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. These may require prospective or retroactive changes to our consolidated financial statements or may identify other areas for further attention or improvement. Any system of internal controls, however well designed and operated, is based in part on certain assumptions, and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any material weaknesses in our internal controls could 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. Our management is required to assess the effectiveness of these controls annually. The annual independent assessment of the effectiveness of our internal controls is very expensive, and 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.

We are continuing to refine our disclosure controls and other procedures that are designed to ensure that the information that we are required to disclose in the reports that we will file with the SEC is properly recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are also continuing to improve our internal controls over financial reporting. We have expended, and anticipate that we will continue to expend, significant resources in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting.

We may pursue acquisitions of new product lines or businesses.

Our acquisition strategy entails numerous risks. Our ability to complete future acquisitions will depend on our ability to identify suitable acquisition candidates. If suitable candidates are identified, we may not be able to negotiate commercially acceptable terms for their acquisition or, if necessary, to finance those acquisitions. We anticipate competition for attractive candidates from other parties, some of whom have substantially greater financial and other resources than we have. Whether or not any particular acquisition is successfully completed, each of these activities is expensive and time consuming and would likely require our management to spend considerable time and effort to complete, which would detract from our management's ability to run our current business. Although we may spend considerable funds and efforts to pursue acquisitions, we may not be able to complete them.

Acquisitions could result in the occurrence of one or more of the following events:

- Dilutive issuances of equity securities;
- Incurrence of additional debt and contingent liabilities;
- Increased amortization of expenses related to intangible assets;
- Difficulties in the assimilation of the operations, technologies, services and products of the acquired companies
- Diversion of management's attention from our other business activities; and
- Assumption of debt and liabilities of the target company

We may have difficulties integrating acquisitions.

We cannot assure you that we will be able to complete acquisitions that we believe are necessary to complement our growth strategy on acceptable terms, or at all. Further, if we do successfully integrate the operations of any companies that we have acquired or subsequently acquire, we may not achieve the potential benefits of such acquisitions. Even if we are able to consummate an acquisition, the transaction would present many risks, including, among others: failing to achieve anticipated revenues, profits, benefits or cost savings; difficulty incorporating and integrating the acquired technologies, services or products; difficulty in coordinating, establishing or expanding sales, distribution and marketing functions, as necessary; diversion of management's attention from other business concerns; being exposed to unanticipated or contingent liabilities from the acquired company, or incurring the impairment of goodwill; the loss of key employees or distribution partners; and difficulties implementing and maintaining sufficient controls, policies and procedures over the systems, products and processes of the acquired company. If we do not achieve the anticipated benefits of an acquisition as rapidly or to the extent anticipated by management, or if others do not perceive the same benefits of the acquisition as we do, there could be a material, adverse effect on our business, cash flows, financial condition or results of operations.

Risks Related to Securities Markets and Investment in Our Stock

We may issue additional shares of our common stock or instruments convertible into shares of our common stock and thereby materially and adversely affect the market price of our common stock.

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.

We may conduct future offerings of our common stock, preferred stock or other securities convertible into our common stock to fund acquisitions, finance operations or for other purposes. In addition, as of December 31, 2019, we had outstanding 52,533,348 shares of common stock, of which approximately 1,959,294 shares are restricted securities that may be sold in accordance with the resale restrictions under Rule 144 of the Securities Act of 1933, as amended (Securities Act), or pursuant to a resale registration statement. Also, as of December 31, 2019, we had outstanding options to purchase 4,606,559 shares of common stock that, if exercised, would result in these additional shares becoming available for sale. Approximately 6% of these shares and options are held by senior management of the Company. 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 1,972,307 and 54,081 shares of our common stock are reserved for future issuance under the 2012 Equity Incentive Plan and the 2012 Employee Stock Purchase Plan, respectively.

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

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

The price of our common stock may fluctuate substantially.

The market price for our common stock historically has been volatile. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, including:

- Fluctuations in stock market prices for the U.S. stock market;
- The commercial performance of Oxtellar XR, Trokendi XR, or any of our product candidates that receive regulatory approval;
- Substitution of our products in favor of generic versions of our products or competitors' products;
- Status of patent infringement law suits, if applicable;
- The filing of ANDAs by generic companies seeking approval to market generic versions of our products;
- Plans for, progress in, and results from clinical trials of our product candidates generally;
- FDA or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- Announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- Market conditions and regulatory changes in the pharmaceutical and biotechnology sectors;
- Fluctuations in stock market prices and trading volumes of similar companies;
- Variations in our quarterly operating results;
- Changes in accounting principles;
- Litigation or public concern about the safety of our products and/or potential products;
- Fluctuations in our quarterly operating results;
- Deviations in our operating results from the estimates of securities analysts;
- Additions or departures of key personnel;
- Sales or purchases of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- Changes in third-party coverage and reimbursement policies for our products and/or product candidates; and
- Discussion by us of our stock price in the financial or scientific press or online investor communities.

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If securities or industry analysts presently covering our business do not continue such coverage, or if additional securities or industry analysts do not commence coverage of our Company, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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

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

- Our board of directors is divided into three classes, serving staggered three-year terms, such that not all members of the board will be elected at one time. This staggered board structure prevents stockholders from replacing the entire board at a single stockholders' meeting;
- Our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- Our board of directors may issue, without stockholder approval, shares of preferred stock. The ability to authorize preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us;
- Stockholders must provide advance notice to nominate individuals for election to the board of directors, or to propose matters that can be acted upon at a stockholders' meeting. Furthermore, stockholders may only remove a member of our board of directors for cause. These provisions may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect such acquiror's own slate of directors or otherwise attempting to obtain control of our Company;
- Our stockholders may not act by written consent. As a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions outside of a stockholders' meeting;
- Special meetings of stockholders may be called only by the chairman of our board of directors or a majority of our board of directors. As a result, a holder, or holders, controlling a majority of our capital stock would not be able to call a special meeting; and
- A supermajority (75%) of the voting power of outstanding shares of our capital stock is required to amend, repeal or adopt any provision inconsistent with certain provisions of our certificate of incorporation and to amend our by-laws, which make it more difficult to change the provisions described above.

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

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

We cannot predict the extent to which investor interest in our common stock will allow us to maintain an active trading market on the NASDAQ Global Market or a similar market or how liquid that market might be. If an active public market is not sustained, it may be difficult to sell shares of common stock at a price that is attractive to the investor, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock, or may impair our ability to enter into strategic partnerships or acquire companies or products, product candidates or technologies by using our shares of common stock as consideration.

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

As of December 31, 2019, we had issued options to purchase 4,606,559 shares of common stock outstanding, with exercise prices ranging from $2.56 to $58.15 per share and a weighted average exercise price of $23.05 per share. Upon the vesting of each of these options, the holder may exercise his or her options, which would result in dilution to investors.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations, and impair our ability to satisfy our obligations under the notes.

We incurred $402.5 million of additional indebtedness as a result of the sale of 0.625% Convertible Senior Notes due 2023 (2023 Notes). We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- Increasing our vulnerability to adverse economic and industry conditions;
- Limiting our ability to obtain additional financing;
- Requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which would reduce the amount of cash available for other purposes;
- Limiting our flexibility to plan for, or react to, changes in our business;
- Diluting the economic interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2023 Notes, notwithstanding the convertible hedge and warrant transactions; and
- Placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the 2023 Notes.

The issuance or sale of shares of our common stock, or rights to acquire shares of our common stock, could depress the trading price of our common stock and the 2023 Notes.

We may conduct future offerings of our common stock, preferred stock or other securities that are convertible into or exercisable for our common stock to finance our operations or fund acquisitions, or for other purposes. In addition, as of December 31, 2019, 4,606,559 shares of our common stock were reserved for future issuance upon the exercise of outstanding options, 1,972,307 shares were reserved for future issuance under our 2012 Equity Incentive Plan and 54,081 shares were reserved for future issuance under our 2012 Employee Stock Purchase Plan.

The indenture for the 2023 Notes will not restrict our ability to issue additional equity securities in the future. If we issue additional shares of our common stock or issue rights to acquire shares of our common stock, if any of our existing stockholders sells a substantial amount of our common stock, or if the market perceives that such issuances or sales may occur, then the trading price of our common stock, and, accordingly, the 2023 Notes, may significantly decrease. In addition, our issuance of additional shares of common stock will dilute the ownership interests of our existing common stockholders, including noteholders who have received shares of our common stock upon conversion of their 2023 Notes.

We may be unable to raise the funds necessary to repurchase the 2023 Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and our other indebtedness may limit our ability to repurchase the 2023 Notes or pay cash upon their conversion.

Noteholders may require us to repurchase their 2023 Notes following a fundamental change, at a cash repurchase price generally equal to the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we must satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the 2023 Notes, or to pay the cash amounts due upon conversion. In addition, applicable law and/or regulatory authorities may restrict our ability to repurchase the 2023 Notes, or to pay the cash amounts due upon conversion. Our failure to repurchase 2023 Notes or to pay the cash amounts due upon conversion when required will constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and under the 2023 Notes.

Provisions in the indenture could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the 2023 Notes and the indenture could make a third party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their 2023 Notes for cash, and we may be required to temporarily increase the conversion rate of the 2023 Notes. In either case, and in other cases, our obligations under the 2023 Notes and the indenture could increase the cost of acquiring us, or otherwise discourage a third party from acquiring us, to remove incumbent management, including in a transaction that noteholders or holders of our common shares may view as favorable.

The accounting method for the 2023 Notes could adversely affect our reported financial condition and results.

The accounting method for reflecting the 2023 Notes on our balance sheet, accruing interest expense for the Notes, and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition.

Under applicable accounting principles, we record the initial liability carrying amount of the 2023 Notes at the fair value of a similar debt instrument that does not have a conversion feature, and is valued using our cost of capital for straight, unconvertible debt. We reflect the difference between the net proceeds from this offering and the initial carrying amount as a debt discount for accounting purposes, with the debt discount being amortized as interest expense over the term of the notes. As a result of this amortization, the interest expense that we recognize for the 2023 Notes for accounting purposes will be greater than the cash interest payments we will pay on the 2023 Notes. This will result in lower reported net income. The lower reported income resulting from this accounting treatment could depress the trading price of our common stock and the 2023 Notes.

In addition, because we intend to settle conversions of the 2023 Notes by paying the conversion value in cash, up to the principal amount being converted and any excess in shares, we are eligible to use the treasury stock method to reflect the shares underlying the 2023 Notes in our diluted earnings per share. In order to continue to apply the treasury stock method, we will need to consider on a quarterly basis our ability and intent to settle conversions by paying the conversion value in cash up to the principal amount being converted.

Under the treasury method, if the conversion value of the 2023 Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the 2023 Notes were converted and that we issue shares of our common stock to settle the excess. However, if reflecting the 2023 Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the 2023 Notes does not exceed their principal amount for a reporting period, then the shares underlying the 2023 Notes will not be reflected in our diluted earnings per share.

If accounting standards change in the future or we determine that we are no longer able or intend to settle the conversion value in cash up to the principal amount being converted, and we, therefore, are no longer permitted to use the treasury stock method, then our diluted earnings per share may decline.

Furthermore, if any of the conditions to the convertibility of the notes are satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their 2023 Notes. This could materially reduce our reported working capital.

The convertible note hedge transactions and the warrant transactions may affect the value of the notes and our common stock.

In connection with the pricing of the 2023 Notes, we entered into privately negotiated convertible note hedge transactions with the hedge counterparties. The convertible note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of common stock that will initially underlie the 2023 Notes sold. We also entered into separate, privately negotiated warrant transactions with the hedge counterparties relating to the same number of shares of our common stock, subject to customary anti-dilution adjustments.

In connection with establishing their initial hedge positions with respect to the convertible note hedge transactions and the warrant transactions, we believe that the hedge counterparties and/or their affiliates entered into various cash-settled, over-the-counter derivative transactions with respect to our common stock, and/or purchased shares of our common stock concurrently. In addition, we expect that the hedge counterparties and/or their affiliates will modify their hedge positions with respect to the convertible note hedge transactions and the warrant transactions from time to time, and are likely to do so during any observation period (as defined in the indenture) for the 2023 Notes, by purchasing and/or selling shares of our common stock and/or other securities of ours, including the 2023 Notes, in privately negotiated transactions and/or open-market transactions, or by entering into and/or unwinding various over-the-counter derivative transactions with respect to our common stock.

The effect, if any, of these activities on the market price of our common stock and the trading price of the 2023 Notes will depend on a variety of factors, including market conditions, and cannot be ascertained at this time. Any of these activities could, however, adversely affect the market price of our common stock and/or the trading price of the 2023 Notes and, consequently, adversely affect noteholders' ability to convert the 2023 Notes and/or affect the value of the consideration that you receive upon conversion of the 2023 Notes. In addition, the hedge counterparties and/or their affiliates may choose to engage in, or to discontinue engaging in, any of these transactions with or without notice at any time, and their decisions will be in their sole discretion and not within our control.

We are subject to counterparty risk with respect to the convertible note hedge transactions.

The hedge counterparties are financial institutions, and we will be subject to the risk that they might default in the fulfillment of their obligations under the convertible note hedge transactions. Our exposure to the credit risk of the hedge counterparties will not be secured by any collateral.

Global economic conditions have from time to time resulted in the actual or perceived failure or financial difficulties of many financial institutions, including the bankruptcy filing by Lehman Brothers Holdings Inc. and its various affiliates, as well as by Bear Stearns. If a hedge counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with that hedge counterparty. Our exposure will depend on many factors, but, generally, the increase in our exposure will be correlated with the increase in the market price and in the volatility of our common stock. In addition, upon a default by a hedge counterparty, we may suffer adverse tax consequences and suffer more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of any hedge counterparty.

Conversion of the 2023 Notes or exercise of the warrants evidenced by the warrant transactions may dilute the ownership interest of existing stockholders, including noteholders who have previously converted their 2023 Notes.

At our election, we may settle 2023 Notes tendered for conversion entirely or partly in shares of our common stock. Furthermore, the warrants evidenced by the warrant transactions are expected to be settled on a net-share basis. As a result, the conversion of some or all of the 2023 Notes, or the exercise of some or all of such warrants may dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion of the 2023 Notes, or such exercise of the warrants, could adversely affect prevailing market price of our common stock. In addition, the existence of the 2023 Notes may encourage short selling by market participants because the conversion of the 2023 Notes could depress the price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal executive offices are located at 9715 and 9717 Key West Avenue, Rockville, Maryland, where we occupy approximately 136,016 square feet of laboratory and office space. The term of this lease commenced on February 1, 2019 and shall continue until April 30, 2034. We believe that these facilities are sufficient for our present and contemplated operations.

ITEM 3. LEGAL PROCEEDINGS.

From time to time and in the ordinary course of business, we may be subject to various claims, charges and litigation. We may be required to file infringement claims against third parties for the infringement of our patents. As of December 31, 2019, the Company has no material pending legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES.

Market and Shareholder Information

Our common stock has been listed on The NASDAQ Global Market under the symbol "SUPN" since May 1, 2012. Prior to that date, there was no public trading market for our common stock.

On December 31, 2019, the closing price of our common stock on The NASDAQ Global Market was $23.72 per share. As of December 31, 2019, we had 19 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our capital stock and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

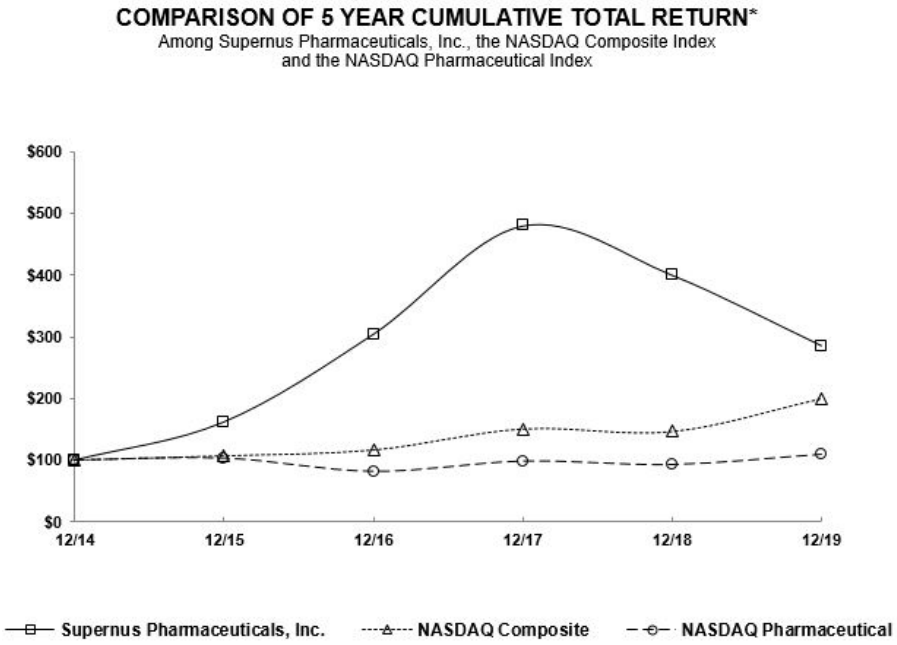
Option Grants

During the three months ended December 31, 2019, the Company granted options to employees to purchase an aggregate of 13,100 shares of common stock at an exercise price of $22.99 per share. The options are exercisable for a period of ten years from the grant date. These issuances were exempt from registration in reliance on Section 4(a)(2) of the Securities Act as transactions not involving any public offering.

