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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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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, 2018

COMMISSION FILE NUMBER: 001-35518

or

o **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)
1550 East Gude Drive, Rockville, MD	**(301) 838-2500**	**20850**
(Address of Principal Executive Offices)	(Registrant's telephone number, including area code)	(zip code)

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

TITLE OF EACH CLASS:	**NAME OF EACH EXCHANGE ON WHICH REGISTERED:**
Common Stock, $0.001 Par Value	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 o

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 o 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 o

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 o

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. o

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 o	Non-accelerated filer o	Smaller reporting company o Emerging growth company o

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. o

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

As of June 30, 2018, 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 $3,020,270,520.

The number of shares of the registrant's common stock outstanding as of February 13, 2019 was 52,320,473.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2019 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 2018 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, 2018

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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 *TM* symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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

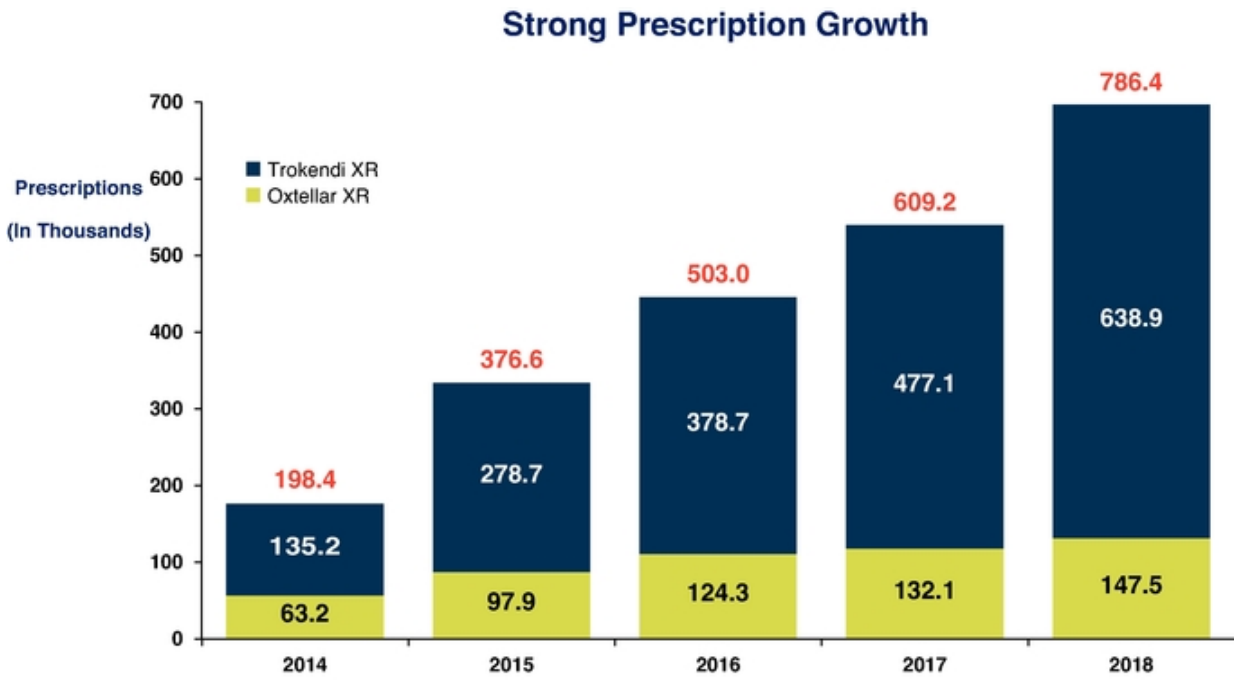
Supernus Pharmaceuticals, Inc. (the Company) was incorporated in Delaware and commenced operations in 2005. The Company became publicly traded in 2012 and is listed on The Nasdaq Stock Exchange under the ticker symbol SUPN. Our principal executive offices are in Rockville, Maryland.

We are a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. 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 and, upon our acquisition of substantially all of the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals.

On October 4, 2018, we acquired Biscayne Neurotherapeutics, Inc. (Biscayne), a privately-held company developing a novel treatment for epilepsy. We obtained worldwide rights, excluding certain markets in Asia where rights have been out-licensed, to Biscayne's product candidate, SPN-817 (huperzine A). SPN-817 is in clinical development and has received an Orphan Drug designation for Dravet Syndrome from the U.S. Food and Drug Administration (FDA).

We 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 December 2018, the FDA approved the Company's supplemental new drug application (sNDA) for Oxtellar XR to include monotherapy treatment of partial onset seizures of epilepsy in adults and in children 6 to 17 years of age. We market our products through our own sales force and seek strategic collaborations with other pharmaceutical companies to license and commercialize our products outside the United States.

Our net product revenues of $399.9 million in 2018 were driven by strong growth in prescriptions for Oxtellar XR and Trokendi XR. Total prescriptions as reported by IQVIA (formerly Intercontinental Marketing Services (IMS)) have shown a steady year over year increase as shown in the following graph.



Source: IQVIA Monthly Prescriptions (as restated by IQVIA for 2017 and 2018)

As of year-end 2018, Trokendi XR represented approximately 5% of the large base of prescriptions for topiramate, and Oxtellar XR represented approximately 3% of the oxcarbazepine market. Total annual prescriptions for the topiramate market and the oxcarbazepine market are approximately 14.6 million and 4.8 million, respectively. We expect to continue to grow our revenues for Oxtellar XR and Trokendi XR by continuing to drive penetration in these markets. We believe these products with their current indications in the neurology market, which include the recently approved monotherapy indication for Oxtellar XR, have the potential to achieve combined annual peak net sales in excess of $500 million.

We are developing multiple proprietary product candidates in the CNS market to address significant unmet medical needs and market opportunities. We are developing SPN-812 (viloxazine hydrochloride) as a novel, non-stimulant candidate to treat patients who have attention deficit hyperactivity disorder (ADHD). In December 2018, we reported favorable results from three of the four pivotal Phase III trials for SPN-812 with data from the fourth trial expected late first quarter 2019. We anticipate filing a new drug application (NDA) with the FDA in the second half of 2019, and to launch SPN-812, pending U.S. Food and Drug Administration approval, in the second half of 2020.

In addition, we are initially developing SPN-810 (molindone hydrochloride) to treat impulsive aggression (IA) in children and adolescents who have ADHD. We plan to subsequently develop SPN-810 for the treatment of IA in other CNS diseases, such as autism, post traumatic stress disorder (PTSD), bipolar disorder, schizophrenia, Alzheimer's and other forms of dementia. There are currently no approved products in the U.S. indicated for the treatment of IA.

Furthermore, we are developing SPN-604 (extended release oxcarbazepine) for the treatment of bipolar disorder, which would be a new indication for oxcarbazepine. Following our acquisition of Biscayne, we are currently developing SPN-817 in severe pediatric epilepsy disorders.

Products and Product Candidates

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

Product	Indication	Status
Oxtellar XR	Epilepsy	In the market
Trokendi XR	Epilepsy	In the market
	Migraine*	In the market
SPN-812	ADHD	Phase III
SPN-810	IA**	Phase III
SPN-604	Bipolar	Phase III***
SPN-809	Depression	Phase II ready
SPN-817	Epilepsy	Phase I

* Prophylaxis of migraine headache in adults and adolescents.

** Initial program is for IA in patients with ADHD, with plans to add other indications, such as IA in patients with autism, PTSD, bipolar disorder, Alzheimer's and other forms of dementia.

*** Phase III clinical program to start in second half of 2019

We have a successful track record of developing and launching novel products by applying proprietary 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 key product candidates SPN-812 and SPN-810.

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

Our Strategy

Our vision is to be 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 are to:

- *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.* We are continuing with the Phase III clinical trials for SPN-812, a novel non-stimulant treatment for ADHD, and with the Phase III clinical trials for SPN-810, a novel treatment for IA in patients who have ADHD. We expect to file an NDA with the FDA for the approval of SPN-812 in second half of 2019.

- *Target 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 such as 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.* We plan to continue to evaluate and develop additional CNS product candidates that we believe have significant commercial potential through our internal research and development efforts.

Our Neurology Portfolio

Our neurology portfolio consists of Oxtellar XR, which is the first and only once-daily extended release oxcarbazepine product indicated for patients with epilepsy, and Trokendi XR, which is the first once-daily extended release topiramate product indicated for patients with epilepsy. We launched Trokendi XR for the prophylaxis of migraine headache in the U.S. market in April 2017. These products differ from immediate release formulations by offering once-daily dosing and unique pharmacokinetic profiles, which we believe can have very positive clinical effects for many patients. We believe a once-daily dosing regimen improves adherence, making it more probable that patients maintain sufficient levels of medication in their bloodstreams to protect against seizures and migraines. In addition, we believe that the unique smooth and steady pharmacokinetic profiles of our once-daily formulations reduce the peak to trough blood level fluctuations, which are typically associated with immediate release products and which may result in increased adverse events (AEs), more side effects and decreased efficacy.

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. Improved tolerability may help patients improve adherence and correspondingly, 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 mechanism of action (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 a MOA that is different from what is currently available and can represent a unique additional treatment alternative for physicians and patients.

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. Improved tolerability may help patients improve adherence, have fewer breakthrough migraines and, correspondingly, help patients enjoy a better quality of life.

Commercial Products

Trokendi XR

Trokendi XR is a once-daily extended release topiramate product indicated for patients with epilepsy and for prevention of migraine headache in the U.S. market, and is designed to improve patient adherence over the current immediate release products which must be taken multiple times per day. 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 headaches in adults and adolescents 12 years of age and older. Trokendi XR's 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 and reduces the likelihood of breakthrough seizures and 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 and migraine headaches.

Oxtellar XR

Oxtellar XR is the only once-daily extended release oxcarbazepine product indicated in the U.S. for treatment of patients with epilepsy. 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 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 adherence compared to the current immediate release products that must be taken multiple times per day.

Product Candidates

SPN-817 (huperzine A)

SPN-817 will utilize a novel synthetic form of huperzine A, whose MOA includes potent acetyl cholinesterase inhibition with pharmacological activities in CNS conditions such as epilepsy. 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 that has been shown in preclinical models for partial seizures and Dravet Syndrome.

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 to study the safety and pharmacokinetic profile of a new extended release formulation of non-synthetic huperzine A.

We will focus on completing and optimizing the synthesis process of the drug and the development of 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 product for commercial use, as well as product for preclinical research and clinical trials.

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

We do not own or operate manufacturing facilities for the production of any of our product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently employ internal resources to manage our manufacturing contractors.

Sales and Marketing

We have a commercial organization in the U.S. to support current and future 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 franchise. Simultaneously promoting two neurology products allows us to leverage our commercial infrastructure.

Assuming we obtain FDA approval for the product candidates currently in our pipeline, we anticipate adding sales representatives to market our products to the relevant population of physicians, primarily psychiatrists.

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, such as anti-CGRP (calcitonin gene related peptide), Botox, beta-blockers, valproic acid and amitriptyline.

Our Psychiatry Portfolio

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

- SPN-812, the most advanced product candidate, is being developed for ADHD. Positive topline data from three successful Phase III clinical trials were reported in 2018, and data from a fourth Phase III trial is expected to be released in late first quarter of 2019.
- SPN-810 has fast track status and is expected to be the first product approved for treatment of IA. Phase III clinical trials are expected to be completed in 2019 in patients 6 years to 11 years old while a trial in adolescents continues into 2020.
- SPN-809 employs the same active ingredient in SPN-812 and is being developed for depression. SPN-809 is Phase II ready.
- SPN-604 is being developed for the treatment of bipolar. Phase III clinical trials are planned to be initiated in the second half of 2019.

ADHD Overview

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States[(1)]. An estimated 50% of children with ADHD continue to meet criteria for ADHD into adolescence[(2)]. Current non-stimulant treatments for ADHD account for about 8% of the total ADHD prescriptions in the U.S. during 2018. The ADHD market is projected to grow at 2% annually, from approximately 74 million prescriptions in 2018 to approximately 78 million prescriptions by 2020. For the year ended December 31, 2018, according to data from IQVIA, the U.S. market for ADHD prescription drugs was $9.1 billion.

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 of what may be behind the underlying symptoms, determine which children meet the diagnosis and should be treated for ADHD.

IA Overview

The ADHD market represented roughly 74 million prescriptions in 2018, growing approximately 2% over 2017. By 2020, we project that the ADHD market will reach approximately 78 million prescriptions. Of these 78 million prescriptions, roughly one-third will be written for patients with IA or with IA and other comorbidities.

IA is not limited to individuals with ADHD. We believe, based on our market research, that IA occurs in patients with other CNS disorders, including autism, Alzheimer's and other forms of dementia, bipolar disorder, PTSD, oppositional defiant disorder, conduct disorder and intermittent explosive disorder. Market research we have conducted indicates that the prevalence of IA in autistic children and adolescents is approximately 45%, and the prevalence of IA in children and adolescents with bipolar disorder is approximately 60%.

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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*.

Current Treatments for IA in Patients with ADHD

Currently, there are no approved medications in the U.S. for the treatment of IA. IA is present in individuals who spontaneously react more aggressively and strongly than normal to stimuli by committing verbal or physical acts against people, property or themselves. Based on our discussions with medical experts, the current treatment options for IA in patients with ADHD include psychosocial interventions, such as school-based or family-based behavioral therapies, which are often not wholly effective. In the large, multisite Multimodal Treatment Study of Children with ADHD[(3)], a seminal clinical trial designed by experts from key stakeholder communities such as the National Institute of Mental Health, researchers observed that after 14 months of either ADHD medication-only or a regimen that combined ADHD medication with behavioral interventions, 44% of those children with ADHD (or 26% of the total sample size in the trial) who initially exhibited aggression still had what can be described as IA at the end of the trial. This demonstrates that psychosocial interventions may not work for a large percentage of children with ADHD who exhibit aggressive behaviors.