Performance Graph

The following graph sets forth the Company's total cumulative stockholder return as compared to the NASDAQ Stock Market Composite Index and the NASDAQ Biotechnology Index, for the period beginning December 31, 2014 and ending December 31, 2019.

Total stockholder return assumes $100 invested at the beginning of the period in the common stock of the Company, the stocks represented in the NASDAQ Composite Index and the NASDAQ Pharmaceutical, respectively. Total return assumes reinvestment of dividends; the Company has paid no dividends on its common stock. Historical price performance should not be relied upon as indicative of future stock performance.



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* $100 invested on 12/31/2014 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

Performance Graph Data

	Supernus Pharmaceuticals, Inc.	NASDAQ Composite Index	NASDAQ Pharmaceuticals Index
December 31, 2014	$ 100.00	$ 100.00	$ 100.00
December 31, 2015	161.93	106.96	103.06
December 31, 2016	304.22	116.45	81.93
December 31, 2017	480.12	150.96	98.23
December 31, 2018	400.24	146.67	92.83
December 31, 2019	285.78	200.49	109.06

The performance graph and related information shall not be deemed "soliciting material" or be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference into such filing.

ITEM 6. SELECTED FINANCIAL DATA.

The following selected financial data should be read together with the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes to those consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended December 31, 2019, 2018 and 2017 and balance sheet data as of December 31, 2019 and 2018 set forth below have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of earnings data for the years ended December 31, 2016 and 2015 and the balance sheet data as of December 31, 2017, 2016 and 2015 set forth below have been derived from the audited consolidated financial statements for such year not included in this Annual Report on Form 10-K. The historical periods presented here are not necessarily indicative of future results.

	Years Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except share and per share data)				
Statements of Earnings Data:					
Revenues	$ 392,755	$ 408,897	$ 302,238	$ 215,003	$ 147,465
Net earnings	113,056	110,993	57,284	91,221	13,944
Earnings per share					
Basic	$ 2.16	$ 2.13	$ 1.13	$ 1.84	$ 0.29
Diluted	2.10	2.05	1.08	1.76	0.28
Weighted-average shares outstanding					
Basic	52,412,181	51,989,824	50,756,603	49,472,434	47,485,258
Diluted	53,816,754	54,098,872	53,301,150	51,708,983	51,160,380
Balance Sheet and Other Data:					
Cash and cash equivalents and marketable securities	$ 347,073	356,018	140,040	90,121	62,190
Long term marketable securities	591,773	418,798	133,638	75,410	55,009
Working capital	312,057	332,134	105,451	70,662	49,012
Total assets	1,160,282	977,811	424,464	309,568	188,626
Convertible notes, net	345,170	329,462	—	4,165	7,085
Non-recourse liability related to sale of future royalties [1]	22,492	24,758	26,541	30,390	30,528
Retained earnings (accumulated deficit)	199,548	86,492	(26,823)	(84,288)	(175,509)
Total stockholders' equity	595,428	453,023	267,480	191,755	88,007

[1] Includes both short term and long term obligations.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes thereto, appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, some of the information in this discussion and analysis contains forward-looking statements reflecting our current expectations and involving risk and uncertainties. For example, statements regarding our expectations as to our plans and strategy for our business, future financial performance, expense levels and liquidity sources are forward-looking statements. Our actual results and the timing of those events could differ materially from those discussed in our forward-looking statements because of many factors, including those set forth under the "Risk Factors" section and elsewhere in this report.

Overview

We are a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. We have a portfolio of commercial products and product candidates.

Commercial Products

Oxtellar XR and Trokendi XR were the first once-daily extended release oxcarbazepine and topiramate products launched in the United States (U.S.) market.

- Oxtellar XR is indicated for the treatment of epilepsy.
- Trokendi XR is indicated for the treatment of epilepsy and for the prophylaxis of migraine headache.

Product Prescriptions

The following table provides data regarding our prescriptions, as reported by IQVIA, during the periods indicated below:

	Years Ended December 31,		Change	
	2019	2018	Volume	Percent
Prescriptions				
Trokendi XR	672,485	638,923	33,562	5%
Oxtellar XR	163,914	147,488	16,426	11%
Total prescriptions	836,399	786,411	49,988	6%

Product Candidates and Recent Developments

- SPN-812, a novel non-stimulant product candidate for the treatment of attention deficit hyperactivity disorder (ADHD). On January 2020, we received the acceptance from the U.S. Food and Drug Administration (FDA) for the review of the New Drug Application (NDA) for SPN-812 for the treatment of ADHD in pediatric patients. We have also initiated a Phase III trial for the treatment of adult patients with ADHD in the third quarter of 2019.
- SPN-604, a novel product candidate for the treatment of bipolar disorder. We initiated a pivotal Phase III study for the treatment of bipolar disorder in the fourth quarter of 2019. If approved, SPN-604 would represent the first approval for the treatment of bipolar disorder with oxcarbazepine in the U.S.
- SPN-817, a novel product candidate for the treatment of severe epilepsy. We initiated an Investigational New Drug (IND) application enabling preclinical activities in the U.S. and have received an Orphan Drug designation for Dravet Syndrome from the FDA.
- SPN-809, a novel product candidate for the treatment of depression is Phase II ready.

We expect to incur significant research and development expenses related to the continued development of each of our product candidates from 2020 through FDA approval or until the program terminates. See Part I, Item I—*Business* for a complete description of our product and product candidates and development programs.

Intellectual property portfolio

We continue to expand our intellectual property portfolio to provide additional protection for our technologies, products, and product candidates. See Part I, Item I—*Business, Intellectual Property and Exclusivity*, for a complete description of our intellectual property position.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and bases of presentation for our consolidated financial statements are described in Note 2, *Summary of Significant Accounting Policies* of the Notes to the Consolidated Financial Statements. The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses, and to disclose contingent assets and liabilities. Actual results could differ materially from those estimates.

We believe the following accounting policies and estimates to be critical:

Revenue Recognition

Revenues from product sales are recognized when physical control of our products is transferred to our customers, who are primarily pharmaceutical wholesalers and distributors. Product sales are recorded net of various forms of variable consideration, including: estimated rebates; sales discounts; and an estimated liability for future product returns (collectively, “sales deductions”). We adjust our estimates at the earlier of when the most likely amount of consideration we expect to receive changes, or when the consideration becomes fixed. For a complete description of our revenue recognition policy, see Part II, Item 8 - Note 2, *Summary of Significant Accounting Policies—Revenue from Product Sales* of the Notes to Consolidated Financial Statements.

Research and Development Expenses and Related Accrued Research and Development Expenses

Research and development expenditures are expensed as incurred. We estimate preclinical and clinical trial expenses based on services performed pursuant to contracts with research institutions, clinical investigators, clinical research organizations (CROs) and other service providers that conduct activities on the Company’s behalf. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust our accrued expenses or our deferred advance payments accordingly. For a complete description of our research and development expense and preclinical and clinical trial accrual policies, see Part II, Item 8 - Note 2, *Summary of Significant Accounting Policies—Research and Development Expense and Related Accrued Research and Development Expenses*, in the Notes to Consolidated Financial Statements.

Preclinical and clinical trials are inherently complex and often involve multiple service providers. Because billing for services often lags by a month or several months, we are often required to estimate, and therefore accrue, a significant portion of the incurred expenses. This process involves reviewing open contracts and communicating with our subject matter expert personnel, as well as with the appropriate service provider personnel to identify services that have been performed on our behalf but for which no invoice has been received. This includes services provided by CROs, as well as services provided by clinical investigators and other service providers. We accrue the cost for unbilled services performed, whether partially or fully completed.

Payments to service providers can either be based on hourly rates for service or based on achievement of performance driven milestones. We work with each service provider to obtain an estimate for services provided but as yet unbilled as of the end of the calendar quarter, including estimates for payments to site investigators. When accruing clinical trial expenses, we estimate the time period over which services will be performed during the life of the entire clinical program, the total cost of the program, and the level of effort to be expended in each intervening period.

We work diligently to minimize, if not eliminate, estimates based solely on Company generated calculations by relying primarily on estimates provided by our vendors. If we and/or the service provider underestimates or overestimates the costs associated with a service at any given point in time, adjustments to research and development expenses may be necessary in the following periods. Historically, our estimated accrued clinical expenses have closely approximated the actual expenses incurred, with minimal adjustments to expense in the subsequent periods.

Results of Operations

Consolidated Results Review

In this section, we discuss the results of our operations for the year ended December 31, 2019, compared to the year ended December 31, 2018. For a discussion of the year ended December 31, 2018 as compared to the year ended December 31, 2017, please refer to Part II, Item 7—*Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2018, which discussion is incorporated by reference herein.

The following table displays our revenues, costs and expenses, other (expense) income and income tax expense for the years ended December 31, 2019, 2018 and 2017 (dollars in thousands):

				2019 vs 2018 Change		2018 vs 2017 Change	
	2019	2018	2017	Dollar	Percent	Dollar	Percent
Net product sales	$ 383,400	$ 399,871	$ 294,097	$ (16,471)	(4)%	$ 105,774	36%
Royalty revenue	9,355	8,276	6,367	1,079	13%	1,909	30%
Cost of goods sold	16,660	15,356	15,215	1,304	9%	141	1%
Research and development	69,099	89,209	49,577	(20,110)	(23)%	39,632	80%
Selling, general and administrative	158,425	159,888	137,905	(1,463)	(1)%	21,983	16%
Other (expense) income	(1,084)	(4,268)	1,077	3,184	(75)%	(5,345)	(496)%
Income tax expense	34,431	29,183	43,334	5,248	18%	(14,151)	(33)%
Net earnings	113,056	110,993	57,284	2,063	2%	53,709	94%

Net Product Sales

Net product sales are computed as gross revenue generated from our product shipments to our customers, which are primarily pharmaceutical wholesalers and distributors, less various forms of variable consideration, including: estimated liability for rebates; estimated liability for future product returns; and estimated allowance for discounts. These are collectively considered "sales deductions."

The table below lists our net product sales by products (dollars in thousands):

	Years Ended December 31,			2019 vs 2018 Change		2018 vs 2017 Change	
	2019	2018	2017	Dollar	Percent	Dollar	Percent
Trokendi XR	$ 295,214	$ 315,295	$ 226,518	$ (20,081)	(6)%	$ 88,777	39%
Oxtellar XR	88,186	84,576	67,579	3,610	4%	16,997	25%
Total	$ 383,400	$ 399,871	$ 294,097	$ (16,471)	(4)%	$ 105,774	36%

Overall

2019 compared to 2018. In the fourth quarter of 2018, wholesalers, distributors and pharmacies increased their inventory holdings when compared to the prevailing inventory levels in the third quarter of 2018. We estimated that this caused net product sales to be approximately $10 million higher in the fourth quarter of 2018 than it would otherwise have been, had channel inventory levels remained consistent from the third to the fourth quarter of 2018. The channel inventory build-up in the fourth quarter of 2018 was effectively reversed in the first quarter of 2019. Specifically, based on analysis of sales and inventory data, inventory levels at wholesalers, distributors and pharmacies returned to the prevailing levels in the third quarter of 2018. As a result of this channel inventory reduction, both gross sales and net product sales decreased in 2019 as compared to the prior year. The adverse impact on net product sales in 2019 due to the reduction in channel inventory is estimated to be approximately $10 million.

In addition to the aforementioned inventory reduction, unfavorable changes in sales deductions more than offset the favorable unit prescription growth of 6%, and the impact of an 8% price increase in 2019. Specifically, as regards sales deductions, patient reimbursement challenges and increased contracting pressure from managed care providers resulted in both increased per patient costs for our co-pay programs, higher per patient rebate payments to managed care providers, and higher Medicaid reimbursement payments. As a result, net product sales decreased by $16.5 million year over year.

Trokendi XR

2019 compared to 2018. Trokendi XR net product sales decreased by 6% in 2019 as compared to 2018. Compared to 2018, favorable unit prescription volume growth of 5% coupled with the impact of an 8% price increase were offset by higher levels of net sales deductions. Increased sales deductions were driven primarily by increased per patient costs for our co-pay programs, higher per patient rebate payments to managed care providers, and higher Medicaid reimbursement payments. In addition, the majority of the impact of the $10 million channel inventory reduction, as described above, was reflected in lower net product sales for Trokendi XR in 2019.

Oxtellar XR

2019 compared to 2018. Oxtellar XR net product sales grew 4% in 2019 as compared to 2018. Compared to 2018, favorable unit prescription volume growth of 11% and the impact of an 8% price increase were offset by higher levels of sales deductions. Increased sales deductions were due primarily by higher per patient payments under both Medicaid and managed care programs, as well as higher co-pay program expenditures.

Sales deductions and related accruals

The Company records accrued product rebates and accrued product returns as current liabilities on our consolidated balance sheets under *Accrued product returns and rebates.* We record sales discounts as a valuation allowance against *Accounts receivable* on the consolidated balance sheets. The outstanding amounts are affected by changes in level of gross sales, the provision for net product sales deductions and the timing of payments/credits.

The following table provides a summary of activities with respect to accrued product returns and rebates for the years ended December 31, 2019, 2018 and 2017 (dollars in thousands):

	Accrued Product Returns and Rebates			
	Product Rebates	Product Returns	Allowance for Sales Discounts	Total
Balance at December 31, 2017	$ 49,460	$ 18,883	$ 8,892	$ 77,235
Provision				
Provision for sales in current year	240,368	10,767	59,245	310,380
Adjustments relating to prior year sales	(1,744)	(75)	(3)	(1,822)
Total provision	238,624	10,692	59,242	308,558
Less: Actual payments/credits	(203,081)	(7,515)	(56,586)	(267,182)
Balance at December 31, 2018	$ 85,003	$ 22,060	$ 11,548	$ 118,611
Balance at December 31, 2018	$ 85,003	$ 22,060	$ 11,548	$ 118,611
Provision				
Provision for sales in current year	307,430	10,199	61,123	378,752
Adjustments relating to prior year sales	(888)	549	(43)	(382)
Total provision	306,542	10,748	61,080	378,370
Less: Actual payments/credits	(302,734)	(13,990)	(61,615)	(378,339)
Balance at December 31, 2019	$ 88,811	$ 18,818	$ 11,013	$ 118,642

2019 compared to 2018. The total provision for sales deductions on gross product sales increased by $69.8 million, from $308.6 million in 2018 to $378.4 million in 2019. Virtually all of this increase was attributable to the year over year increase in the provision for product rebates, from $238.6 million in 2018 to $306.5 million in 2019, or $67.9 million. The year over year increase in the provision for product rebates of $67.9 million was primarily attributable to greater utilization of our patient co-pay programs. In addition, patient reimbursement challenges and increased contracting pressure from managed care providers resulted in both increased per patient costs for our co-pay programs, higher per patient rebate payments to managed care providers, and higher Medicaid reimbursement payments. Growth in prescriptions and the impact of the 8% price increase taken in January contributed, to a lesser extent, to the increase in product rebates.

The provision for product returns of $10.7 million in 2019, remained essentially the same year over year due primarily to favorable returns experience, which offset the impact of the 8% price increase taken in January.

The provision for sales discounts increased by $1.9 million, from $59.2 million to $61.1 million in 2018 and 2019, respectively, because of the prescription volume growth.

Adjustments related to prior year sales due to changes in our estimates was relatively minor in both years; i.e., $0.4 million as compared to $383.4 million of net product sales in 2019, and $1.8 million as compared to $399.9 million of net product sales in 2018.

Royalty Revenue

Royalty revenue includes royalties from the following products (dollars in thousands):

	2019	2018	2017
Mydayis [1]	$ 2,428	$ 2,243	$ 1,034
Orenitram [2]	6,927	6,033	5,283
Total	$ 9,355	$ 8,276	$ 6,317

[1] Royalty from net product sales of Mydayis, a product of Shire Plc (a subsidiary of Takeda Pharmaceuticals Company Ltd).

[2] Noncash royalty revenue pursuant to our agreement with Healthcare Royalty Partners III, L.P. (HC Royalty). HC Royalty receives royalty payments from United Therapeutics Corporation (United Therapeutics) based on net product sales of United Therapeutics' product Orenitram. Supernus records noncash royalty based on such product sales.

2019 Compared to 2018. Royalty revenue increased by approximately $1.1 million, or 13%, in 2019 as compared to 2018, due to increased product sales of Mydayis and Orenitram.

Cost of Goods Sold

The following table provides information regarding our cost of goods sold for the years indicated (dollars in thousands):

				2019 vs 2018 Change		2018 vs 2017 Change	
	2019	2018	2017	Dollar	Percent	Dollar	Percent
Cost of goods sold	$ 16,660	$ 15,356	$ 15,215	$ 1,304	9%	$ 141	1%

2019 Compared to 2018. The year over year increase in cost of goods sold was attributable primarily to higher volume of products sold to our customers.