In response, doctors have also tried to treat patients with IA by off-label use of prescription medicines, such as mood stabilizers, stimulants and anti-psychotic drugs. Results have varied, but anti-psychotic drugs appear to have the best therapeutic potential. Unfortunately, many of these agents are associated with adverse effects, including obesity, dyskinesia, lipid abnormalities, marked increases in prolactin and increase in diabetes, which is of particular concern when treating pediatric populations. None of these agents are approved for treatment of IA.

Product Candidates

SPN-812 (viloxazine hydrochloride)

We are developing SPN-812 as a novel non-stimulant treatment for ADHD with the potential to address a $9.1 billion market opportunity in the U.S. for the treatment of ADHD. SPN-812, a norepinephrine reuptake inhibitor with selective serotonin modulation activity, would provide an additional option to the few non-stimulant therapies currently available. We believe that SPN-812 could be more effective than other non-stimulant therapies due to its unique pharmacological profile, and offers physicians an alternative to stimulant therapy.

We expect to submit an NDA for SPN-812 in the second half of 2019, and to launch it, pending FDA approval, in the second half of 2020. We expect SPN-812, if approved, to have five year market exclusivity given its NCE status in the U.S. Further, 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.

SPN-812 Development Program

We initiated four Phase III clinical trials for SPN-812 in September 2017, three of which are clinically complete. The program consists of four three-arm, placebo-controlled trials: P301 and P303 trials in patients 6 years to 11 years old and P302 and P304 trials in patients 12-17 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) are expected by the end of the first 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 Phase IIb trials.

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

Results of P301 and P303 Phase III trials

Both studies were randomized, double-blind, placebo controlled, multicenter, parallel group clinical trials in children 6 years to 11 years of age diagnosed with ADHD. Each treatment was administered orally once a day over five weeks in study P301 and seven weeks in study P302, after the titration phase.

A total of 477 patients were randomized in the P301 study across placebo and two doses of SPN-812 (100mg/200mg). A total of 313 patients were randomized in the P303 study across placebo and two doses of SPN-812 (200mg/400mg). The primary objective of both studies was to assess the effect 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 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 that is currently on-going.

On December 6, 2018, we announced positive topline results from our Phase III studies of SPN-812 in children for the treatment of ADHD. The trials were successful in meeting the primary endpoint, demonstrating that SPN-812 at daily doses of 100mg and 200mg in study P301 and 200mg and 400mg in study P303 achieved a statistically significant improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD-RS-5. All SPN-812 doses tested in the trials were well tolerated.

At the end of the P301 Study, SPN-812 100 mg and 200 mg doses reached statistical significance compared to placebo in the primary endpoint. 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. –10.9 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, $p<0.0001$).

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 compared to placebo in the primary endpoint. Patients receiving SPN-812 200 mg and 400 mg had a –17.6 point change ($p=0.0038$) and a –17.5 point change ($p=0.0063$) from baseline, respectively, in the primary endpoint vs. –11.7 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. Similar to 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, SPN-812 200 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 of 2.2% to 4.8%. Treatment related AEs that reported at more than or equal to 5% for SPN-812 were 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 a 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 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 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 (200mg/400mg). 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 that is currently on-going.

At the end of the P302 Study, SPN-812 200 mg and 400 mg doses reached statistical significance compared to placebo in the primary endpoint. Patients receiving SPN-812 200 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. –11.4 for placebo at week 6. This primary result, based on MMRM analysis in the Intent-To-Treat (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 differences compared to placebo starting by week 1, reaching statistical significance at week 3, which was sustained through the rest of the trial. Similar to the P301 and P303 studies, at the end of the P302 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 0.0005 to 0.0424. In addition, SPN-812 200 mg and 400 mg 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 of 1.9% to 4.1%. Treatment related AEs that reported at more than or equal to 5% for SPN-812 were somnolence, fatigue, decreased appetite, headache and nausea.

SPN-810 (molindone hydrochloride)

We are developing SPN-810 as a novel treatment for IA in patients who have ADHD. Molindone hydrochloride was previously marketed in the United States as an anti-psychotic drug to treat schizophrenia in patients, under the trade name Moban, albeit at much higher dosages (up to 225mg/day) than we are using in our development program (36 and 54 mg/day). Moban has not been commercially available since 2010 and the FDA has confirmed that the withdrawal from the

market was not due to issues with safety or efficacy. A generic-equivalent approval is listed in the FDA's Orange Book. Molindone hydrochloride is differentiated from other anti-psychotic drugs in that it is less likely to be associated with weight gain and, in preclinical models, has not caused increases in prolactin levels as seen with other anti-psychotic drugs.

We believe the lower doses tested for the proposed indication of IA in ADHD should be better tolerated than the higher doses approved to treat schizophrenia. If we are successful in developing SPN-810 as a novel treatment for IA in patients who have ADHD, we may then develop the product as a candidate for treating other indications; e.g., patients with IA in autism, PTSD, bipolar disorder, Alzheimer's and other forms of dementia. In the aggregate, we believe the addressable market for SPN-810 is greater than $6.3 billion, including $3.2 billion in ADHD, $0.8 billion in autism and $2.3 billion in PTSD. We are developing IP covering the novel synthesis process for the active ingredient in SPN-810, its novel use in IA and its novel extended release delivery.

SPN-810 Development Program: Phase III Trials

SPN-810 has been granted fast-track designation by the FDA. Our first Phase III clinical trial (P301) was designed under a Special Protocol Assessment (SPA) with the FDA, using a novel measurement scale developed by us. The second Phase III clinical trial (P302), which is also being conducted in children, uses the same trial design of P301 and the same novel measurement scale except that under the SPA, an interim analysis was conducted in the P301 trial. The purpose of the interim analysis was to assess the efficacy of the doses being tested and to allow for optimization of the trial design of both trials. The interim analysis was completed in 2017 and, as a result, we discontinued the 18 mg dose arm. Moving forward, all patients in each of the two trials are randomized to either the 36 mg dose arm or placebo.

The first Phase III trial (P301) has reached its original enrollment target with data originally scheduled to be released in the second quarter of 2019. However, given that the data readout from the second trial (P302) is now expected in the second half of 2019, we have decided to keep enrolling in the P301 trial until data from both trials can be released concurrently instead of sequentially. We believe this change in the plan has no impact on the timing of the NDA filing because the completion of the second Phase III trial (P302) and the generation of data from the adolescent patient population (P503) are now rate-limiting for the NDA filing. We expect to submit the NDA for SPN-810 in the second half of 2020, and to launch it, pending FDA approval, in the second half of 2021.

Patients completing the Phase III trials can continue treatment under our open label extension trial. Enrollment from the P301 and P302 trials into the open label extension trial continues at 90% or higher. On average, a patient in the open label extension study stays on SPN-810 for approximately 10 months, which we believe is an encouraging sign of both tolerability and efficacy of SPN-810.

In addition, patient enrollment began in December 2018 in a Phase III trial for SPN-810 (P503) treating IA in adolescents who have ADHD.

SPN-810 Development Program: Phase II Trials

We completed a Phase IIb multicenter, randomized, double-blind, placebo-controlled trial in the United States in pediatric subjects 6 to 12 years of age diagnosed with ADHD and with IA that is not controlled by optimal stimulant and behavioral therapy. The primary objective of the study was to assess the effect of SPN-810 in reducing IA as measured by the Retrospective-Modified Overt Aggression Scale (R-MOAS) after at least three weeks of treatment. Secondary endpoints included the rate of remission of IA and measurement of the effectiveness of SPN-810 on the Clinical Global Impression (CGI) and ADHD scales as well as evaluation of the safety and tolerability of the drug. Patients who completed the study were offered the opportunity to continue into an open-label phase of six months duration.

Analysis of treatment was performed using both parametric and non-parametric statistical methods. The parametric method assumes that data are normally distributed. Under this method, mean results of each treatment group at the end of three weeks of treatment were compared to the baseline R-MOAS score for each of the four dose groups (high, medium, low and placebo) using the t-test. The non-parametric method does not assume that data are normally distributed. Under this method, the median results of the change in R-MOAS score from baseline at the end of three weeks of treatment were computed for each of the four dose groups (high, medium, low and placebo). These were compared using the Wilcoxon Rank-sum test. Statistical analyses were performed to compare the median of each of the treatment groups (high, medium, and low versus placebo) at the end of three weeks of treatment. The change in score from baseline to visit 10 was used as the outcome variable.

There was a statistically significant difference between the low dose and placebo (p=0.031) and also between the medium dose and placebo (p=0.024) at the a=0.05 level. There was no statistically significant difference between the high dose and placebo. Both the medium dose and low dose were superior to placebo. These results convinced us that both low and medium doses were effective. This range of doses is being further evaluated in the on-going Phase III clinical trials.

A secondary efficacy variable was the proportion of children whose impulsive aggressive behavior remitted, with remission defined as R-MOAS £ 10 at the end of the study. Low and medium doses of SPN-810 showed statistically significant results versus placebo, with the percent of patients who experienced remission of impulsive aggressive behavior of 51.9% (p=0.009) and 40.0% (p=0.043), respectively.

The CGI results (Severity and Improvement) are consistent with the findings on the R-MOAS scale, in that notable improvement (reduction in severity) occurred primarily in the low dose and medium dose groups. Scores on SNAP-IV Hyperactivity and Impulsivity items did not exhibit statistically significant differences across treatment groups, indicating that efficacy against IA was specific, rather than being efficacious against the underlying ADHD. Numerical trends in SNAP-IV Oppositional Defiant Disorder scores, while not always significant, consistently favored the low dose and medium dose groups over placebo.

SPN-810 was well tolerated throughout the study across all doses. Sedation was the most frequently reported adverse reaction, with two subjects (7%) reporting this event in each of the four treatment groups, including the placebo group. The next most frequently reported adverse reaction was increased appetite with two subjects (7%) reporting this event in each of the three active treatment groups and one subject (3%) in the placebo group.

The two serious AEs that occurred were not drug-related. One patient in the low dose arm and two patients in the medium dose arm had severe AEs that were considered either possibly or definitely related to the drug. Six patients in total discontinued the study because of AEs in the active treatment arms: one in low dose; two in medium dose; and three in the high dose arm. AEs requiring dose reduction were infrequent.

The frequency of AEs associated with extra-pyramidal symptoms was also low and the events were reversible. The data are too sparse to evaluate dose-related aspects of these reports; thus, no clear dose-response relationship can be assessed. SPN-810 exhibited a very good safety and tolerability profile, with low incidence of AEs, and no unexpected, life threatening, or dose-limiting safety issues.

The Phase IIb trial with SPN-810, which included 121 patients, showed that there was no meaningful difference in weight gain between patients treated with SPN-810 and those treated with placebo.

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 new drug application

(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. It 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)

We continue to progress our plans to initiate pivotal Phase III studies for the treatment of bipolar disorder in the second half of 2019. If approved, this would represent the first approval for treatment of bipolar patients with oxcarbazepine in the U.S. Recently, we completed certain activities, including market research and claims database analysis on the use of oxcarbazepine in bipolar patients. We will be using information generated from these activities to finalize plans for the pivotal Phase III trials.

We expect to incur significant research and development expenses related to the continued development of each of our product candidates from 2019 through FDA approval or until the program terminates. We incurred total research and development expense of $89.2 million, $49.6 million and $42.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

ADHD Competition

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

Treatment options for ADHD in the U.S. market can be broadly classified as either stimulants or non-stimulants. Shire Plc is one of the leaders in the U.S. ADHD market with four marketed products: Vyvanse, a stimulant drug product launched in 2007; Intuniv, a non-stimulant treatment launched in November 2009; Adderall XR, an extended release stimulant treatment designed to provide once-daily dosing, launched in October 2001; and Mydayis, a stimulant treatment launched in August 2017. Other marketed stimulant products for the treatment of ADHD in the U.S. include the following once-daily formulations: Mydayis, 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 organizations including Sunovion, Ironshore/Highland and Otsuka to develop additional treatment options for ADHD. Sunovion recently filed its non-stimulant product, dasotraline, with the FDA in September of 2017 for treatment of adults, children and adolescents with ADHD and received a non-approvable letter. In 2018, Ironshore/Highland received FDA approval of Jornay PM, a new stimulant product that is expected to be launched in 2019.

Our Proprietary Technology Platforms

We have a successful track record of developing novel, products by applying proprietary technologies to known drugs to improve existing therapies and to enable the treatment of new indications. Our key proprietary technology platforms include Microtrol, Solutrol and EnSoTrol. These technologies create novel, customized product profiles designed to enhance efficacy, reduce the frequency of dosing, and improve patient compliance and tolerability. We have employed our technologies in the development of a total of ten products that are currently on the market, including Trokendi XR and Oxtellar XR, along with eight products being marketed by our partners. Trokendi XR uses the Microtrol multiparticulate delivery platform and 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 in 2014. Microtrol was utilized to develop Mydayis, which was launched by Shire in 2017.

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 and Trokendi XR. We seek patent protection, where appropriate, in the U.S. and internationally for our products and product candidates. 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, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

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

We have established and continue to build proprietary positions for Oxtellar XR, Trokendi XR, our pipeline product candidates and our technologies in the U.S. and abroad.