Research and Development Expenses

The following table provides information regarding our research and development (R&D) expenses for the years indicated (dollars in thousands):

				2019 vs 2018 Change		2018 vs 2017 Change	
	2019	2018	2017	Dollar	Percent	Dollar	Percent
Research and development expense	$ 69,099	$ 89,209	$ 49,577	$ (20,110)	(23)%	$ 39,632	80%

2019 Compared to 2018. R&D expenses decreased by $20.1 million in 2019 as compared to 2018, primarily driven by the completion of the four Phase III clinical trials for SPN-812 in late 2018/early 2019, and the one-time $14 million expense incurred in 2018 due to the acquisition of Biscayne Neurotherapeutics Inc. These reductions were partially offset by the cost to manufacture registration/validation materials for SPN-812 to support the NDA filing for SPN-812 and commercial sales if the NDA is approved.

Selling, General and Administrative Expense

The table below provides information regarding our selling, general and administrative (SG&A) expenses for the years indicated (dollars in thousands):

				2019 vs 2018 Change		2018 vs 2017 Change	
	2019	2018	2017	Dollar	Percent	Dollar	Percent
Selling and marketing expense	$ 113,609	$ 121,645	$ 104,072	$ (8,036)	(7)%	$ 17,573	17%
General and administrative expense	44,816	38,243	33,833	6,573	17%	4,410	13%
Total	$ 158,425	$ 159,888	$ 137,905	$ (1,463)	(1)%	$ 21,983	16%

Selling and Marketing Expense

2019 Compared to 2018. Selling and marketing expenses decreased by $8.0 million in 2019 as compared to 2018, primarily as a result of decreased professional and consulting expenses of $4.3 million and decreased sample expense of $3.1 million to support our existing commercial products.

General and Administrative Expense

2019 Compared to 2018. General and administrative (G&A) expenses increased by $6.6 million in 2019 as compared to 2018, primarily due to higher employee-related expenses of $3.6 million, including $2.3 million in share-based compensation, and an increase of $1.6 million in professional and consulting fees.

Other (Expense) Income

The following table provides the components of other (expense) income during the years indicated (dollars in thousands):

				Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
Interest income	$ 21,623	$ 13,843	$ 2,864	$ 7,780	$ 10,979
Interest expense	(18,207)	(13,840)	(134)	(4,367)	(13,706)
Interest expense on nonrecourse liability related to sale of future royalties	(4,500)	(4,271)	(1,434)	(229)	(2,837)
Changes in fair value of derivative liabilities	—	—	76	—	(76)
Loss on extinguishment of debt	—	—	(295)	—	295
Total	$ (1,084)	$ (4,268)	$ 1,077	$ 3,184	$ (5,345)

Interest Income

2019 Compared to 2018. The year over year increase in interest income, $7.8 million, was primarily due to an increase in cash, cash equivalents and marketable securities holdings. The increase in securities holdings primarily resulted from the net proceeds of the March 2018 0.625% 2023 Convertible Senior Note issuance (2023 Notes), with a principal amount of $402.5 million.

Interest Expense

2019 Compared to 2018. Interest expense in 2019 increased by $4.4 million, as compared to 2018, because of full year interest expense recognized in 2019 on the 2023 Notes issued in March 2018.

Interest Expense on Non-recourse Liability Related to Sale of Future Royalties

2019 Compared to 2018. Noncash interest expense related to our nonrecourse royalty liability remained generally unchanged, from 2018 to 2019.

Income Tax Expense

The following table provides information regarding our income tax expense during the periods indicated (dollar in thousands):

				Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
Income tax expense	$ 34,431	$ 29,183	$ 43,334	$ 5,248	$ (14,151)
Effective tax rate	23.3%	20.8%	43.1%		

2019 Compared to 2018. The increase in income tax expense was primarily due to a low effective tax rate in 2018 as the effective tax rate was favorably impacted by employee stock option exercises. The 2019 effective tax rate is favorably impacted by a decrease in our uncertain tax position reserve due to expiring statute of limitations and partially offset by an increase in our state effective tax rates due to an increase in the number of states in which we owe taxes.

Net Earnings

The following table provides information regarding our income tax expense during the periods indicated (dollar in thousands):

				2019 vs 2018 Change		2018 vs 2017 Change	
	2019	2018	2017	Dollar	Percent	Dollar	Percent
Net earnings	$ 113,056	$ 110,993	$ 57,284	$ 2,063	2%	$ 53,709	94%

2019 Compared to 2018. The increase in net earnings was primarily due to revenue generated from the sale of our two commercial products. Trokendi XR and Oxtellar XR, partially offset by decreased R&D and SG&A spending and increased income tax expense.

Liquidity and Capital Resources

We have financed our operations primarily with cash generated from product sales, supplemented by revenues from royalty and licensing arrangements as well as proceeds from the sale of equity and debt securities. Continued cash generation is highly dependent on the commercial success of our two commercial products, Trokendi XR and Oxtellar XR.

We were cash flow positive and profitable from operations in 2019. While we expect continued profitability for future years, we anticipate there may be significant variability from year to year in our profitability, and particularly as we move forward with the anticipated commercial launch of SPN-812 in 2020, assuming FDA approval.

We believe our existing cash and cash equivalents, marketable securities and cash received from product sales will be sufficient to finance ongoing operations, development of our new products, and label expansions for existing products. To continue to grow our business over the long-term, we plan to commit substantial resources to: product development and clinical trials of product candidates; product acquisition; product in-licensing; and supportive functions such as compliance, finance, management of our intellectual property portfolio, information technology systems and personnel. In each case, spending would be commensurate with the growth of the business.

We may, from time to time, consider raising additional capital through: new collaborative arrangements; strategic alliances; additional equity and/or debt financings; or financing from other sources, especially in conjunction with opportunistic business development initiatives. We will continue to actively manage our capital structure and to consider all financing opportunities that could strengthen our long-term financial profile. Any such capital structure may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

Financial Condition

Cash and cash equivalents, marketable securities, long term marketable securities, working capital, convertible notes and total stockholder's equity as of the periods presented below are as follows (dollars in thousands):

				Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
Cash and cash equivalents	$ 181,381	$ 192,248	$ 100,304	$ (10,867)	$ 91,944
Marketable securities	165,692	163,770	39,736	1,922	124,034
Long term marketable securities	591,773	418,798	133,638	172,975	285,160
Total	$ 938,846	$ 774,816	$ 273,678	$ 164,030	$ 501,138
Working capital	$ 312,057	$ 332,134	$ 105,451	$ (20,077)	$ 226,683
Convertible notes, net (2023 Notes)	$ 345,170	$ 329,462	$ —	$ 15,708	$ 329,462
Total stockholder's equity	$ 595,428	$ 453,023	$ 267,480	$ 142,405	$ 185,543

2019 Compared to 2018

Total cash and cash equivalents, marketable securities and long term marketable securities increased in 2019 as compared to 2018 by $164.0 million, primarily due to cash generated from operations in 2019.

Working capital decreased in 2019 as compared to 2018 by $20.1 million, primarily due to increased investment in long term marketable securities in 2019.

As of December 31, 2019, the outstanding principal on the 2023 Notes was $402.5 million. No 2023 Notes were converted as of December 31, 2019. Contemporaneous with the issuance of the 2023 Notes, the Company also entered into separate convertible note hedge transactions (collectively, the Convertible Note Hedge Transactions), issuing 402,500 convertible note hedge options. The Convertible Note Hedge Transactions are expected to reduce the potential dilution of the Company's common stock upon conversion of the 2023 Notes. Concurrently with entering into the Convertible Note Hedge Transactions, the Company also entered into separate warrant transactions, issuing a total of 6,783,939 warrants (the Warrant Transactions). See Note 9, *Convertible Senior Notes Due 2023* in the Notes to the Consolidated Financial Statements for further discussion of the 2023 Notes and our other indebtedness.

Stockholders' equity increased in 2019 as compared to 2018 by $142.4 million, as a result of net earnings of $113.1 million, unrealized gains on marketable securities of $10.6 million, issuance of common stock of $3.9 million and share-based compensation of $14.8 million.

Summary of Cash Flows

The following table summarizes the major sources and uses of cash for the periods set forth below (dollars in thousands):

	December 31,		
	2019	2018	2017
Net cash provided by (used in):			
Operating activities			
Operating earnings	$ 142,516	$ 133,720	$ 90,930
Working capital	613	(4,734)	23,710
Total operating activities	143,129	128,986	114,640
Investing activities	(157,924)	(413,480)	(86,415)
Financing activities	3,928	376,438	5,681
Net change in cash and cash equivalents	$ (10,867)	$ 91,944	$ 33,906

Operating Activities

Net cash provided by operating activities is comprised of two components: cash provided by operating earnings; and cash provided by (used in) changes in working capital. The net cash provided by operating activities, $143.1 million, was primarily driven by increased operating earnings, reduced by incremental cash absorbed by increased working capital.

Cash utilized in working capital reflects the timing impacts of cash collections on receivables and settlement of payables, as described below.

The changes in certain operating assets and liabilities are as follows (dollars in thousands):

	Years Ended December 31,			
	2019	2018	2017	Explanation of Change
(Increase) Decrease in:				*2019 Compared to 2018*
Accounts receivable	$ 15,751	$ (35,856)	(24,059)	Receivables decreased in 2019 because of channel inventory reduction in first quarter 2019.
Inventories	(969)	(9,355)	497	Increased inventory to support increased product demand.
Prepaid expenses, other current assets and other non-assets	(2,864)	(2,367)	(3,566)	Timing differences related to deposits for equipment purchases and prepaid expenses for new clinical trials costs.
Increase (Decrease) in:				
Accounts payable and accrued other noncurrent liabilities	3,151	6,854	2,268	Timing of vendor payments.
Accrued product returns and rebates	566	38,720	26,400	Timing of product rebate payments; impact of channel inventory reduction in first quarter 2019; increased provision due to greater utilization of patient co-pay program and higher per patient Medicaid rebates, managed care rebates, and patient co-pay payments.
Income taxes payable	(9,934)	(3,561)	15,931	Increased current tax provision due to increased state taxes and higher taxable income.
Other	(5,088)	831	6,239	Decreased employee-related costs.
Total	$ 613	$ (4,734)	23,710	

Investing Activities

2019 Compared to 2018. Net cash used in investing activities decreased by $255.6 million, from $413.5 million in 2018 to $157.9 million in 2019, for the year ended December 31, 2019. This year over year change was driven by changes in the net purchase of marketable securities. In 2018, proceeds from the issuance of the 2023 Notes in March 2018 were used to purchase marketable securities and long term marketable securities.

Financing Activities

2019 Compared to 2018. Net cash provided by financing activities decreased to $3.9 million for the year ended December 31, 2019 versus $376.4 million provided in the same period in 2018. This year over year decrease is primarily attributable to the issuance of the 2023 Notes in March 2018, coupled with the related convertible note hedges and warrants.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2019, except as noted below (dollars in thousands):

Contractual Obligations	FY2020	FY2021 - FY2022	FY2023 - FY2024	Thereafter	Total
2023 Convertible Notes	$ —	$ —	$ 402,500	$ —	$ 402,500
Interest on 2023 Convertible Notes[(1)]	2,516	5,031	629	—	8,176
Operating Leases[(2)]	4,212	7,727	5,124	26,784	43,847
Purchase Obligations[(3)]	215,240	4,524	25	84	219,873
Total[(4)(5)]	$ 221,968	$ 17,282	$ 408,278	$ 26,868	$ 674,396

(1) Relates to the 2023 Notes (see Note 9 in the Notes to consolidated Financial Statements in Part II, Item 8 of this report.)

(2) Our commitments for operating leases relate to our leases of office equipment, fleet vehicles and the lease of the current headquarters office and laboratory space, as of December 31, 2019.

(3) Relates primarily to agreements and purchase orders with contractors and vendors.

(4) This table does not include (i) any milestone payments which may become payable to third parties under license agreements or contractual agreements regarding our clinical trials or those which may become payable upon achieving sales and developmental milestones per contractual agreements, as the timing and likelihood of such payments are not known, (ii) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known, and (iii) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

(5) As of December 31, 2019, we had liabilities related to uncertain tax positions. Due to uncertainties in the timing of potential tax audits, the timing and the amounts associated with the resolution of these positions is uncertain. As such, we are unable to make a reasonably reliable estimate regarding the timing of payments beyond 12 months. Liabilities related to uncertain tax positions are not included in the above table.

In addition to the table above, we are contractually obligated to pay to HC Royalty all royalty payments earned by us under a licensing agreement with United Therapeutics for Orenitram. Although we have recorded a liability of $22.5 million as of December 31, 2019 related to this obligation, it is a non-recourse liability for which we have no obligation to make any cash payments to HC Royalty, under any circumstances. Accordingly, this obligation has no impact on our liquidity at any time. The non-recourse liability has not been included in the table above.

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

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

For a discussion of new accounting pronouncements, see Note 2 in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve our capital to fund operations and to facilitate business development activities. We also seek to maximize income from our investments without assuming significant interest rate risk, liquidity risk or risk of default by investing in investment grade securities, with maturities of four years or less. Our exposure to market risk is confined to investments in cash, cash equivalents, marketable securities and long term marketable securities. As of December 31, 2019, we had unrestricted cash, cash equivalents, marketable securities and long term marketable securities of $938.8 million.

In connection with the 2023 Notes, we have separately entered into Convertible Note Hedge Transactions and Warrant Transactions to reduce the potential dilution of the Company’s common stock upon conversion of the 2023 Notes, and to partially offset the cost to purchase the Convertible Note Hedge Transactions, respectively.

Our cash and cash equivalents consist primarily of cash held at banks, certificates of deposit and money market funds, and have short-term maturities. Our marketable securities consist of investments in commercial paper, investment grade corporate and U.S. government agency and state debt securities, which are reported at fair value. We generally hold these securities to maturities of one to four years. Because of the relatively short period that we hold our investments and because we generally hold these securities to maturity, we do not believe that an increase in interest rates would have any significant impact on the realizable value of our investments. We do not have any currency or other derivative financial instruments other than outstanding warrants to purchase common stock and the convertible note hedges.

We may contract with CROs and investigational sites globally. Currently, we have only one ongoing trial, for SPN-817, outside the U.S. We do not hedge our foreign currency exchange rate risk. Transactions denominated in currencies other than the U.S. dollar are recorded based on exchange rates at the time such transactions arise. As of December 31, 2019 and December 31, 2018, substantially all of our liabilities were denominated in the U.S. dollar.

Inflation generally affects us by increasing our cost of labor and the cost of services provided by our vendors. We do not believe that inflation and changing prices over the years ended December 31, 2019 and 2018 had a significant impact on our consolidated results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Supernus Pharmaceuticals, Inc.
Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Supernus Pharmaceuticals, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Supernus Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of earnings, comprehensive earnings, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 28, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Change in Accounting Principal

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2018, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*. This change was adopted using the modified retrospective method.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgment. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of the Company's accrued product returns

As disclosed in notes 2 and 8 to the consolidated financial statements, the Company has recorded an accrual of $18.8 million in accrued product returns in current liabilities as of December 31, 2019. The related provision for product returns is reflected as a reduction of gross products sales, and is recorded at the time of sale when the customer takes title to the product. Sale of the Company's products are not subject to a general right of return; however, the Company will accept return of expired product six months prior to and up to 12 months subsequent to the product's expiry date. The Company's products have a shelf life of up to 48 months from date of manufacture.