Patents for both Oxtellar XR and Trokendi XR have received numerous challenges, in the form of Paragraph IV Notice Letters and we have filed claims for infringement of our patents against the third-parties. On Oxtellar XR, the Company prevailed in its litigation against the 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 on 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

Our extended release oxcarbazepine patent portfolio currently includes eleven U.S. patents, eight of which cover Oxtellar XR. We have also obtained two patents each for extended release oxcarbazepine in Europe and Australia, and one patent each in Canada, Japan, China and Mexico. In addition, we have certain pending U.S. patent applications that cover various extended release formulations containing oxcarbazepine. The eight issued U.S. patents covering Oxtellar XR will expire no earlier than 2027. We own all of the issued patents and the pending patent applications.

In addition to the patents and patent applications relating to Oxtellar XR, we currently have nine U.S. patents that cover Trokendi XR. We have one patent issued each in Mexico, Australia, Japan and Canada for extended release topiramate. We also have two patents issued in Europe for extended release topiramate. The nine issued U.S. patents covering Trokendi XR will expire no earlier than 2027. We own all of the issued patents and pending patent applications.

Our patent portfolio also contains patent applications relating to our other pipeline products.

With regard to our SPN-810 product candidate, we are developing an IP position covering the novel process of synthesis of the active ingredient, its novel use in IA and novel formulation. We have four families of pending U.S. non-provisional and foreign counterpart patent applications relating to our SPN-810 product candidate. Patents, if issued, could have terms expiring from 2029 to 2033. We have

two patents issued in the U.S., and one patent issued each in Canada, Mexico, Europe, Australia and Japan, covering modified release formulations of molindone hydrochloride. In another patent family, covering the novel process of synthesis of the active ingredient, we have four patents issued in the U.S, two patents issued in Japan, and one patent issued each in Europe, Mexico, and Australia. The third patent family, covering use of molindone hydrochloride in treating aggression, includes three patents issued in the U.S., two patents issued each in Japan and Austrailia, and one patent issued in Canada. We own all of the issued and pending patent applications.

With regard to our SPN-812 product candidate, 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. In another family, covering the novel process of active ingredient synthesis, 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 three patents issued in the U.S. covering modified release formulations of viloxazine and one patent issued in Japan, Mexico and Australia. We own all of the issued patents and the pending patent applications.

The U.S. patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by 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 by patent term adjustment (PTA), which compensates a patentee for administrative delays by the USPTO in granting a patent. In view of a recent court decision, the USPTO is under greater scrutiny regarding its calculations of PTAs because the USPTO erred in calculating the PTA in that case, which resulted in denying the patentee a portion of the patent term to which it was entitled. Alternatively, a patent's term may be shortened if a patent is terminally disclaimed over another patent.

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 is prior art. If certain requirements are satisfied, a non-provisional patent application can claim the benefit of the filing date of an earlier filed provisional patent application. As a result, the filing date accorded by the provisional patent application may supersede information that otherwise could preclude the patentability of an invention.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension (PTE), which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA or other regulatory approval, we may be able to apply for PTEs on patents covering those products. Depending upon the timing, duration and specifics of FDA approval of our SPN-810 and SPN-812 product candidates and issuance of a U.S. patent, we may obtain a U.S. patent that is eligible for limited patent term restoration.

Other Intellectual Property Rights

We seek trademark protection in the 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 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 a lawsuit pending against TWi Pharmaceuticals Inc. to enforce our patent rights concerning Oxtellar XR patents. 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 an adverse outcome in litigation, we could be prevented from commercializing a product or using certain aspects of our technology platforms if patent infringement claims are asserted against us. This could have a material adverse effect on our business. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize products or use technologies that are similar to ours, and then compete directly with us, without payment to us. See Part I, Item 1A Risk Factor: "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

Afecta Pharmaceuticals, Inc.

We have two license agreements with Afecta Pharmaceuticals, Inc. (Afecta) pursuant to which we obtained exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. We may pay up to $300,000 upon the achievement of certain milestones. If a product candidate is successfully developed and commercialized, we will be obligated to pay royalties to Afecta at a rate in the low-single digits, based on worldwide net product sales.

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 to Rune at a rate in the low-single digits, based on worldwide net sales.

SPN-817

We obtained worldwide rights, excluding certain markets in Asia where rights have been out-licensed, to SPN-817, which has received an 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. We may be obligated to pay additional payments if certain milestones are met including $73 million contingent on achieving certain development milestones and up to $95 million contingent upon achieving certain sales milestones. 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 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 or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions resulting from work performed for us or relating to our business and conceived or completed by the individual during employment or assignment, as applicable, shall be our exclusive property to the extent permitted by applicable law.

We seek to protect our 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. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information are submitted to the FDA as part of the approval process for a new drug, filed as an NDA. The NDA requests approval to market the product. The submission of an NDA is subject to the payment of a substantial user fee, although a waiver of such fee may be obtained under certain limited circumstances.

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 and complete preclinical, clinical and manufacturing information. The 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 that has been already approved by the FDA for the same or a different indication. For a 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 interprets Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

We will need to file a Section 505(b)(1) NDA for SPN-812 and for certain products in the future. A 505(b)(1) NDA for SPN-812 carries a higher degree of regulatory approval risk than a 505(b)(2) NDA. In addition, a requirement for more extensive testing and development for some other reason can adversely impact our ability to compete with alternative products that arrive on the market more

quickly than our product candidate. In addition, the time and financial resources required to obtain FDA approval for SPN-812 could substantially and materially increase. After Supernus gains one approval for SPN-812, additional indications may be considered for NDA applications using the 505(b)(2) regulatory pathway. The FDA may not approve of our filing under Section 505(b)(2) for SPN-812 for other indication(s), such as PTSD, and therefore would require a full NDA filing. In such a case, the time and financial resources required to obtain approval could also significantly increase.

In addition, under the Pediatric Research Equity Act of 2003 (PREA), which was reauthorized under the Food and Drug Administration Safety and Innovation Act of 2012, an NDA must contain, *a priori*, or propose clinical work that supports the product's use in all relevant pediatric subpopulations. The FDA may grant deferrals for submission of data or full or partial waivers of the data requirements.

Pursuant to the FDA's approval of Oxtellar XR, we committed to conduct 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 gained knowledge about our abilities to create formulations and successfully execute programs that would enable us to meet our deferred pediatric commitments. We have identified a need to renegotiate the commitments made at the time of NDA approvals for both Oxtellar XR and Trokendi XR. Supernus is actively interfacing with the FDA on these programs and these commitments.

Section 505(b)(2) New Drug Applications

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that 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, such as, for example, five-year exclusivity for obtaining approval of an NCE, or three year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the referenced product, has expired.

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.

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

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited 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 the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the drug. The 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 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. Such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness, without 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, or 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 patent protection for a drug. This six month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial. The current pediatric exclusivity provision was reauthorized in September 2007.