We identified the evaluation of accrued sales deductions related to product returns, and specifically the assessment of the expected long-term return rates, as a critical audit matter. The assessment of the expected long-term return rates involved a high degree of auditor judgment due to the significant passage of time between product sale and the time at which the Company issues credit on expired product. As a result, a high degree of auditor judgment was required to evaluate the expected long-term return rates as compared to actual returns experience.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's product returns accrual process to develop the expected long-term return rate assumptions used in estimating the accrued product returns. We assessed the Company's long-term return rate assumptions by evaluating the consistency of those assumptions with the trend of actual historical return rates. We compared prior period expected long-term return rate assumptions against actual return rates experience.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

Baltimore, Maryland
February 28, 2020

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Supernus Pharmaceuticals, Inc.:

Opinion on Internal Control Over Financial Reporting

We have audited Supernus Pharmaceuticals, Inc. and subsidiaries (the Company) internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of earnings, comprehensive earnings, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements), and our report dated February 28, 2020 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

Baltimore, Maryland
February 28, 2020

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 181,381	$ 192,248
Marketable securities	165,692	163,770
Accounts receivable, net	87,332	102,922
Inventories, net	26,628	25,659
Prepaid expenses and other current assets	11,611	8,888
Total current assets	472,644	493,487
Long term marketable securities	591,773	418,798
Property and equipment, net	17,068	4,095
Intangible assets, net	24,840	31,368
Lease assets	21,279	—
Deferred income taxes	32,063	29,683
Other assets	615	380
Total assets	1,160,282	977,811
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	10,141	3,195
Accrued product returns and rebates	107,629	107,063
Accrued expenses and other current liabilities	37,130	36,535
Income taxes payable	2,443	12,377
Nonrecourse liability related to sale of future royalties; current portion	3,244	2,183
Total current liabilities	160,587	161,353
Convertible notes, net	345,170	329,462
Nonrecourse liability related to sale of future royalties; long term	19,248	22,575
Lease liabilities, long term	30,440	—
Other liabilities	9,409	11,398
Total liabilities	564,854	524,788
Stockholders' equity		
Common stock, $0.001 par value; 130,000,000 shares authorized; 52,533,348 and 52,316,583 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	53	52
Additional paid-in capital	388,410	369,637
Accumulated other comprehensive earnings (loss), net of tax	7,417	(3,158)
Retained earnings	199,548	86,492
Total stockholders' equity	595,428	453,023
Total liabilities and stockholders' equity	1,160,282	977,811

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Earnings

(in thousands, except share and per share data)

	Years Ended December 31,		
	2019	**2018**	**2017**
Revenue			
Net product sales	$ 383,400	$ 399,871	$ 294,097
Royalty revenue	9,355	8,276	6,367
Licensing revenue	—	750	1,774
Total revenues	392,755	408,897	302,238
Costs and expenses			
Cost of goods sold	16,660	15,356	15,215
Research and development	69,099	89,209	49,577
Selling, general and administrative	158,425	159,888	137,905
Total costs and expenses	244,184	264,453	202,697
Operating earnings	148,571	144,444	99,541
Other (expense) income			
Interest expense	(22,707)	(18,111)	(1,568)
Interest income, net	21,623	13,843	2,645
Total other (expense) income	(1,084)	(4,268)	1,077
Earnings before income taxes	147,487	140,176	100,618
Income tax expense	34,431	29,183	43,334
Net earnings	$ 113,056	$ 110,993	$ 57,284
Earnings per share			
Basic	$ 2.16	$ 2.13	$ 1.13
Diluted	$ 2.10	$ 2.05	$ 1.08
Weighted-average shares outstanding			
Basic	52,412,181	51,989,824	50,756,603
Diluted	53,816,754	54,098,872	53,301,150

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Earnings

(in thousands)

	Years Ended December 31,		
	2019	2018	2017
Net earnings	$ 113,056	$ 110,993	57,284
Other comprehensive earnings (loss)			
Unrealized gain (loss) on marketable securities, net of tax	10,575	(2,411)	(613)
Other comprehensive earnings (loss)	10,575	(2,411)	(613)
Comprehensive earnings	$ 123,631	$ 108,582	$ 56,671

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity

For the Years Ended December 31, 2017, 2018 and 2019

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Earnings (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2016	49,971,267	$ 50	$ 276,127	$ (134)	$ (84,288)	$ 191,755
Cumulative-effect of adoption of ASU 2016-09	—	—	211	—	181	392
Balance, January 1, 2017	49,971,267	50	276,338	(134)	(84,107)	192,147
Share-based compensation	—	—	8,433	—	—	8,433
Issuance of employee stock purchase plan shares	71,256	—	1,888	—	—	1,888
Exercise of stock options	407,477	—	3,793	—	—	3,793
Equity issued on conversion of convertible notes	864,850	1	4,547	—	—	4,548
Net earnings	—	—	—	—	57,284	57,284
Unrealized loss on marketable securities, net of tax	—	—	—	(613)	—	(613)
Balance, December 31, 2017	51,314,850	51	294,999	(747)	(26,823)	267,480
Cumulative-effect of adoption of ASC 606	—	—	—	—	2,322	2,322
Balance, January 1, 2018	51,314,850	51	294,999	(747)	(24,501)	269,802
Share-based compensation	—	—	11,291	—	—	11,291
Issuance of employee stock purchase plan shares	71,250	—	2,209	—	—	2,209
Exercise of stock options	930,483	1	9,372	—	—	9,373
Equity component of convertible notes, net of tax	—	—	56,215	—	—	56,215
Purchase of convertible note hedges, net of tax	—	—	(70,137)	—	—	(70,137)
Issuance of warrants	—	—	65,688	—	—	65,688
Net earnings	—	—	—	—	110,993	110,993
Unrealized loss on marketable securities, net of tax	—	—	—	(2,411)	—	(2,411)
Balance, December 31, 2018	52,316,583	52	369,637	(3,158)	86,492	453,023
Share-based compensation	—	—	14,846	—	—	14,846
Issuance of employee stock purchase plan shares	102,012	1	2,447	—	—	2,448
Exercise of stock options	114,753	—	1,480	—	—	1,480
Net earnings	—	—	—	—	113,056	113,056
Unrealized gain on marketable securities, net of tax	—	—	—	10,575	—	10,575
Balance, December 31, 2019	52,533,348	$ 53	$ 388,410	$ 7,417	$ 199,548	$ 595,428

See accompanying notes.

Supernus Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities			
Net earnings	$ 113,056	$ 110,993	$ 57,284
Adjustments to reconcile net earnings to net cash provided by operating activities:			
Loss on extinguishment of debt	—	—	295
Change in fair value of derivative liability	—	—	(76)
Depreciation and amortization	6,659	7,063	8,132
Noncash operating lease cost	3,566	—	—
Amortization of deferred financing costs and debt discount	15,708	11,848	50
Amortization of premium/discount on marketable securities	(4,335)	(1,665)	(563)
Noncash interest expense	5,775	4,271	1,434
Noncash royalty revenue	(6,927)	(5,914)	(5,283)
Share-based compensation expense	14,846	11,291	8,433
Deferred income tax (benefit) provision	(5,832)	(4,167)	21,224
Changes in operating assets and liabilities:			
Accounts receivable	15,751	(35,856)	(24,059)
Inventories	(969)	(9,355)	497
Prepaid expenses and other current assets	(2,723)	(2,367)	(3,566)
Other noncurrent assets	(141)	—	—
Accounts payable	6,962	(3,578)	(620)
Accrued product returns and rebates	566	38,720	26,400
Accrued expenses and other current liabilities	(3,811)	10,432	2,888
Income taxes payable	(9,934)	(3,561)	15,931
Deferred licensing revenue	—	—	(274)
Other liabilities	(5,088)	831	6,513
Net cash provided by operating activities	143,129	128,986	114,640
Cash flows from investing activities			
Purchases of marketable securities	(409,707)	(491,654)	(101,889)
Sales and maturities of marketable securities	253,170	79,827	28,657
Purchases of property and equipment	(2,736)	(844)	(2,029)
Deferred legal fees	1,349	(809)	(11,154)
Net cash used in investing activities	(157,924)	(413,480)	(86,415)
Cash flows from financing activities			
Proceeds from issuance of convertible notes	—	402,500	—
Convertible notes issuance financing costs	—	(10,435)	—
Proceeds from issuance of warrants	—	65,688	—
Purchases of convertible note hedges	—	(92,897)	—
Proceeds from issuance of common stock	3,928	11,582	5,681
Net cash provided by financing activities	3,928	376,438	5,681
Net change in cash and cash equivalents	(10,867)	91,944	33,906
Cash and cash equivalents at beginning of year	192,248	100,304	66,398
Cash and cash equivalents at end of period	$ 181,381	$ 192,248	$ 100,304
Supplemental cash flow information:			
Cash paid for interest on convertible notes	$ 2,516	$ 1,342	$ 134
Cash paid for Biscayne acquisition	$ —	$ 15,000	$ —
Income taxes paid	$ 51,540	$ 34,772	$ 1,588
Noncash investing and financing activity:			
Conversion of convertible notes and interest make-whole	$ —	$ —	$ 4,548
Deferred legal fees and fixed assets included in accounts payable and accrued expenses	$ 1,832	$ 250	$ 521
Unsettled purchase of marketable securities included in accrued expenses	$ —	$ —	$ 1,004
Property and equipment additions from utilization of tenant improvement allowance	$ 10,151	$ —	$ —

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

1. Organization and Nature of Operations

Supernus Pharmaceuticals, Inc. (the Company) was incorporated in Delaware and commenced operations in 2005. The Company is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company markets two products: Oxtellar XR for the treatment of epilepsy and Trokendi XR for the prophylaxis of migraine headache and the treatment of epilepsy. The Company is also developing multiple proprietary CNS product candidates to address significant unmet medical needs and market opportunities.

The Company launched Oxtellar XR and Trokendi XR for the treatment of epilepsy in 2013, followed by the launch of Trokendi XR for the prophylaxis of migraine headache in adolescents and adults in April 2017. The Company launched Oxtellar XR with an expanded indication to include monotherapy for partial seizures in January 2019.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP).

The Company’s consolidated financial statements include the accounts of: Supernus Pharmaceuticals, Inc.; Supernus Europe Ltd.; Biscayne Neurotherapeutics, Inc. and Biscayne Neurotherapeutics Australia Pty Ltd. These are collectively referred to herein as “Supernus” or “the Company.” All significant intercompany transactions and balances have been eliminated in consolidation.

The Company, which is primarily located in the United States (U.S.), operates in one operating segment.

Use of Estimates

The Company bases its estimates on: historical experience; various forecasts; information received from its service providers and from other sources; and other assumptions that the Company believes are reasonable under the circumstances. Actual results could differ materially from the Company’s estimates. The Company evaluates the methodologies employed in making its estimates on an ongoing basis.

Cash and Cash Equivalents

The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less to be cash equivalents.

Marketable Securities

Marketable securities consist of investments in: U.S. Treasury bills and notes; certificates of deposit; various U.S. governmental agency debt securities; corporate and municipal bonds; and other fixed income securities. The Company places all investments with governmental, industrial or financial institutions whose debt is rated as investment grade.

The Company classifies all available-for-sale marketable securities with maturities greater than one year from the balance sheet date as non-current assets. The Company's investments are furthermore classified as available-for-sale and are carried at fair value.

Any unrealized holding gains or losses on debt securities are reported net of any tax effects as a component of other comprehensive earnings (loss) in the consolidated statement of comprehensive earnings. Realized gains and losses are included in interest income and are determined using the specific identification method for determining the cost of securities sold.

Declines in value judged to be other-than-temporary, if any, are included in the consolidated statement of earnings. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, with that reduction charged to earnings in that period. A new cost basis for the security is then established at the time the reduction is recognized.

2. Summary of Significant Accounting Policies (Continued)

Dividend and interest income is recognized when earned. Premiums and discounts on marketable securities are amortized and accreted, respectively, to maturity and included in interest income in the consolidated statement of earnings.

Accounts Receivable, Net

Accounts receivable are reported on the consolidated balance sheets at outstanding amounts due from customers, less an allowance for doubtful accounts, sales discounts and sales allowances. The Company extends credit without requiring collateral.

The Company writes off uncollectible receivables when the likelihood of collection is remote. The Company evaluates the collectability of accounts receivable on a regular basis. An allowance, when needed, is based upon various factors including: the financial condition and payment history of customers; an overall review of collections experience on other accounts; and economic factors or events expected to affect future collections experience. Payment terms for receivables are based on customary commercial terms and are predominantly less than one year.

The Company recorded zero, $0.1 million and zero for doubtful accounts for the years ended December 31, 2019, 2018 and 2017, respectively. No receivable was written-off for the years ended December 31, 2019, 2018 and 2017.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, marketable securities and accounts receivable. The counterparties are various corporations, governmental institutions, and financial institutions of high credit standing.

Substantially all of the Company's cash and cash equivalents and marketable securities are maintained in U.S. government agency debt and debt of well-known, investment grade corporations. Deposits held with banks may exceed the amount of governmental insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, these bear minimal default risk.

The following table shows the percentage of the Company's sales made to and percentage of accounts receivables from wholesalers and distributors representing more than 10% of the Company's total net product sales and more than 10% of the Company's accounts receivables, net:

	Percentage to Net Product Sales			Percentage to Accounts Receivable, net	
	2019	2018	2017	2019	2018
Customer A	32%	33%	30%	45%	46%
Customer B	32%	33%	30%	21%	24%
Customer C	34%	32%	37%	30%	27%
	98%	98%	97%	96%	97%

Refer to Note 16 for concentration of net product sales.

Inventories

Inventories, which are recorded at the lower of cost or net realizable value, include materials, labor, direct costs and indirect costs and are valued using the first-in, first-out method. The Company writes down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related costs are recognized as *Cost of goods sold* in the consolidated statement of earnings.

2. Summary of Significant Accounting Policies (Continued)

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand when future commercialization of a product is probable and future economic benefit is expected to be realized. The determination to capitalize is based on the particular facts and circumstances relating to the product. Capitalization of such inventory begins when the Company determines that (i) positive results have been obtained for the clinical trials that are necessary to support regulatory approval; (ii) uncertainties regarding regulatory approval have been significantly reduced; and (iii) it is probable that these capitalized costs will provide some future economic benefit in excess of capitalized costs.

In evaluating whether these conditions are met, the Company considers the following: the product's current status in the regulatory approval process; results from the related pivotal clinical trials; results from meetings with relevant regulatory agencies prior to the filing of regulatory applications; compilation of the regulatory application and consequent acceptance by the regulatory body; potential impediments to the approval process such as product safety or efficacy concerns, potential labeling restrictions and other impediments: historical experience with manufacturing and commercializing similar products and the relevant product candidate; and the Company's manufacturing environment including its supply chain in determining logistical constraints that could hamper approval or commercialization. In assessing the economic benefit that the Company is likely to realize, the Company considers the shelf life of the product in relation to the expected timeline for approval and patent related or contract issues that may prevent or delay commercialization and product stability data of all pre-approval production to date to determine whether there is adequate expected shelf life; viability of commercialization taking into account trends in the marketplace and market acceptance; and anticipated future sales and anticipated reimbursement strategies that may prevail with respect to the product.

In applying the lower of cost or net realizable value to pre-launch inventory, the Company estimates a range of likely commercial prices based on comparable commercial products and sales deductions.

The Company could be required to write down previously capitalized costs related to pre-launch inventories upon a change in such judgment, due to, among other potential factors, a denial or significant delay of approval by regulatory bodies, a delay in commercialization or other potential factors.

As of December 31, 2019 and 2018, there was no pre-launch inventory recognized on the consolidated balance sheets.

Intangible Assets

Intangible assets consist of patent defense costs, which are deferred legal fees that have been incurred in connection with legal proceedings related to the defense of patents for Oxtellar XR and Trokendi XR. Patent defense costs are charged to expense in the event of an unsuccessful outcome of the litigation.

Patent defense costs are carried at cost less accumulated amortization, which is calculated on a straight line basis over the estimated useful lives of the patents. Amortization commences in the quarter after the costs are incurred. The amortization period is based initially upon the remaining patent life and is adjusted, if necessary, for any subsequent settlements or other changes to the expected useful life of the patent. Carrying value is assessed for impairment annually during the fourth quarter of each year, or more frequently if impairment indicators exist.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and patent defense costs. The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying value of the asset to determine whether the asset's value is recoverable. Evaluating for impairment requires judgment, including estimating future cash flows, future growth rates and profitability, and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in market conditions could adversely affect impairment analyses, requiring recognition of an impairment charge equal to the excess of the carrying value of the long-lived asset over its estimated fair value at the time at which that determination is made.

2. Summary of Significant Accounting Policies (Continued)

Deferred Financing Costs

Deferred financing costs were incurred by the Company in connection with the issuance of $402.5 million of 0.625% Convertible Senior Notes due 2023 (2023 Notes), (see Note 9). The Company amortizes deferred financing costs over the term of the debt, using the effective interest method.

Revenue Recognition

The Company recognizes revenue when physical control of goods or provision of services are transferred to the Company's customers, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company does not adjust revenue for any financing effects in transactions where the Company expects the period between the transfer of the goods or services and collection to be less than one year.

No contract assets or liabilities were recorded as of or December 31, 2019 or 2018.

Revenue from Product Sales

The Company's customers, who are primarily pharmaceutical wholesalers and distributors, purchase product to fulfill orders from retail pharmacy chains and independent pharmacies of varying size and purchasing power. The Company recognizes gross revenue when its products are physically received by its customers, after shipment from a third party fulfillment center. Customers take control of the products, including title and ownership, upon physical receipt of the products at the customers' facilities.

Product sales are recorded net of various forms of variable consideration, including: estimated liability for rebates; estimated liability for future product returns; and estimated allowance for discounts. These are collectively considered "sales deductions."

As described below, variability in the net transaction price for the Company's products arises primarily from the aforementioned sales deductions. Variable consideration is only recognized when it is probable that a significant reversal will not occur. Significant judgment is required in estimating certain sales deductions. In making these estimates, the Company considers: historical experience; product price increases; current contract prices under applicable payor programs; unbilled claims; processing time lags; and inventory levels in the distribution channel. The Company adjusts its estimates of revenue either when the most likely amount of consideration it expects to receive changes, or when the consideration becomes fixed.

If actual results in the future vary from the estimates, the Company adjusts these estimates. These adjustments could materially affect net product sales and earnings in the period that such adjustments are recorded.

Sales Deductions

The Company records product sales, net of the following sales deductions:

- *Rebates:* Rebates are discounts which the Company pays under either public sector or private sector health care programs. Public sector rebate programs encompass: various Medicaid drug rebate programs; Medicare coverage gap programs; and programs covering public health service institutions and government entities. All federal employees and agencies purchase drugs under the Federal Supply Schedule. Private sector rebate programs include: contractual agreements with managed care providers, under which the Company pays fees to gain access to that provider's patient drug formulary; and Company sponsored programs, under which the Company defrays or eliminates patient co-payment charges that the patient would otherwise be obligated to pay to their managed care provider.