Customers

The majority of our product sales are to wholesalers and distributors who, in turn, sell the products to pharmacies, hospitals and other customers, including federal and state entities. Three customers, AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation, individually accounted for more than 30% of our total revenue in 2018, and collectively accounted for 98% of our total revenue in 2018.

Employees

As of December 31, 2018, we employed 448 full-time employees; 104 employees are engaged in research and development activities and 344 employees are engaged in selling, general and administrative activities. 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). You may request, orally or in writing, a copy of these filings, which will be provided to you at no cost, by contacting our investor relations department at our principal executive offices, which are located at 1550 East Gude Drive, Rockville, Maryland 20850. 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 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 Business and Industry

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

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.

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 inventory 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 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, including therapeutically equivalent 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. In addition, we have expressed certain long term revenue expectations. If 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.

Increases in sales of Oxtellar XR or Trokendi XR may slow for a variety of reasons, including competing products or safety issues. If we are not successful in broadening the current commercial acceptance of either Oxtellar XR or Trokendi XR, our business would be harmed.

Any increase in sales of Oxtellar XR and Trokendi XR will be dependent on several factors, including our ability to educate physicians and to increase physician awareness and 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 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;
- The prevalence, nature, and severity of any adverse side effects;
- Availability of alternative treatments including branded and generic products; and
- Pricing and cost effectiveness.

In addition, 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 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.

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. For example, we 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 ANDA product. These matters included claims related to Oxtellar XR, and are discussed in Part I, Item 3—*Legal Proceedings*.

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

Interference proceedings brought by the 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 those of our collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us or at all. Litigation or interference proceedings may fail. Even if successful, litigation may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators,

misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In addition, there could be public announcements of the results of hearings, motions or other interim proceeding or developments. If securities analysts or investors perceive these results to be negative, 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.

We are dependent on obtaining regulatory approval of our product candidates and for additional indications for existing products.

Our ability to successfully commercialize any of our product candidates and to obtain additional indications for existing products will depend on, among other things, our ability to:

- Successfully complete our clinical trials;
- Receive marketing approvals from the FDA;
- Produce, through a validated process, sufficiently large quantities of our product candidates to permit successful clinical development and commercialization;
- Establish commercial manufacturing arrangements with third-party manufacturers;
- Build and maintain strong sales, distribution and marketing capabilities sufficient to commercially launch our product candidates;
- Secure acceptance of our product candidates from physicians, health care payors, pharmacies, wholesalers, patients and the medical community; and
- Manage our spending as costs and expenses increase due to undertaking clinical trials and commercially launching product candidates.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize any of our product candidates in a timely manner, or at all, in which case we may be unable to maximize our revenues. In addition, if we experience unanticipated delays or problems, development costs could substantially increase and our business, financial condition and results of operations would likely be adversely affected.

Our clinical trials for our product candidates may fail to demonstrate acceptable levels of safety, efficacy or any 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 to obtain 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 or perform 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

and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

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, our clinical development programs might be terminated.

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

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

- Difficulties 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;
- Delays in reaching or failure to reach agreement on acceptable terms with prospective Clinical Research Organization (CRO) trial sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly;
- Insufficient or inadequate supply or quantity of a product candidate for use in trials;
- Difficulties obtaining Investigational Research Board (IRB) or ethics committee approval to conduct a trial at a prospective site;
- Challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;
- Severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- Difficulty retaining patients who have enrolled in a clinical trial but 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
- Clinical trials may be delayed as a result of ambiguous or negative interim results.

Clinical trials may be suspended or terminated by us, at a trial site by a Data Safety Monitoring Board (DSMB) or ethics committee overseeing the clinical trial, the FDA, or other regulatory authorities due to a number of factors, including:

- Failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols;
- Observations during inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that ultimately result in the imposition of a 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 costs, 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 of, or if we terminate any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues 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 and 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 as a whole.

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, infant 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, SPN-810, SPN-812 (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-810, SPN-812, 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 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 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 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 or are unable to do so in a timely manner, we may not be able to generate sufficient product revenues from these product candidates to be profitable.

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

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the 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 and 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 a prior approval supplement 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 of our product candidates;
- Could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;
- May not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- May disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials, the outcome and measurement scale used in the trials, and 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 manufactured product candidates 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; or

- 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 success

- May not approve the addition of new indications to the label of our existing products.

Notwithstanding the approval of many products by the FDA pursuant to Section 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 significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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

Our ability or our collaborators' ability to successfully commercialize our products, including Oxtellar XR and Trokendi XR and our product candidates, 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 also 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 and the amount of reimbursement for particular medications or 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 at what level. Moreover, they will consider the efficacy and cost effectiveness of comparable or competitive 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 that could require us to provide scientific or clinical support for the use of each of our products or product candidates separately to each third-party payor. In some cases, it could take several months or years before a particular private insurer or managed care organization reviews a particular product. We may ultimately be unsuccessful in obtaining coverage. Our competitors may, as well as more extensive existing business relationships with third-party payors relating to their products. Our business would be materially adversely affected if we do not receive approval for reimbursement of our products or product candidates from private insurers on a timely or satisfactory basis. Our products and product candidates may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products or product candidates on a profitable basis. Our business would also be adversely affected if private insurers, managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which our products or product candidates will be reimbursed.

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 six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products or product candidates, 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 price of products and establish formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. If our products or product candidates are not included within an adequate number of formularies or at adequate payment or reimbursement 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 to experience pricing pressures due to potential healthcare reforms discussed elsewhere in this Annual Report on Form 10-K, as well as due to cost control measures instituted by health maintenance organizations.

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 several years completing the development of a particular current or future internal product candidate, during which process we can experience failure at any stage. 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 technology 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.

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 approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or 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 resources to potential acquisitions or 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;
- Incurring substantial debt or dilutive issuances of securities or depletion of cash to pay for acquisitions;
- Incurring higher than expected acquisition, integration, and operating costs;
- Difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- Impairing relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- An inability 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, manufacturing of our compounds and product candidates beyond Phase II clinical trials and the manufacturing 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 CROs and CMO, 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, 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 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 suppliers and manufacturers for the production and packaging 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, necessary quality standards for our development or commercialization products would be adversely affected. Further, if we were required to change vendors, it could result in substantial delays in our regulatory approval

efforts and significantly increase our costs. Accordingly, the loss of any of our current or future third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition and business prospects.

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 may receive approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate AEDs in the U.S. For example, Upsher-Smith launched Qudexy XR (extended release topiramate) and a branded generic version of Qudexy XR. Upsher Smith also entered into settlement with a generic company to launch a generic to Qudexy XR in 2020, and with another generic company to enter the market at a date that is unknown to us. Such generics could adversely impact the sales or prescriptions for Trokendi XR or result in an earlier entry of generics to Trokendi XR. In addition, since Trokendi XR was not granted marketing exclusivity by the FDA, we may not be able to prevent the submission or approval of another Full NDA for a competitor's extended or controlled release topiramate product candidate. However, we do 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 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., and 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.