  Rebates paid under public sector programs are generally mandated under law, whereas private sector rebates are generally contractually negotiated by the Company with managed care providers. Both types of rebates vary over time.

2. Summary of Significant Accounting Policies (Continued)

Rebates are owed upon dispensing our product to a patient; i.e., filling a prescription. The accrual balance for rebates consists of the following three components. First, because rebates are generally invoiced and paid quarterly in arrears, the accrual balance consists of an estimate of the amount expected to be incurred for prescriptions dispensed in the current quarter. Second, the accrual balance also includes an estimate for known or estimated prior quarters' unpaid rebates, to cover prescriptions dispensed in past quarters, but for which no invoice has yet been received. Third, the accrual balance includes an estimate for rebates that will be prospectively owed, for prescriptions filled in future quarters. This pertains to product that has been sold to wholesalers or distributors, and which resides either as wholesaler/distributor inventory, or as inventory held at pharmacies, but as of the end of the reporting period, has not been sold to a patient.

The Company's estimates of expected rebate claims vary by program and by type of customer, because the period from the date at which the prescription is filled to the date at which the Company receives and pays the invoice varies substantially. For each of its products, the Company bases its estimates of expected rebate claims on multiple factors, including: historical levels of deductions; contractual terms with managed care providers; actual and anticipated changes in product price; prospective changes in managed care fee for service contracts; prospective changes in co-pay assistance programs; and anticipated changes in program utilization rates (i.e., patient participation rates under each specific program). The Company records an estimated liability for rebates at the time the customer takes title to the product (i.e., at the time of sale to wholesalers/distributors), and records this liability as a reduction to gross product sales, and an increase in *Accrued product returns and rebates*, in current liabilities on its consolidated balance sheets.

The sensitivity of the Company's estimates varies by program and by type of customer. If actual rebates vary from estimated amounts, the Company will adjust the balances of such accrued rebates to reflect actual experience with respect to these programs. These adjustments could materially affect the estimated liability balance, net product sales and earnings in the period in which the adjustment is made.

- *Returns:* Sale of the Company's products are not subject to a general right of return. Product that has been used to fill patient prescriptions is no longer subject to any right of return. However, the Company will accept return of product that is damaged or defective when shipped from its third party fulfillment center.

  The Company will accept return of expired product six months prior to and up to 12 months subsequent to the product's expiry date. Expired or defective returned product cannot be re-sold and is therefore destroyed.

  The Company records an estimated liability for product returns at the time the customer takes title to the product (i.e., at time of sale) as a reduction to gross product sales, and an increase in *Accrued product returns and rebates*, in current liabilities on the consolidated balance sheets. The Company estimates the liability for returns primarily based on the actual returns experience for its two commercial products.

  Because the Company's products have a shelf life of up to 48 months from date of manufacture, and because the Company accepts return of product up to 12 months post expiry, there is a time lag of several years between the time at which the product is sold and the time when the Company issues credit on expired product. Because the Company's returns policy generally permits product returns to be processed at current wholesaler price rather than historical acquisition price, the Company's estimated liability for product returns is affected by price increases taken subsequent to the date of sale.

  When the Company adjusts its estimates for product returns, the adjustment affects the estimated liability, product sales and earnings in the period of adjustment. Those adjustments may be material to our financial results.

- *Sales discounts*: Distributors and wholesalers of the Company's pharmaceutical products are generally offered various forms of consideration, including allowances, service fees and prompt payment discounts for distributing our products. Distributor and wholesaler allowances and service fees arise from contractual agreements, and are estimated as a percentage of the price at which the Company sells product to them. In addition, distributors and wholesalers are offered a prompt pay discount for payment within a specified period. The Company accounts for these discounts at the time of sale, as a reduction to gross product sales, and records these amounts as a valuation allowance against *Accounts receivable* on the consolidated balance sheets.

2. Summary of Significant Accounting Policies (Continued)

Customer orders are generally fulfilled within a few days of receipt, resulting in minimal order backlog. There are no minimum product purchase requirements.

License Revenue

License and Collaboration Agreements

The Company has entered into collaboration agreements to commercialize both Oxtellar XR and Trokendi XR outside of the U.S. Those agreements include the right to use the Company's intellectual property as a functional license, and generally include an up-front license fee and ongoing milestone payments upon the achievement of certain specific events. These agreements may also require minimum royalty payments, based on sales of products which use the applicable intellectual property.

Up-front license fees are recognized once the license has been executed between the Company and its licensee.

Milestones are a form of variable consideration that are recognized when either the underlying events have transpired (i.e., event-based milestone) or when the sales-based targets have been met by the collaborative partner (i.e., sales-based milestone). Both types of milestone payments are nonrefundable. The Company evaluates whether achieving the milestone is considered probable, and estimates the amount of the milestone to be included in the transaction price using the most likely amount method. The value of the associated milestone is not included in the transaction price if it is probable that a significant revenue reversal would occur. This estimation is based on management's judgment, and may require assessing factors that are outside of the Company's influence, such as: likelihood of regulatory success; availability of third party information; and expected time period until achievement of the event. These factors are evaluated based on the specific facts and circumstances.

Event-based milestones are recognized in the period that the related event, such as regulatory approval, occurs. Milestones that are not within the control of the Company, such as approval from regulatory authorities, or where attainment of the specified event is dependent on the success of a third-party, are not considered probable until the specified event occurs.

Sales-based milestones are recognized as revenue only when the sales-based target is achieved.

There are no guaranteed minimum amounts owed to the Company related to license and collaboration agreements.

Royalty Revenue

The Company recognizes noncash royalty revenue for amounts earned pursuant to our royalty agreement with United Therapeutics Corporation (United Therapeutics). This agreement includes the right to use the Company's intellectual property as a functional license. In 2014, the Company sold certain of these royalty rights to Healthcare Royalty Partners III, L.P. (HC Royalty) (see Note 17, Commitments and Contingencies). Sales by United Therapeutics results in payments made by United Therapeutics to HC Royalty, in accordance with these agreements. As a result, the Company recorded a nonrecourse liability related to this transaction, and amortizes this amount as noncash royalty revenue. The Company records noncash royalty revenue based on estimated product sales by United Therapeutics (see Note 16). The Company also recognizes noncash interest expense related to this liability and accrues interest expense at an effective interest rate (see Note 10). The interest rate is determined based on projections of HC Royalty's rate of return.

Royalty revenue also includes royalty amounts received from collaboration partners, including from Shire Plc (Shire, a subsidiary of Takeda Pharmaceutical Company Ltd), based on net product sales in the current period of Shire's product, Mydayis. Royalty revenue is only recognized when the underlying product sale by Shire occurs. The Shire arrangement also includes Shire's right to use the Company's intellectual property as a functional license.

No guaranteed minimum amounts are owed to the Company related to any of these royalty revenue agreements.

Cost of Goods Sold

The cost of goods sold consists primarily of: materials; third-party manufacturing costs; freight and distribution costs; direct labor; and manufacturing overhead costs, including quality control and assurance.

2. Summary of Significant Accounting Policies (Continued)

Research and Development Expenses and Related Accrued Research and Development Expenses

Research and development expenditures are expensed as incurred. These expenses include: salaries, benefits and share-based compensation; contract research and development services provided by third parties; costs for preclinical and clinical studies; cost of acquiring or manufacturing clinical trial material; regulatory costs; facilities costs; depreciation expense and other allocated expenses; and license fees and milestone payments related to in-licensed products and technologies. Assets acquired that are used for research and development and that have no future alternative use are expensed as in-process research and development.

The Company estimates preclinical and clinical trial expenses based on the services performed pursuant to contracts with research institutions, clinical investigators, clinical research organizations (CROs) and other service providers that perform services on the Company's behalf. In recording service fees, the Company estimates the cost of those services which have been performed on behalf of the Company during the current period, and compares those costs with the cumulative expenses recorded and payments made for such services. As appropriate, the Company accrues additional service fees, or defers any nonrefundable advance payments, until the related services are performed. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts its accrued expenses, or its deferred advance payments, accordingly. If the Company subsequently determines that it no longer expects the services associated with a nonrefundable advance payment to be rendered, the remaining portion of that advance payment is charged to expense in the period in which such determination is made.

Share-Based Compensation

The Company recognizes share-based compensation expense over the service period using the straight-line method. Employee share-based compensation is measured based on estimated fair value as of the grant date, using the Black-Scholes option-pricing model in calculating the fair value of option grants as of the grant date. The Company uses the following assumptions for estimating fair value of option grants:

Fair Value of Common Stock—The fair value of the common stock underlying the option grants is determined based on observable market prices of the Company's common stock.

Expected Volatility—Volatility is a measure of the amount by which the Company's share price has historically fluctuated or is expected to fluctuate (i.e., expected volatility) during a period. Beginning in the first quarter of 2019, the Company began using the historical volatility of its common stock to measure expected volatility. Prior to the first quarter of 2019, volatility was estimated using the observed volatility of the common stock of several public entities of similar size, complexity, and stage of development, as well as taking into consideration the Company's actual volatility since the Company's IPO in 2012.

Dividend Yield—The Company has never declared or paid dividends, and has no plans to do so in the foreseeable future.

Expected Term—This is the period of time during which options are expected to remain unexercised. Options have a maximum contractual term of ten years. Beginning in the first quarter of 2019, the Company began estimating the average expected life of stock options using its historical experience. Prior to the first quarter of 2019, the Company determined the average expected life of stock options according to the "simplified method", as described in Staff Accounting Bulletin 110, which is the mid-point between the vesting date and the end of the contractual term.

Risk-Free Interest Rate—This is the observed U.S. Treasury Note rate as of the week each option grant is issued, with a term that most closely resembles the expected term of the option.

Expected Forfeiture Rate—Forfeitures are accounted for as they occur.

2. Summary of Significant Accounting Policies (Continued)

Self-Insurance Liabilities

As of January 1, 2019, the Company self-insures its employee medical insurance liability. The self-insurance liability is undiscounted and is determined actuarially, is based on claims filed, historical and industry claims experience, and an estimate of claims incurred but not yet paid. The Company has established stop-loss amounts that limit the Company's further exposure after any individual claim reaches the designated stop-loss threshold, which effectively transfers any additional liability to a third party. The stop-loss limit for self-insured employee medical claims is $150,000 per employee per year.

The Company recorded a self-insurance liability of approximately $600,000 as of December 31, 2019 in *Accrued expenses and other current liabilities* on the consolidated balance sheets.

Leases

On January 1, 2019, the Company adopted Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842) (New Lease Standard) using the modified retrospective transition approach. We applied the new standard to all leases existing at the date of initial application. Results and disclosure requirements for reporting periods beginning after January 1, 2019 are presented consistent with Topic 842, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Topic 840.

The Company elected the package of practical expedients permitted under the transition guidance, which, among other things, allowed the Company to carryforward the historical lease classification, the assessment on whether a contract was or contains a lease, and the initial direct costs for any leases that existed prior to January 1, 2019. The Company also elected to combine the lease and non-lease components, and to keep leases with an initial term of 12 months or less off the balance sheet. We recognize the associated lease payments in the consolidated statements of earnings on a straight-line basis over the lease term. Additionally, for certain equipment leases, we apply a portfolio approach to effectively account for the operating lease right-of-use (ROU) assets and lease liabilities.

The adoption of the New Lease Standard resulted in the recognition of lease assets and lease liabilities as of January 1, 2019 of approximately $4.0 million. The adoption did not impact the beginning retained earnings, or the prior year consolidated statements of earnings and statements of cash flows (see Note 14, *Leases*).

Under Topic 842, the Company determines if an arrangement is a lease at inception. ROU assets and lease liabilities are recognized at commencement date based on the present value of remaining lease payments over the lease term. For this purpose, the Company considers only payments that are fixed and determinable at the time of commencement. The Company calculates the present value of future payments by using an estimated incremental borrowing rate which approximates the rate at which the Company would borrow, on a secured basis and over a similar term. This rate is estimated based on information available at commencement date of the lease, and may differ for individual leases or for portfolios of leased assets.

Some of the Company's leases include options to terminate prior to the end of the lease term, or to extend the lease for one or more years. These options are included in the lease term when it is reasonably certain that the option will be exercised. When determining the probability of exercising such options, the Company considers contract-based, asset-based, entity-based, and market-based factors.

The Company's lease agreements may contain variable costs such as common area maintenance, insurance, real estate taxes or other costs. Variable lease costs are expensed as incurred on the consolidated statements of earnings. The Company's lease agreements generally do not contain any material residual value guarantees or material restrictive covenants.

Leases with an initial term of 12 months or less are not recorded on the balance sheet.

Operating leases are included in *Lease assets*, *Accrued expenses and other current liabilities*, and *Lease liabilities, long term* on the consolidated balance sheets. Lease expense for operating leases is recognized as an operating cost.

2. Summary of Significant Accounting Policies (Continued)

Advertising Expense

Advertising expense includes costs of promotional materials and activities, such as marketing materials, marketing programs and speaker programs. The costs of the Company's advertising efforts are expensed as incurred.

The Company incurred approximately $40.8 million, $43.3 million and $33.8 million in advertising costs for the years ended December 31, 2019, 2018 and 2017, respectively. These expenses are recorded in *Selling, general and administrative expenses* in the consolidated statement of earnings.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities, and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. When appropriate, valuation allowances are established to reduce deferred tax assets to the amounts expected to be realized.

The Company accounts for uncertain tax positions in its consolidated financial statements when it is more-likely-than-not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be estimated as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authorities, assuming full knowledge of the position and relevant facts. The Company's policy is to recognize any interest and penalties related to income taxes as income tax expense in the relevant period.

Recently Issued Accounting Pronouncements

Accounting Pronouncements Adopted

On January 1, 2018, the Company adopted Accounting Standards Update (ASU) No. 2014-9, "Revenue from Contracts with Customers," and has subsequently issued a number of amendments to ASU 2014-9. ASU 2014-9 and all the related amendments are codified in ASC 606, "Revenue from Contracts with Customers" (the New Revenue Standard). The New Revenue Standard provides a comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance.

The Company adopted the new guidance using the New Revenue Standard using the modified retrospective method and applied this method to those contracts which had not been completed as of January 1, 2018. While results for reporting periods beginning after January 1, 2018 are presented under the new guidance, prior period amounts were not adjusted and continue to be reported under the accounting standards in effect for the prior periods. The Company recognized the cumulative effect of initially applying the New Revenue Standard as an adjustment to the opening balance of retained earnings.

The impact of the adoption of the New Revenue standard was as follows:

	December 31, 2018 As Reported	Adjustments	January 1, 2018
Accounts receivable, net	$ 65,586	$ 1,620	$ 67,206
Deferred licensing revenue	287	(287)	—
Deferred licensing revenue, net of current portion	1,149	(1,149)	—
Deferred income taxes (asset)	20,843	(734)	20,109
Accumulated deficit	26,823	(2,322)	24,501

The Company recorded a decrease of $2.3 million to the accumulated deficit as of January 1, 2018 due to the cumulative impact of adopting the New Revenue Standard. The adoption of the New Revenue Standard resulted to the acceleration of both up-front licensing fees from license and collaboration agreements and the acceleration of royalties from sales of licensed product. Under the New Revenue Standard, up-front licensing fees are recognized when the license is delivered to the customer. Royalties from the sale of licensed product will be recognized as the underlying sales of product occur by the licensee. There were no changes in

2. Summary of Significant Accounting Policies (Continued)

the timing of revenue recognition related to net product sales. Adoption of the New Revenue Standard had no material impact on the Company's consolidated financial statements.

On January 1, 2019, the Company adopted Topic 842, as amended, which supersedes the lease accounting guidance under Topic 840, which generally requires lessees to recognize operating and financing lease liabilities and corresponding ROU assets on the balance sheet, and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. The Company adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases. For information regarding the impact of the New Lease Standard adoption, see Significant Accounting Policies - Leases above and Note 14 - *Leases*.

The adoption of the New Lease Standard resulted in the recognition of lease assets and lease liabilities for operating leases as of January 1, 2019 of approximately $4.0 million. Financial reporting for periods on or after January 1, 2019 are presented under the new guidance. Prior period amounts have not been adjusted and continue to be reported in accordance with previous guidance. The standard did not materially impact the Company’s consolidated net earnings and had no impact on cash flows (see Note 14, *Leases*).

New Accounting Pronouncements Not Yet Adopted

ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)* - The new standard, issued in July 2016, requires credit losses on financial assets to be measured as the net amount expected to be collected, rather than based on incurred losses. Further, credit losses on available-for-sale debt securities should be recorded through an allowance for credit losses, limited to the amount by which fair value is below amortized cost. The new standard also requires enhanced disclosure of credit risk associated with respective assets. The Company will adopt the new standard effective January 1, 2020, and expects the adoption will not have a material impact on its consolidated financial statements.

ASU 2018-15, *Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* - The new standard, issued in August 2018, aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or to obtain internal-use software. This includes hosting arrangements that include an internal-use software license. This ASU also requires the implementation costs of a hosting arrangement that is a service contract to be expensed over the term of the hosting arrangement, which includes reasonably certain renewals. The Company will adopt the new standard effective January 1, 2020, and expects the adoption will not have a material impact on its consolidated financial statements.