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, which prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such exclusivity, however, would not prevent the approval of another application if the applicant submits a Full NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product or Section 505(b)(2) product that did not incorporate the exclusivity-protected changes of the approved drug product.

Under the Hatch-Waxman Amendments, newly-approved drugs and indications may also benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Amendments provide five-year marketing exclusivity to the first applicant to gain approval of an NDA for an NCE, meaning that the FDA has not previously approved any other drug containing the same 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. 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. Our future revenues could be reduced, possibly materially.

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.

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 the first FDA approval for the drug and indication for which it has orphan drug designation, the drug is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of 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 intend to continue to expand our designation for these 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 may result from a competing product reaching the market that has 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 the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Also, a competitor may receive approval of different products for the same indication for which our orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, 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 the 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 a showing of 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, and 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.

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

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 necessary 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 transitions involving key employees and members of our management team could hinder our strategic planning and execution. In addition, our failure to adequately plan for succession of senior management and 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 and 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 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.

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 competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products and product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. The availability of new products or approval for 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 with 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 the commercialization process for these products.

There are currently no marketed products and no known products in development for the treatment of IA in patients with ADHD, autism or PTSD. However, the off-label use of risperidone (Risperdal) and aripiprazole (Abilify) to treat these conditions is common. These products are approved for irritability in autism which, as a result, may influence use of products to treat IA in patients with ADHD.

In addition, we are aware of several companies that have various product candidates under development for ADHD which may compete with our SPN-812 product candidate. Such companies include Sunovion, Ironshore/Highland and Otsuka.

Further 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 realize revenues from their commercialization. Further, many competitors have substantially greater:

- Capital resources;
- Research and development resources and experience, including personnel and technology;
- Drug development, clinical trial and regulatory resources and experience;

- Sales and marketing resources and experience;
- Manufacturing and distribution resources and experience;
- Name recognition; and
- Resources, experience and expertise in prosecution and enforcement of intellectual property rights.

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

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 still impose significant restrictions on their indicated uses or marketing or impose ongoing requirements for costly post-approval studies. For example, both Trokendi XR and Oxtellar XR were approved on the basis of post-approval commitments, including development of additional age-appropriate formulations of the drugs and conduct of post-approval clinical studies in accordance with certain timelines laid out in the approval letters. Although we have made significant efforts, in certain cases we have been unable to meet these timelines. The post-approval commitments required the creation of new drug product formulations, which we have not been able to accomplish. To date, the only consequence of our failure to meet our PREA commitment deadlines has been a notation on FDA websites devoted to 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.

Our product candidates would also be, and our approved product and our collaborators' approved products are subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing 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 the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing.

If we or our collaborators, or our or our collaborators' approved products or product candidates, or the manufacturing facilities for our or our collaborators' approved products or product candidates fail to comply with applicable regulatory requirements, a regulatory authority may:

- Issue warning letters or untitled letters;
- Impose civil or criminal penalties;
- Suspend regulatory approval;
- Suspend any ongoing bioequivalence and/or clinical trials;
- Refuse to approve pending applications or supplements to applications filed by us;
- Impose restrictions on operations, including costly new manufacturing requirements, or suspension of production 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 our 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 uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we are found to have promoted off-label uses, we may be enjoined from such off-label promotion and become subject to significant liability, which would have an adverse effect on our reputation, business and revenues.

Further, the FDA's policies may change and 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 the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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 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 for commercial products in the foreseeable future. We currently depend on third-party CMOs for the supply of the APIs 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. 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.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Pharmaceutical companies often encounter difficulties in manufacturing, particularly in scaling up production of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, stability of the product and quality assurance testing and shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to maintain or obtain 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 foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for such product candidate or successfully commercialize such products, and 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, and consequently lose potential revenues.

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 to wholesalers and distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2018, three wholesale pharmaceutical distributors, AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation, individually accounted for more than 30% of our total revenue in 2018, and collectively accounted for 98% of our total revenue in 2018. The loss by us 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, and, as a result, may continue to increase 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 carry. We monitor wholesaler 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 inventory level reports. For other wholesalers where we do not receive inventory level 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 (requiring us to hold substantial quantities of unsold inventory), inadequate supplies of products in distribution channels, and/or insufficient product available 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 or the expectations of securities analysts or investors.

In addition, at times, wholesaler purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters, which 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.

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 materially, permanently and adversely impact our revenues, profitability and cash flows from those products and substantially limit our ability to obtain a return on the investments we have made in our products and product candidates. In particular, as disclosed in Part I, Item 3—*Legal Proceedings* of this Annual Report on Form 10-K, we had received Paragraph IV Notice Letters against our Oxtellar XR Orange Book patents from Twi Pharma. In August 2017, the U.S. District Court ruled in our favor against TWi concerning our Oxtellar XR patents. TWi filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit. On September 6, 2018, the Court of Appeals affirmed the District Court's Final Judgement and issued a mandate on October 16, 2018.

We intend to rely on third-party collaborators to market and commercialize our products and product candidates outside the U.S., who may fail to effectively commercialize our products and product candidates.

Outside the U.S., we utilize strategic partners 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 will rely on third parties to financially support their local operations, including that required for development, commercialization, sales, marketing and regulatory activities as well as expertise in each of those subject areas. Our collaborators may fail to develop or

effectively commercialize our products or product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our products or product candidates outside the U.S. would diminish our revenues and harm our results of operations.

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 and our products and product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. To that end, we seek patent protection in the U.S. and internationally for our products and product candidates. Our policy is to actively seek to protect our proprietary position 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, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we were the first to conceive inventions covered by our patents and pending patent applications or that we were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property or that such patents will not be challenged, narrowed, invalidated or circumvented.

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

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

If we are sued for infringing intellectual property rights of third parties, it 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.

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, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the pharmaceutical

industry expands and more patents are issued, the risk increases that our collaborators' approved products 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 of which we are currently unaware that may be infringed by our collaborators' approved products or Oxtellar XR or Trokendi XR, which 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 currently may be pending patent applications which may later result in issued patents that our collaborators' approved products, our products, or our product candidates may infringe.

We may be exposed to, or threatened with, future litigation by third parties alleging that our collaborators' approved products or our products or product candidates infringe their intellectual property rights. If one of our collaborators' approved products, 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. We could be unable to commercialize 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 generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- Infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- Substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights. If the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' 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, which may not be possible or may require substantial monetary expenditures and time.

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 for an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension, as well as for other indications. United Therapeutics Corporation launched Orenitram (treprostinil) in 2014, which triggered a milestone payment to us of $2.0 million. In the third quarter of 2014, we received a cash payment of $30.0 million as a result of HealthCare Royalty Partners III, L.P.'s (HC Royalty) purchase of certain of our rights under our license agreement with United Therapeutics Corporation related to the commercialization of Orenitram. We will retain full ownership of the royalty rights 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 other indications. 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.