ASU 2018-18, *Clarifying the Interaction Between Topic 808 and Topic 606* - The new standard, issued in November 2018, clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB’s revenue standard, Topic 606. The Company will adopt the new standard effective January 1, 2020, and expects the adoption will not have a material impact on its consolidated financial statements.

ASU 2018-13, *Changes to Disclosure Requirements for Fair Value Measurements (Topic 820)* - The new standard, issued in August 2018, improved the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements. The Company will adopt the new standard effective January 1, 2020, and expects the adoption will not have a material impact on its consolidated financial statements.

ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* - The new standard, issued in December 2019, simplifies the accounting for income taxes. This guidance will be effective on January 1, 2021 on a prospective basis, with early adoption permitted. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements and will adopt the new standard effective January 1, 2021.

The Company has evaluated all other ASUs issued through the date the consolidated financial statements were issued in this Annual Report on Form 10-K, and believes that no other ASU will have a material impact on the Company's consolidated financial statements.

3. Fair Value of Financial Instruments

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

3. Fair Value of Financial Instruments (Continued)

The fair value of an asset or liability represents the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

The Company reports assets and liabilities measured at fair value using a three level hierarchy that prioritizes the inputs used to measure fair value. The three levels of inputs used to measure fair value are as follows:

- Level 1—Inputs are unadjusted quoted prices in active markets for identical assets. The Company has the ability to access these prices as of the measurement date.
- Level 2—Level 2 securities are valued using third-party pricing sources that apply applicable inputs and other relevant data in their models to estimate fair value. Inputs are quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; inputs other than quoted prices, that are observable for the asset or liability (e.g., interest rates; yield curves); and inputs that are derived principally from or corroborated by observable market data by correlation or by other means (i.e., market corroborated inputs).
- Level 3—Unobservable inputs that reflect the Company's own assumptions. These are based on the best information available, including the Company's own data.

Financial Assets

The Company's financial assets that are required to be measured at fair value on a recurring basis are as follows (dollars in thousands):

		Fair Value Measurements as of December 31, 2019	
	Total Fair value at December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash and cash equivalents			
Cash	$ 78,912	$ 78,912	$ —
Money market funds	102,469	102,469	—
Marketable securities			
Corporate debt securities	165,527	—	165,527
Municipal debt securities	165	—	165
Long term marketable securities			
Corporate debt securities	571,828	254	571,574
U.S. government agency debt securities	19,945	—	19,945
Other noncurrent assets			
Marketable securities - restricted (SERP)	418	3	415
Total assets at fair value	$ 939,264	$ 181,638	$ 757,626

3. Fair Value of Financial Instruments (Continued)

	Total Fair Value at December 31, 2018	Fair Value Measurements as of December 31, 2018	
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash and cash equivalents			
Cash	$ 106,918	$ 106,918	$ —
Money market funds	85,330	85,330	—
Marketable securities			
Corporate debt securities	163,770	245	163,525
Long term marketable securities			
Corporate debt securities	415,650	445	415,205
U.S. government agency debt securities	2,983	—	2,983
Municipal debt securities	165	—	165
Other noncurrent assets			
Marketable securities - restricted (SERP)	326	1	325
Total assets at fair value	$ 775,142	$ 192,939	$ 582,203

Level 1 assets include: cash held at banks; certificates of deposit; money market funds; and investment grade corporate debt securities.

Level 2 assets include: commercial paper; investment grade corporate, U.S. government agency, state and municipal debt securities; other fixed income securities and SERP (Supplemental Executive Retirement Plan) assets. The fair value of the restricted marketable securities is recorded in *Other assets* on the consolidated balance sheets.

There were no level 3 assets as of December 31, 2019 or 2018.

The carrying amounts of other financial instruments, including accounts receivable, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

Unrestricted available-for-sale marketable securities held by the Company are as follows (dollars in thousands):

	December 31, 2019	December 31, 2018
Corporate and U.S. government agency and municipal debt securities		
Amortized cost	$ 747,598	$ 586,726
Gross unrealized gains	10,031	55
Gross unrealized losses	(164)	(4,213)
Total fair value	$ 757,465	$ 582,568

3. Fair Value of Financial Instruments (Continued)

The contractual maturities of the unrestricted available-for-sale marketable securities held by the Company are as follows (dollars in thousands):

	December 31, 2019
Less Than 1 Year	$ 165,692
1 year to 2 years	188,378
2 year to 3 years	201,491
3 years to 4 years	201,904
Greater Than 4 Years	—
Total	$ 757,465

The Company has not experienced any other-than-temporary losses on its marketable securities.

Financial Liabilities

The following table sets forth the Company's financial liabilities that are not carried at fair value (dollars in thousands):

	December 31, 2019		December 31, 2018	
	Carrying Value	Fair Value (Level 2)	Carrying Value	Fair Value (Level 2)
2023 Notes	$ 345,170	$ 366,023	$ 329,462	$ 375,834

The fair value is estimated based on actual trade information, as well as quoted prices provided by bond traders.

4. Inventories

Inventories consist of the following (dollars in thousands):

	December 31, 2019	December 31, 2018
Raw materials	$ 4,582	$ 5,742
Work in process	11,428	7,275
Finished goods	10,618	12,642
	$ 26,628	$ 25,659

5. Property and Equipment

Property and equipment consist of the following (dollars in thousands):

	December 31, 2019	December 31, 2018
Lab equipment and furniture	$ 11,053	$ 8,995
Leasehold improvements	14,217	2,731
Software	2,225	2,181
Computer equipment	1,839	1,313
Construction-in-progress	433	94
	29,767	15,314
Less accumulated depreciation and amortization	(12,699)	(11,219)
Total	$ 17,068	$ 4,095

Depreciation and amortization expense on property and equipment was approximately $1.5 million, $1.9 million, and $1.2 million for the years ended December 31, 2019, 2018 and 2017, respectively.

The Company annually performs an impairment assessment of its property and equipment in the fourth quarter of each year, or earlier if impairment indicators exist. As of December 31, 2019, there were no identified indicators of impairment.

6. Intangible Assets

Intangible assets consist of patent defense costs, which are deferred legal fees incurred in conjunction with defending patents for Oxtellar XR and Trokendi XR. The Company amortizes these costs over the useful life of the respective patents.

The following sets forth the gross carrying amount and related accumulated amortization of the intangible assets (dollars in thousands):

	Weighted-Average Life	December 31, 2019	December 31, 2018
Capitalized patent defense costs	3.01 - 7.25 years	$ 43,375	$ 44,724
Less accumulated amortization		(18,535)	(13,356)
Total		$ 24,840	$ 31,368

U.S. patents covering Oxtellar XR and Trokendi XR will expire no earlier than 2027. As regards Trokendi XR, the Company entered into settlement agreements that allow third parties to enter the market by January 1, 2023, or earlier under certain circumstances.

Amortization expense on intangible assets was approximately $5.2 million, $5.2 million and $6.9 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Anticipated annual amortization expense for intangible assets from 2020 to 2022 is estimated at $5.0 million per year. Anticipated annual amortization expense for intangible assets in 2023 and 2024 is estimated at $2.3 million per year.

The Company annually performs an impairment assessment of its intangible assets in the fourth quarter of each year, or earlier, if impairment indicators exist. As of December 31, 2019, there were no identified indicators of impairment.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (dollars in thousands):

	December 31, 2019	December 31, 2018
Accrued clinical trial costs [1]	$ 13,285	$ 14,034
Accrued compensation	11,223	13,546
Accrued professional fees	3,936	3,706
Lease liabilities, current	2,825	—
Other accrued expenses	5,861	5,249
Total	$ 37,130	$ 36,535

[1] Includes preclinical and all clinical trial-related costs.

8. Accrued Product Returns and Rebates

Accrued product returns and rebates consist of the following (dollars in thousands):

	December 31, 2019	December 31, 2018
Accrued rebates	$ 88,811	$ 85,003
Accrued product returns	18,818	22,060
Total	$ 107,629	$ 107,063

9. Convertible Senior Notes Due 2023

On March 14, 2018, the Company entered into a Purchase Agreement (the Purchase Agreement) with Jefferies LLC, J.P. Morgan Securities LLC and Cowen and Company, LLC, as the initial purchasers (collectively, the Initial Purchasers), in connection with the offering and sale of $350 million aggregate principal amount of 2023 Notes. The Company also granted the Initial Purchasers an over-allotment option to purchase, within a 30-day period, up to an additional $52.5 million principal amount of 2023 Notes, on the same terms and conditions which the Initial Purchasers exercised in full on March 15, 2018. The total principal amount of 2023 Notes was $402.5 million.

On March 19, 2018, the sale of the 2023 Notes was settled, and the 2023 Notes were issued pursuant to an Indenture, dated as of March 19, 2018 (the Indenture), between the Company and Wilmington Trust, National Association, as trustee. The Indenture includes customary terms and covenants, including certain events of default upon which the 2023 Notes may be due and payable immediately. The Indenture governing the 2023 Notes does not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness, or the issuance or repurchase of securities by the Company.

Interest on the 2023 Notes is at an annual rate of 0.625%, payable semi-annually in arrears, on April 1 and October 1 of each year, beginning on October 1, 2018. The 2023 Notes will mature on April 1, 2023, unless earlier converted or repurchased by the Company.

Noteholders may convert their 2023 Notes at their option only in the following circumstances: (1) during any calendar quarter, if the last reported sale price per share of the Company's common stock for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on, and including the last trading day of the immediately preceding calendar quarter, exceeds 130% of the conversion price, or a price of approximately $77.13 per share on such trading day; (2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "measurement period") in which the trading price per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day; (3) upon the occurrence of certain corporate events or distributions on the Company's common stock, as specified in the Indenture; and (4) at any time from and including October 1, 2022, until the close of business on the second scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, cash, shares of the Company's common stock, or a combination of cash and shares of the Company's common stock, at its election, based on the applicable conversion rate. The initial conversion rate is 16.8545 shares per $1,000 principal amount of the 2023 Notes, which represents an initial conversion price of approximately $59.33 per share, and is subject to adjustment as specified in the Indenture.

If a "make-whole fundamental change", as defined in the Indenture occurs, then the Company will in certain circumstances increase the conversion rate for a specified period of time. If a "fundamental change", as defined in the Indenture occurs, then noteholders may require the Company to repurchase their 2023 Notes at a cash repurchase price equal to the principal amount of the 2023 Notes to be repurchased, plus accrued and unpaid interest, if any.

The Company may not redeem the 2023 Notes at its option before maturity.

In the event of conversion, if converted in cash, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2023 Notes will be paid pursuant to the terms of the Indenture. In the event that all of the 2023 Notes are converted, the Company would be required to repay the $402.5 million in principal value and any conversion premium in cash, shares, or any combination of cash and shares of its common stock (at the Company's option).

The 2023 Notes are the Company's senior, unsecured obligations and will be equal in right of payment with the Company's future senior, unsecured indebtedness. The 2023 Notes are senior in right of payment to the Company's future indebtedness that is expressly subordinated to the 2023 Notes. The 2023 Notes are effectively subordinated to the Company's future secured indebtedness, to the extent of the value of the collateral securing that indebtedness, and will be structurally subordinated to all future indebtedness and other liabilities, including trade payables.

Convertible Notes Hedge and Warrant Transactions

Contemporaneously with the pricing of the 2023 Notes on March 14, 2018, and in connection with the exercise of the over-allotment option by the Initial Purchasers on March 15, 2018, the Company entered into separate privately negotiated convertible note hedge transactions (collectively, the Convertible Note Hedge Transactions) with each of the call spread counterparties. The Convertible Note Hedge Transactions cover, subject to customary anti-dilution adjustments substantially similar to those applicable to the 2023 Notes, the number of shares of the Company's common stock underlying the 2023 Notes, as described above. The Company issued 402,500 convertible note hedge options, including options purchased on the exercise of the overallotment option. In the event that shares or cash are deliverable to holders of the 2023 Notes upon conversion at limits defined in the Indenture, counterparties to the convertible note hedges will be required to deliver up to approximately 6.8 million shares of the Company's common stock, or to pay cash to the Company in an amount approximately equivalent to the value that the Company delivers to the holders of the 2023 Notes, based on a conversion price of $59.33 per share. The total cost of the convertible note hedge transactions was $92.9 million.

Concurrently with entering into the Convertible Note Hedge Transactions on each such date, the Company also entered into separate privately negotiated warrant transactions (collectively, the Warrant Transactions) with each of the call spread counterparties, whereby the Company sold to the call spread counterparties warrants to purchase, subject to customary anti-dilution adjustments, up to the same number of shares of the Company's common stock.

The Convertible Note Hedge Transactions and the Warrant Transactions are separate contracts entered into by the Company with the Call Spread Counterparties, and are not part of the terms of the 2023 Notes. These contracts will not affect the noteholders' rights under the 2023 Notes. Holders of the 2023 Notes will not have any rights with respect to the Convertible Note Hedge Transactions or the Warrant Transactions. The Company issued a total of 6,783,939 warrants. The warrants entitle the holder to one share per warrant at an initial strike price of $80.9063 per share of the Company's common stock (subject to adjustment). The Company received proceeds of approximately $65.7 million from the sale of these warrants.

The Convertible Note Hedge Transactions are expected to reduce the potential dilution with respect to the Company's common stock, upon conversion of the 2023 Notes, and/or offset any potential cash payments the Company is required to make in excess of the principal amount of converted 2023 Notes, as the case may be. The Warrant Transactions were entered into to partially offset the cost to the Company of the purchased Convertible Note Hedge Transactions; however, the Warrant Transactions could have a dilutive effect with respect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the Warrant Transactions, exceeds the strike price of the warrants.

As these transactions meet certain accounting criteria under ASC 815-40-25, the convertible note hedges and warrants are recorded in stockholders' equity and are not accounted for as derivatives. The net cost incurred in connection with the convertible note hedges and warrant transactions was recorded as a reduction to additional paid-in capital.

In accordance with accounting guidance on embedded conversion features, the Company valued and bifurcated the conversion option associated with the 2023 Notes from the respective host debt instrument, which is referred to as debt discount. The Company initially recorded the conversion option of $76.4 million in additional paid-in capital. The resulting debt discount of $76.4 million on the 2023 Notes is being amortized to interest expense at an effective interest rate of 5.41% over the contractual term of the 2023 Notes.

The Company incurred approximately $10.4 million of debt financing costs. Approximately $2.0 million of this amount is allocated to the additional paid-in capital. The remainder, $8.4 million, is recorded as deferred costs and is being amortized to interest expense over the contractual term of the 2023 Notes.

The long term debt consists of the following (dollars in thousands):

	December 31, 2019	December 31, 2018
2023 Notes	$ 402,500	$ 402,500
Unamortized debt discount and deferred financing costs	(57,330)	(73,038)
Total carrying value	$ 345,170	$ 329,462

No 2023 Notes were converted as of December 31, 2019.

10. Other (Expense) Income

Other (expense) income consist of the following (dollars in thousands):

	Years Ended December 31,		
	2019	2018	2017
Interest income	$ 21,623	$ 13,843	$ 2,864
Interest expense	(18,207)	(13,840)	(134)
Interest expense on nonrecourse liability related to sale of future royalties	(4,500)	(4,271)	(1,434)
Changes in fair value of derivative liabilities	—	—	76
Loss on extinguishment of debt	—	—	(295)
Total	$ (1,084)	$ (4,268)	$ 1,077

Interest expense includes noncash interest expense related to amortization of deferred financing costs, and amortization of the debt discount on the 2023 Notes, in the amount of $15.7 million and $11.8 million for the years ended December 31, 2019, and 2018, respectively (see Note 9).

11. Stockholders' Equity

Common Stock

The holders of the Company's common stock are entitled to one vote for each share of common stock held.

Stock Option Plan

The Company has adopted the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan, as amended (the 2012 Plan), which is stockholder approved. This plan provides for the grant of stock options and certain other equity awards, including: stock appreciation rights (SARs); restricted and unrestricted stock; stock units; performance awards; cash awards; and other awards that are convertible into or otherwise based on the Company's common stock, to the Company's key employees, directors, consultants and advisors. The 2012 Plan is administered by the Company's Board of Directors and the Company's Compensation Committee of the Board, and provides for the issuance of up to 8 million shares of the Company's common stock. Option awards are granted with an exercise price equal to the closing price of the Company's common stock as of the grant date. Option awards granted to employees, consultants and advisors generally vest in four equivalent annual installments, starting on the first anniversary of the date of the grant. Awards have ten year contractual terms. Option awards granted to the directors generally vest over a one year term, and have a ten year contractual term.

11. Stockholders' Equity (Continued)

Employee Stock Purchase Plan

The Company has adopted the Supernus Pharmaceuticals, Inc. 2012 Employee Stock Purchase Plan, as amended (the ESPP). The ESPP allows eligible employees the opportunity to acquire shares of the Company's common stock at periodic intervals through accumulated payroll deductions. These deductions are applied at the semi-annual purchase dates of June 30 and December 31, to purchase shares of common stock at a discount. Eligible employees may purchase shares at the lower of 85% of the fair market value at either the first day of the purchase period or the fair market value at the end of the purchase period. The ESPP provides for issuance of up to 700,000 shares of the Company's common stock. The Company records compensation expense related to its ESPP.

Share-based Compensation

Share-based compensation expense is as follows (dollars in thousands):

	Years Ended December 31,		
	2019	2018	2017
Research and development	$ 2,599	$ 1,943	$ 1,387
Selling, general and administrative	12,247	9,348	7,046
Total	$ 14,846	$ 11,291	$ 8,433

The fair value of each option award is estimated on the date of the grant, using the Black-Scholes option-pricing model and the assumptions in the following table:

	Years Ended December 31,		
	2019	2018	2017
Fair value of common stock	$22.99 - $37.78	$37.20 - $58.15	$25.30 - $41.00
Expected volatility	61.36% - 63.28%	57.95% - 60.56%	53.61% - 60.60%
Dividend yield	0%	0%	0%
Expected term	5.53 years - 6.18 years	6.25 years	6.25 years
Risk-free interest rate	1.69% - 2.55%	2.69% - 2.85%	1.90% - 2.18%
Expected forfeiture rate	0%	0%	0%

As of December 31, 2019 and 2018, total unrecognized compensation expense was approximately $26.3 million and $22.4 million, respectively. The Company expects to prospectively recognize these expenses over a weighted-average period of 2.52 years and 2.65 years, respectively.

11. Stockholders' Equity (Continued)

The following table summarizes stock option and SAR activity:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding , December 31, 2017	4,280,670	$ 14.50	7.37	$ 108,520
Granted	762,915	$ 39.91		
Exercised	(930,483)	$ 10.07		$ 36,317
Forfeited	(196,139)	$ 25.01		
Outstanding, December 31, 2018	3,916,963	$ 19.98	7.10	$ 57,220
Granted	880,235	$ 36.43		
Exercised	(114,753)	$ 12.90		$ 2,423
Forfeited	(75,886)	$ 34.80		
Outstanding, December 31, 2019	4,606,559	$ 23.05	6.66	$ 27,716
As of December 31, 2019				
Vested and expected to vest	4,606,559	$ 23.05	6.66	$ 27,716
Exercisable	2,598,112	$ 15.68	5.48	$ 25,594

The weighted-average grant date fair value of options granted for the years ended December 31, 2019, 2018 and 2017 was $21.50, $23.43 and $14.35 per share, respectively.

The total fair value of the underlying common stock related to shares that vested during the years ended December 31, 2019, 2018, and 2017 was approximately $10.8 million, $8.3 million and $5.4 million, respectively.

12. Earnings per Share

Basic earnings per share (EPS) is calculated using the weighted-average number of common shares outstanding. Diluted EPS is calculated using the weighted-average number of common shares outstanding, including the dilutive effect of the Company’s: stock option grants; SARs; warrants; ESPP awards; and the 2023 Notes, as determined per the treasury stock method.

Effect of Convertible Notes and Related Convertible Note Hedges and Warrants

In connection with the issuance of the 2023 Notes, the Company entered into Convertible Note Hedge and Warrant Transactions as described further in Note 9, *Convertible Senior Notes Due 2023*. The expected collective impact of the Convertible Note Hedge and Warrant Transactions is to reduce the potential dilution that may occur between the conversion price of $59.33 per share and the strike price of the warrants of $80.9063 per share.

The 2023 Notes and related Convertible Note Hedge and Warrant Transactions are excluded in the calculation of diluted EPS because their inclusion would be anti-dilutive. Specifically, the denominator of the diluted EPS calculation excludes the additional shares related to the 2023 Notes and warrants, because the average price of the Company's common stock was less than the conversion price of the 2023 Notes of $59.33 per share and the strike price of the warrants of $80.9063 per share. Prior to actual conversion, the Convertible Note Hedge Transactions are not considered in calculating diluted earnings per share, as their impact would be anti-dilutive.

12. Earnings per Share (Continued)

In addition to the above described effect of the 2023 Notes and the related Convertible Note Hedge and Warrant Transactions, the Company also excluded the common stock equivalents for outstanding stock-based awards in the calculation of diluted EPS, because their inclusion would be anti-dilutive.

	Years Ended December 31,		
	2019	2018	2017
Stock options	1,145,446	199,982	40,009

The following table sets forth the computation of basic and diluted net earnings per share for the years ended December 31, 2019, 2018 and 2017:

	Years Ended December 31,		
	2019	2018	2017
Numerator, dollars in thousands:			
Net earnings	$ 113,056	$ 110,993	$ 57,284
Adjustments:			
Interest expense on Convertible Senior Secured Notes due 2019	—	—	134
Changes in fair value of derivative liabilities	—	—	(76)
Loss on extinguishment of debt	—	—	295
Loss on extinguishment of outstanding debt, as if converted	—	—	(321)
Total adjustments	—	—	32
Net earnings used for calculation of diluted EPS	$ 113,056	$ 110,993	$ 57,316
Denominator:			
Weighted average shares outstanding, basic	52,412,181	51,989,824	50,756,603
Effect of dilutive securities:			
Shares underlying Convertible Senior Secured Notes due 2019	—	—	285,257
Shares issuable to settle interest make-whole derivatives	—	—	7,012
Stock options and SAR	1,404,573	2,109,048	2,252,278
Total dilutive potential common shares	1,404,573	2,109,048	2,544,547
Weighted average shares outstanding, diluted	53,816,754	54,098,872	53,301,150
Earnings per share, basic	$ 2.16	$ 2.13	1.13
Earnings per share, diluted	$ 2.10	$ 2.05	1.08

13. Income Taxes

The significant components of income tax are as follows (dollars in thousands):

	Years Ended December 31,		
	2019	2018	2017
Current			
Federal	$ 29,333	$ 26,772	$ 18,288
State	10,930	5,621	3,822
Deferred			
Federal	(4,551)	(2,450)	21,493
State	(1,281)	(760)	(269)
Total income tax expense	$ 34,431	$ 29,183	$ 43,334

13. Income Taxes (Continued)

A reconciliation of income tax expense at the U.S. federal statutory income tax rate to annual income tax expense at the Company's effective tax rate is as follows (dollars in thousands):

	Years Ended December 31,		
	2019	2018	2017
Income tax expense computed at U.S. federal statutory income tax rate	$ 30,972	$ 29,437	$ 35,217
State income taxes	7,543	3,674	2,714
Permanent items	1,332	(2,196)	(2,311)
Research and development credits	(2,071)	(3,199)	(2,196)
Uncertain income tax position	(2,992)	716	(1,137)
Effect of U.S. tax law change[(1)]	—	—	9,694
Other	(353)	751	1,353
Income tax expense	$ 34,431	$ 29,183	$ 43,334

[(1)] Due to the 2017 Tax Cuts and Job Act, which lowered the U.S. Corporate income tax rate from 35% to 21% effective January 1, 2018. As a result, existing deferred taxes were remeasured.

13. Income Taxes (Continued)

The significant components of the Company's deferred income tax assets (liabilities) are as follow (dollars in thousands):

	As of December 31,	
	2019	2018
Deferred tax assets:		
Convertible bond hedge	$ 17,197	$ 21,412
Accrued product returns and rebates	15,123	13,205
Accrued compensation and stock based compensation	10,349	8,218
Non-recourse liability related to sale of future royalties	5,320	5,571
Research and development credit carryforwards	3,817	3,817
Amortization of intangibles	4,617	3,289
Net operating loss carryforwards	2,245	2,900
Operating lease liability	8,187	—
Inventory	1,385	499
Alternative Minimum Tax (AMT) credit	926	978
Other	199	1,268
Total deferred tax assets	69,365	61,157
Less: valuation allowance	(11)	(9)
Total deferred tax asset, net of valuation allowance	69,354	61,148
Deferred tax liability:		
Debt discount on 2023 Notes	(14,109)	(17,568)
Patent infringement legal costs	(10,613)	(10,697)
Operating lease assets	(5,237)	—
Depreciation	(2,778)	(236)
IRC Section 481(a) liability	(2,126)	(2,964)
Unrealized gain on marketable securities	(2,428)	—
Total deferred tax liabilities	(37,291)	(31,465)
Net deferred tax assets	$ 32,063	$ 29,683

In assessing the realizability of deferred income tax assets, management considers whether it is more-likely-than-not that some or all of the deferred income tax assets will not be realized. The ultimate realization of the deferred income tax assets is dependent upon the generation of future taxable income during the periods in which the net operating loss (NOL) and tax credit carryforwards are available. Management considers projected future taxable income, the scheduled reversal of deferred income tax liabilities, and available tax planning strategies that can be implemented by the Company in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the NOL and credit carryforwards are available to reduce income taxes payable, management had determined it is more-likely-than-not to realize such net deferred tax assets.

The Company has NOL and other tax credit carryforwards in several jurisdictions. Due to changes in the Company's ownership, the utilization of net operating loss carryforwards and research and development credit carryforwards, that can be used to offset future taxable income, are subject to annual limits in accordance with Internal Revenue Code (IRC) provisions, as well as similar state provisions. In addition, states may also impose other future limitations through state legislation or similar measures. Despite the NOL carryforwards, the Company may incur higher state income tax expense in the future.

As of December 31, 2019, the U.S. federal and state NOL carryforwards amounted to $10.8 million and $9.9 million, respectively, and will expire in various years beginning in 2033. For the year ended December 31, 2019, the Company utilized NOLs of $10.2 million and expects the remaining federal and state NOL carryforwards to become available in the future years.

13. Income Taxes (Continued)

As of December 31, 2019, the Company has available research and development credit carryforwards of $4.2 million, which will become available in 2020 and will expire, if unused, starting in 2026.

The Company is no longer subject to U.S. Federal income tax examinations for years prior to 2016, with the exception that operating loss or tax credit carryforwards generated prior to 2016 may be subject to tax audit adjustment.

The Company accounts for uncertain income tax positions pursuant to the guidance in ASC Topic 740, *Income Taxes*. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. Some uncertain income tax position liabilities have been recorded against the Company's deferred income tax assets to offset such tax attribute carryforwards and other positions that cannot be offset by tax attributes until a liability has been booked.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows (dollars in thousands):

	Years Ended December 31,		
	2019	2018	2017
Balance as of January 1	$ 8,848	$ 8,859	$ 9,299
Gross increases related to current year tax positions	208	1,108	1,178
Gross increases related to prior year tax positions	—	—	947
Gross decreases related to prior year tax positions	(49)	(484)	—
Lapse of statute of limitations	(3,029)	(635)	—
Change in tax rates	—	—	(2,565)
Balance as of December 31	$ 5,978	$ 8,848	$ 8,859

The Company recorded $3.0 million and $0.6 million of tax benefit in 2019 and 2018, respectively, as a result of the expiration of statutes of limitation. The Company also recorded $0.2 million and $0.3 million for uncertain tax positions related to research and development tax credits in 2019 and 2018, respectively. The Company does not anticipate a material impact to the financial statements in the next 12 months as a result of uncertain tax positions and expiring statutes of limitation.

14. Leases

The Company has operating leases for its former headquarters office and lab space at 1550 East Gude Drive in Rockville, MD and for its fleet vehicles. The Company’s existing leases for its former headquarters office and lab space run through April 2020. With respect to the fleet vehicle leases, given the volume of individual leases involved in the overall arrangement, the Company applies a portfolio approach to effectively account for the operating lease assets and liabilities.

New Headquarters Lease

The Company entered into a new lease agreement, effective January 31, 2019, with Advent Key West, LLC (Landlord), for its new headquarters in Rockville, MD (Premises). The term of the new headquarters lease commenced on February 1, 2019 (the Commencement Date) and will continue until April 30, 2034, unless earlier terminated in accordance with the terms of the lease. The lease includes options to extend the lease for up to 10 years. Fixed rent with respect to the Premises began on the Commencement Date; however, the Landlord agreed to a rent abatement from the Commencement Date through April 30, 2020.

The initial fixed rental rate is approximately $195,000 per month for the first 12 months, and will automatically increase by 2% on each anniversary of the Commencement Date. Under the terms of the Lease, the Company provided a security deposit of approximately $195,000, and will be required to pay all utility charges for the Premises in addition to its pro rata share of any operating expenses and real estate taxes. The Company will occupy the Premises upon completion of the build-out of the Premises, which is anticipated to occur in the first half of 2020.

The lease also provides for a tenant improvement allowance of approximately $10.2 million, in aggregate. All tenant improvement allowance have been utilized as of December 31, 2019 (see Note 5). The full amount of the tenant improvement allowance was initially recorded in *Prepaid expenses and other current assets* on the consolidated balance sheets.

Operating lease assets, lease-related assets and lease liabilities as reported on the consolidated balance sheets are as follows (dollars in thousands):

	December 31, 2019
Assets	
Lease assets	$ 21,279
Liabilities	
Accrued expenses and other current liabilities	
Lease liabilities, current	$ 2,825
Noncurrent	
Lease liabilities, long term	30,440
Total lease liabilities	$ 33,265

Operating lease costs are as follows (dollars in thousands):

	December 31, 2019
Fixed lease cost	$ 4,990
Variable lease cost	1,887
Total operating leases cost	$ 6,877

Supplemental cash flow information related to leases is as follows (dollars in thousands):

	December 31,	
	2019	2018
Cash paid for operating leases	$ 5,337	$ 5,196
Lease assets and tenant receivables obtained for new operating leases	35,594	—

Weighted average lease term, and weighted average discount rate for operating leases as of December 31, 2019, are as follows:

Weighted-average remaining lease term (years)	12.48
Weighted-average discount rate	4.39%

Future minimum lease payments under noncancellable operating leases as of December 31, 2019 are as follows (dollars in thousands):

Year ending December 31:	
2020	$ 4,212
2021	4,130
2022	3,597
2023	2,537
Thereafter	29,372
Total future minimum lease payments	$ 43,848
Less: Imputed interest [(1)]	(10,583)
Present value of lease liabilities	$ 33,265

[(1)] Calculated using the interest rate for each lease.

Disclosure Related to Periods Prior to Adoption of the New Lease Standard

Rent expense for the leased facilities and leased vehicles for the years ended 2018 and 2017 was approximately $3.6 million and $2.7 million, respectively.

Future minimum lease payments under noncancelable operating leases as of December 31, 2018 were as follows (dollars in thousands):

Year ending December 31:		
2019	$	3,400
2020		2,287
Thereafter		1,840
Total	$	7,527

15. Accounts Receivable

As of December 31, 2019 and December 31, 2018, the Company recorded allowances of approximately $11.0 million and $11.5 million, respectively, for prompt pay discounts and contractual service fees paid to the Company's customers, who are primarily pharmaceutical wholesalers/distributors.

16. Disaggregated Revenues

The following tables summarize the disaggregation of revenue by nature (dollars in thousands):

	Years Ended December 31,		
	2019	2018	2017
Net product sales			
Trokendi XR	$ 295,214	$ 315,295	$ 226,518
Oxtellar XR	88,186	84,576	67,579
Total net product sales	383,400	399,871	294,097
Royalty revenues	9,355	8,276	6,367
Licensing revenues	—	750	1,774
Total revenues	$ 392,755	$ 408,897	$ 302,238

Trokendi XR accounted for more than 70% of the Company's total net product sales in 2019, 2018 and 2017.

The Company recognized noncash royalty revenue of $6.9 million, $5.9 million and $5.3 million for the years ended December 31, 2019, 2018 and 2017, respectively, consequent to the Company's agreement with HC Royalty (see Note 2).

For the year ended December 31, 2019, revenues recognized from performance obligations related to prior periods (for example, due to changes in transaction price) were not material in the aggregate, to either *Net Product Sales* or to *Royalty Revenue*.

17. Commitments and Contingencies

Product Licenses

The Company has obtained exclusive licenses from third parties for proprietary rights to support the product candidates in the Company's neurology and psychiatry portfolio. Under these license agreements, the Company may be required to pay certain amounts upon the achievement of defined milestones. If these products are ultimately commercialized, the Company is also obligated to pay royalties to third parties, as percentage of net product sales, for each respective product under a license agreement.

Royalty Agreement

In the third quarter of 2014, the Company received a $30.0 million payment pursuant to a Royalty Interest Acquisition Agreement related to the purchase by HC Royalty of certain of the Company's rights under the Company's agreement with United Therapeutics related to the commercialization of Orenitram (treprostinil) Extended-Release Tablets. Full ownership of the royalty rights will revert to the Company if and when a certain cumulative payment threshold is reached, per the terms of the agreement (see Note 2, Note 10 and Note 16).

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

18. Employee Benefit Plan

On January 2, 2006, the Company established the Supernus Pharmaceuticals, Inc. 401(k) Profit Sharing Plan (the 401(k) Plan) for its employees under Section 401(k) of the Internal Revenue Code (Code). Under the 401(k) Plan, all full-time employees who are at least 18 years old are eligible to participate in the 401(k) Plan. Employees may participate starting on the first day of the month following employment. Employees may contribute up to the lesser of 90% of eligible compensation, or the applicable limit, as established by the Code.

The Company matches 100% of a participant's contribution for the first 3% of their salary deferral, and matches 50% of the next 2% of their salary deferral. As determined by the Board, the Company may elect to make a discretionary contribution not exceeding 60% of the annual compensation paid to all participating employees. The Company's contributions to the 401(k) Plan were approximately $2.3 million, $2.1 million, and $1.8 million for the years ended December 31, 2019, 2018 and 2017, respectively.

19. Quarterly Financial Information (unaudited), see accompanying accountants' report

Quarterly financial information for fiscal years 2019 and 2018 are presented in the following table (dollars in thousands), except per share data:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2019				
Revenues	$ 85,474	$ 104,695	$ 102,140	100,446
Total costs and expenses	60,046	62,097	62,411	59,630
Operating earnings	25,428	42,598	39,729	40,816
Net earnings	18,340	32,727	28,860	33,129
Earnings per share, basic	0.35	0.62	0.55	0.63
Earnings per share, diluted	0.34	0.61	0.54	0.62
2018				
Revenues	$ 90,429	$ 99,538	$ 102,996	$ 115,934
Total costs and expenses	59,035	63,818	65,521	76,079
Operating earnings	31,394	35,720	37,475	39,855
Net earnings	26,352	30,737	28,011	25,893
Earnings per share, basic	0.51	0.59	0.54	0.50
Earnings per share, diluted	0.49	0.57	0.52	0.48

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Attached to this Annual Report on Form 10-K as Exhibits 31.1 and 31.2 there are two certifications, termed the Section 302 certifications, one by each of our Chief Executive Officer (CEO) and our Chief Financial Officer (CFO). This Item 9A contains information concerning the evaluation of our disclosure controls and procedures and internal control over financial reporting that is referred to in the Section 302 Certifications. This information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed by us in the reports we file or submit under the Exchange Act has been appropriately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, to allow timely decisions regarding required disclosure.

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2019, the end of the period covered by this report. Based on that evaluation, under the supervision and with the participation of our management, including our CEO and CFO, we concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Management Report on Internal Control over Financial Reporting

Our management, under the supervision and with the participation of the CEO and CFO, is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting is defined in Exchange Act Rule 13a-15(f) as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. The Company's internal control over financial reporting includes those policies and procedures that (1) pertain to the management of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Because of their inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 based on criteria related to internal control over financial reporting described in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO 2013 Framework). Based on management's assessment using these criteria, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2019.

KPMG LLP, an independent registered public accounting firm, has audited the Company's consolidated financial statements included in this Annual Report on Form 10-K and their opinion with respect to the fairness of the presentation of the financial statements is included in this Annual Report on Form 10-K. KPMG has also audited the Company's internal control over financial reporting as of December 31, 2019. Their responsibility is to evaluate whether internal controls over financial reporting was designed and operating effectively. Their report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2019 included in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

Our management, including our CEO and CFO, evaluated changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2019. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 that occurred during the quarter ended December 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2020 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2019.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2020 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2019.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by Item 201(d) of Regulation S-K is set forth below. The remainder of the information required by this Item 12 is incorporated by reference to our definitive proxy statement for our 2020 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2019.

The following table shows the number of securities that may be issued pursuant to our equity compensation plans (including individual compensation arrangements) as of December 31, 2019:

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)	Weighted-average exercise price of outstanding options, warrants and rights(1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column(2))
Equity compensation plans approved by security holders	4,606,559	$ 23.05	1,972,307
Equity compensation plans not approved by security holders	—	—	—
Total	4,606,559	$ 23.05	1,972,307

(1) The securities that may be issued are shares of the Company's Common Stock, issuable upon conversion of outstanding stock options.

(2) The securities that remain available for future issuance are issuable pursuant to the 2012 Equity Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2020 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2019.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference to the similarly named section of our Proxy Statement for our 2020 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2019.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a)(1) Index to consolidated Financial Statements

The Financial Statements listed in the Index to consolidated Financial Statements are filed as part of this Annual Report on Form 10-K. See Part II, Item 8—*Financial Statement and Supplementary Data*.

(a)(2) Financial Statement Schedules

Other financial statement schedules for the years ended December 31, 2019 and 2018 have been omitted since they are either not required, not applicable, or the information is otherwise included in the consolidated financial statements or the notes to consolidated financial statements.

(a)(3) Exhibits

The Exhibits listed in the accompanying Exhibit Index are attached and incorporated herein by reference and filed as part of this report.

ITEM 16: FORM 10-K SUMMARY

None.

EXHIBIT INDEX

Exhibit Number		Description
2.1	†*	Agreement and Plan of Merger, dated September 12, 2018, by and between Supernus Pharmaceuticals, Inc., Supernus Merger Sub, Inc. Biscayne Neurotherapeutics, Inc. and Reich Consulting Group, Inc., as amended by Amendment No. 1, dated September 21, 2018 (incorporated by reference to Exhibit 2.1 to the Form 10-Q filed on November 9, 2018, File No. 001-35518).
3.1	*	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1, File No. 333-184930, as amended on November 14, 2012).
3.2	*	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1, File No. 333-184930, as amended on November 26, 2012).
4.1	*	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
4.2	*	Indenture, dated as of March 19, 2018, between Supernus Pharmaceuticals, Inc. and Wilmington Trust, National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
4.3	*	Form of 0.625% Convertible Senior Note due 2023 (included in Exhibit 4.2).
10.1	*+	2005 Stock Plan and form agreements there under (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.2	*+	Supplemental Executive Retirement Plan (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.3	*+	Employment Agreement, dated as of December 22, 2005, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.4	*+	Stock Restriction Agreement, dated December 22, 2005, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.5	*	Lease, dated as of April 19, 1999, by and between ARE Acquisitions, LLC and Shire Laboratories Inc. (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.6	*	First Amendment to Lease, dated as of November 1, 2002, by and between ARE Acquisitions, LLC and Shire Laboratories Inc. (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.7	*	Second Amendment to Lease, dated as of December 22, 2005, by and among ARE-East Gude Lease, LLC, Shire Laboratories Inc. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).

Exhibit Number		Description
10.8	*	Third Amendment to Lease, dated as of November 24, 2010, by and between ARE-East Gude Lease, LLC and the Registrant (successor-in-interest to Shire Laboratories Inc.) (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.9	†*	Asset Purchase and Contribution Agreement, dated as of December 22, 2005, by and among the Registrant, Shire Laboratories Inc. and Shire plc (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.10	†*	Guanfacine License Agreement, dated as of December 22, 2005, by and among the Registrant, Shire LLC and Shire plc, as amended (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.11	†*	Exclusive License Agreement, dated as of June 6, 2006, by and between the Registrant and United Therapeutics Corporation (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.12	†*	Exclusive Option and License Agreement, dated as of April 27, 2006, by and between the Registrant and Afecta Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.13	†*	Purchase and Sale Agreement, dated as of June 9, 2006, by and between the Registrant and Rune HealthCare Limited (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.14	†*	Exclusive License Agreement, dated as of November 2, 2007, by and between the Registrant and Afecta Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.15	*	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on February 14, 2012.
10.16	*+	Offer Letter, dated June 10, 2005, to Dr. Padmanabh P. Bhatt from the Registrant (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.17	*+	Amended and Restated Employment Agreement, dated February 29, 2012, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.18	*+	Form of Time-Based Incentive Stock Option Agreement under the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on April 11, 2012).
10.19	*+	Form of Non-Statutory Time-Based Stock Option Agreement under the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on April 11, 2012).

Exhibit Number		Description
10.20	*+	Offer letter to Stefan K.F. Schwabe dated June 25, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2012, filed on November 2, 2012, File No. 001-35518).
10.21	†*	Commercial Supply Agreement, dated August 23, 2012, by and among Patheon, Inc. and the Company (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 7, 2013, File No., 001-35518).
10.22	*	Lease Agreement, dated February 6, 2013, by and among ARE-1500 East Gude, LLC and the Company (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K for the period ended December 31, 2012, filed on March 15, 2013, File No. 001-35518).
10.23	†*	Commercial Supply Agreement dated December 15, 2012 by and among Catalent Pharma Solutions, LLC and the Company (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 21, 2013, File No. 001-35518).
10.24	*+	Compensatory Arrangements of Certain Executive Officers for 2020 (incorporated by reference to Item 5.02 of the Form 8-K filed on February 27, 2020, File No. 001-35518).
10.25	*	Royalty Interest Acquisition Agreement, dated July 1, 2014, by and between Supernus Pharmaceuticals, Inc. and HealthCare Royalty Partners III, L.P. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on July 8, 2014, File No. 001-35518).
10.26	*	Security Agreement, dated July 1, 2014, by and between Supernus Pharmaceuticals, Inc. and HealthCare Royalty Partners III, L.P. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on July 8, 2014, File No. 001-35518).
10.27	*+	Form of Executive Retention Agreement (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 18, 2014, File No. 001-35518).
10.28	*+	Amendment to Amended and Restated Employment Agreement, dated August 8, 2014, by and between Supernus Pharmaceuticals, Inc. and Jack Khattar (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on August 11, 2014, File No. 001-35518).
10.29	*	Fourth Amendment to Lease Agreement, dated October 20, 2014, by and between ARE-Acquisitions, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 24, 2014, File No. 001-35518).
10.30	*	First Amendment to Lease Agreement, dated October 20, 2014, by and between ARE-1500 East Gude, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on October 24, 2014, File No. 001-35518).
10.31	*+	Second Amendment to Amended and Restated Employment Agreement, dated March 2, 2016, by and between Supernus Pharmaceuticals, Inc. and Jack Khattar (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on March 4, 2016, File No. 001-35518).
10.32	†*	Settlement Agreement, dated October 14, 2015, by and between Supernus Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the period ended December 31, 2015, filed on March 9, 2016, File No. 001-35518).

Exhibit Number		Description
10.33	*+	Supernus Pharmaceuticals, Inc. Third Amended and Restated 2012 Equity Incentive Plan (incorporated by reference to Appendix A to the Company's Proxy Statement on Form DEF 14A, filed on April 27, 2018, File No. 001-35518).
10.34	*+	Supernus Pharmaceuticals, Inc. Second Amended and Restated 2012 Employee Stock Purchase Plan (incorporated by reference to Appendix B to the Company's Proxy Statement on Form DEF 14A, filed on April 19, 2016, File No. 001-35518).
10.35	†*	Settlement Agreement, dated March 6, 2017, by and between Supernus Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Limited (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2017, filed on May 9, 2017, File No. 001-35518).
10.36	†*	Term Sheet Agreement, dated March 6, 2017, by and between Supernus Pharmaceuticals, Inc., Actavis Laboratories, FL, Inc., Actavis Pharma, Inc., and Watson Laboratories, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2017, filed on May 9, 2017, File No. 001-35518).
10.37	†*	Settlement Agreement, dated March 13, 2017, by and between Supernus Pharmaceuticals, Inc., Actavis Laboratories, FL, Inc., Actavis Pharma, Inc., and Watson Laboratories, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2017, filed on May 9, 2017, File No. 001-35518).
10.38	*	Base Convertible Bond Hedge Transaction, dated March 14, 2018, between Deutsche Bank AG, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.39	*	Base Convertible Bond Hedge Transaction, dated March 14, 2018, between Bank of America, N.A. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.40	*	Base Convertible Bond Hedge Transaction, dated March 14, 2018, between JPMorgan Chase Bank, National Association, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.41	*	Base Issuer Warrant Transaction, dated March 14, 2018, between Deutsche Bank AG, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.42	*	Base Issuer Warrant Transaction, dated March 14, 2018, between Bank of America, N.A. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.5 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.43	*	Base Issuer Transaction, dated March 14, 2018, between JPMorgan Chase Bank, National Association, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.6 to the Form 8-K filed on March 20, 2018, File No. 001-35518).

Exhibit Number		Description
10.44	*	Additional Convertible Bond Hedge Transaction, dated March 15, 2018, between Deutsche Bank AG, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.7 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.45	*	Additional Convertible Bond Hedge Transaction, dated March 15, 2018, between Bank of America, N.A. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.8 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.46	*	Additional Convertible Bond Hedge Transaction, dated March 15, 2018, between JPMorgan Chase Bank, National Association, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.9 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.47	*	Additional Issuer Warrant Transaction, dated March 15, 2018, between Deutsche Bank AG, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.10 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.48	*	Additional Issuer Warrant Transaction, dated March 15, 2018, between Bank of America, N.A. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.11 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.49	*	Additional Issuer Transaction, dated March 15, 2018, between JPMorgan Chase Bank, National Association, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.12 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.50	*+	Third Amendment to Amended and Restated Employment Agreement, dated May 8, 2018, between Supernus Pharmaceuticals, Inc. and Jack Khattar (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on May 11, 2018, File No. 001-35518).
10.51	*+	Form of Amendment to Executive Retention Agreement (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on May 11, 2018, File No. 001-35518).
10.52	*	Lease Agreement, dated January 31, 2019, between Advent Key West, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 5, 2019, File No. 001-35518).
10.53	*	Form of Restricted Stock Unit Award Agreement for Non-Management Directors, issued under the Supernus Pharmaceuticals, Inc., 2012 Equity Incentive Plan, as amended, for grants made to non-management directors (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 27, 2020. File No. 001-35518).
10.54	*	Form of Performance Share Unit Award Agreement, issued under the Amended and Restated Stock Incentive Plan, for grants made to Jack A. Khattar (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on February 27, 2020, File No. 001-35518).
14	*	Code of Ethics (incorporated by reference to Exhibit 14 to the Company's Annual Report on Form 10-K for the period ended December 31, 2012, filed on March 15, 2013, File No. 001-35518).
21	**	Subsidiaries of the Registrant.
23.1	**	Consent of KPMG LLP

Exhibit Number		Description
31.1	**	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	**	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1	**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	**	The following financial information from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, formatted in Inline XBRL: (i) Cover Page; (ii) Consolidated Statement of Earnings; (iii) Consolidated Statement of Comprehensive Earnings; (iv) Consolidated Balance Sheets; (v) Consolidated Statements of Equity; (vi) Consolidated Statements of Cash Flows; and (vii) the Notes to Consolidated Financial Statements, tagged in summary and detail.
104	**	The Cover Page of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, formatted in Inline XBRL (included with the Exhibit 101 attachments).

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† Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the Confidential Treatment Request.

+ Indicates a management contract or compensatory plan, contract or arrangement in which directors or officers participate.

* Previously filed.

** Filed herewith.

SIGNATURES

Pursuant to the requirements of Securities 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SUPERNUS PHARMACEUTICALS, INC.

By: /s/ JACK A. KHATTAR
Name: Jack A. Khattar
Title: *President and Chief Executive Officer*

Date: February 28, 2020

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and the dates indicated below:

Signature	Title	Date
/s/ JACK A. KHATTAR	President and Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2020
/s/ GREGORY S. PATRICK	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 28, 2020
/s/ CHARLES W. NEWHALL, III.	Director and Chairman of the Board	February 28, 2020
/s/ CARROLEE BARLOW, M.D., PH.D.	Director	February 28, 2020
/s/ GEORGES GEMAYEL, PH.D.	Director	February 28, 2020
/s/ FREDERICK M. HUDSON	Director	February 28, 2020
/s/ JOHN M. SIEBERT, PH.D.	Director	February 28, 2020

EXHIBIT 21

SUBSIDIARIES OF SUPERNUS PHARMACEUTICALS, INC.

Name of Subsidiaries	Jurisdiction of Organization
Supernus Europe Ltd.	United Kingdom
Biscayne Neurotherapeutics, Inc.	Delaware
Biscayne Neurotherapeutics Australia Pty Ltd.	Australia

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors

Supernus Pharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statements Nos. 333-181479, 333-201049, 333-216135 on Form S-8, and No. 333-200716 on Form S-3 of Supernus Pharmaceuticals, Inc. of our reports dated February 28, 2020, with respect to the consolidated balance sheets of Supernus Pharmaceuticals, Inc. and subsidiaries as of December 31, 2019 and 2018, and the related consolidated statements of earnings, comprehensive earnings, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the "consolidated financial statements"), and the effectiveness of internal control over financial reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10-K of Supernus Pharmaceuticals, Inc.

Our report on the consolidated financial statements refers to the Company's adoption of Financial Accounting Standards Board (FASB) Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*.

/s/ KPMG LLP

Baltimore, Maryland

February 28, 2020

EXHIBIT 31.1

CERTIFICATION

I, Jack A. Khattar, certify that:

1. I have reviewed this Annual Report on Form 10-K of Supernus Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2020

By: /s/ JACK A. KHATTAR

Jack A. Khattar
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Gregory S. Patrick, certify that:

1. I have reviewed this Annual Report on Form 10-K of Supernus Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2020

By: /s/ GREGORY S. PATRICK

Gregory S. Patrick
Senior Vice President and Chief Financial Officer

EXHIBIT 32.1

SUPERNUS PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. sec. 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Supernus Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jack A. Khattar, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2020

By: s/ JACK A. KHATTAR
Jack A. Khattar
President and Chief Executive Officer

EXHIBIT 32.2

SUPERNUS PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. sec. 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Supernus Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregory S. Patrick, Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2020

By: /s/ GREGORY S. PATRICK

Gregory S. Patrick
Senior Vice President and Chief Financial Officer