Our future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties. Much of the potential revenues from these future collaborations may consist of contingent payments, such as payments for achieving development milestones and royalties payable on sales of developed products. The milestone and royalty revenues that we may receive under these collaborations will depend upon our collaborators' ability to successfully develop, introduce, market and sell new products. Future collaboration partners may fail to develop or effectively commercialize products using our 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 decrease or fail to increase 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 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 carry the product candidate through clinical development, marketing approval and commercialization;
- Fail to comply with applicable regulatory requirements;
- Be 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, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on our own.

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 which 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 would result in our inability to develop, manufacture, market and sell products that are covered by such IP.

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 products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than those in the 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 negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds and time.

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

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our products and product candidates, 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 and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our products.

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

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

- Decreased demand for any product that has received approval and is being commercialized;
- Impairment of our business reputation and exposure to adverse publicity;
- Withdrawal of bioequivalence and/or clinical trial participants;
- Initiation of investigations by regulators;
- Costs of related litigation;

- Distraction of management's attention from our primary business;
- Substantial monetary awards to patients or other claimants;
- Loss of revenues; and
- Our inability to commercialize products for which we obtain marketing approval.

Our product liability insurance coverage for our clinical trials is limited to $15 million per claim and $15 million in the aggregate, and covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline. If judgments exceed our insurance coverage, our cash balance could decrease and our business could be adversely affected.

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

The U.S. and certain states and foreign governments have shown significant and 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 and adversely impact the amount of reimbursement available from governmental agencies or commercial third-party payors. The continuing efforts of U.S., states and foreign governments, insurance companies, managed care organizations, employers and other third-party payors of healthcare services to contain or reduce health care costs may adversely affect our ability to set prices for any approved product or to increase price once launched. These initiatives could adversely impact our ability to generate revenues and to achieve and maintain profitability.

In both the U. S., at the federal and state level, and in some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could adversely affect our ability to sell any approved product profitably. Some of these proposed reforms could result in reduced reimbursement rates for our products, which would adversely affect our business strategy, operations and financial results. In March 2010, 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 HealthCare 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, and possible revisions to the HealthCare Reform Law are the subject of ongoing legislative debates and litigation. In addition, the FDA 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. However, any future regulatory changes could make it more difficult for us to maintain or attain approval to develop and commercialize our products and technologies.

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

burdens 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 by any entity that manufactures or imports specified branded prescription drugs and biologic agents payable to the U.S. federal government 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;
- A methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated 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 50% point-of-sale discounts 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 drug samples that manufacturers and distributors provide to physicians; and
- A Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and to conduct comparative clinical effectiveness research, along with funding for such research.

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 and other directives designed to delay, circumvent or loosen the implementation of certain provisions mandated by the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed repeal legislation, on December 22, 2017, the President signed the Tax Cuts and Jobs Act (Tax Act), which includes a provision repealing, effective January 1, 2019, 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 that is commonly referred to as the "individual mandate." Additionally, on January 23, 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, on December 14, 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 saw the individual mandate as in severable from the rest of the Affordable Care Act, the entire Affordable Care Act was rendered unconstitutional. The

case will be appealed to the Fifth Circuit Court of Appeals and could ultimately end up in the U.S. Supreme Court. Also, 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 financial condition.

In addition, 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 on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 also 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 to five years. Recently, the Trump Administration put forth a proposal to eliminate certain rebates pharmaceutical companies pay insurance companies in 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 U.S. 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.

Individual states in the U.S. have also 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 certain product access. Marketing cost disclosure and transparency measures, in some cases 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 and other healthcare programs. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects or prevent us from being able to commercialize our products, or to generate an acceptable return on investment.

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

The Drug Quality and Security Act (DQSA) became law in 2013. The DQSA creates the requirement for companies to trace, verify and identify all products across all changes of ownership from manufacturer to dispenser.

On December 13, 2016, the 21st Century Cures Act (Cures Act) was signed into law. The Cures Act is 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 authorizes increased funding for the FDA to spend on innovation projects. The new law also amends the Public Health Service Act (PHSA) to reauthorize and expand funding for the National Institutes of Health (NIH). The Cures Act establishes the NIH Innovation Fund to pay for the cost of development and implementation of a strategic plan, early stage investigators and research. It also charges NIH with leading and coordinating expanded pediatric research. Further, the Cures Act directs the Centers for

Disease Control and Prevention to expand surveillance of neurological diseases. On August 18, 2017, President Trump signed the FDARA into law. FDARA reauthorizes 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 includes 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 seeks to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act reauthorizes the existing priority review voucher program for certain drugs intended to treat rare pediatric diseases until 2020; creates a new priority review voucher program for drug applications determined to be material national security threat medical countermeasure applications; revises the FDCA to streamline review of combination product applications; requires FDA to evaluate the potential use of "real world evidence" to help support approval of new indications for approved drugs; provides a new "limited population" approval pathway for antibiotic and antifungal drugs intended to treat serious or life-threatening infections; and authorizes FDA to designate a drug as a "regenerative advanced therapy," thereby making it eligible for certain expedited review and approval designations.

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

Implementation of any change in any health care 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 financial impact of the HealthCare Reform Law on our business is on-going, and there can be no assurance that our business will not be materially harmed by future implementation of or changes to the HealthCare Reform Law. In addition, if we are not in full compliance with the HealthCare Reform Law, we could face enforcement action, fines and other penalties and we could receive adverse publicity.

The HealthCare Reform Law includes various provisions designed to strengthen fraud and abuse enforcement, such as increased funding for enforcement efforts and lowering the intent requirement of the federal anti-kickback statute and criminal health care 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, including civil and criminal penalties, damages, fines, exclusion from federal health care 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 of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against them, 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 and our business, operations and financial condition could be adversely affected.

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

- Federal healthcare program Anti-Kickback 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, discussed below;

- 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, and which 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 other transfers of value and 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 and to 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, or 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 which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations could be costly. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and 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.

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 part, on our ability to effectively manage our recent and any future growth. In 2018, we increased from 422 employees to 448 employees and increased revenues to $408.9 million from $302.2 million in 2017. Our need to effectively execute our growth strategy requires that we:

- Manage our regulatory approvals and clinical trials effectively;
- Manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- Commercialize our product candidates;
- Improve our operational, financial and management controls, 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 recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity.

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 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. Moreover, acquiring such additional resources could increase our legal and financial compliance costs, divert management attention from other matters, and/or make some 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. This could result in continuing uncertainty regarding compliance matters and 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 and equipment 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, equipment systems, and 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 and inventory management, transaction processing, financial, commercial and operational data, human resources management, legal and tax compliance information and other information and processes necessary to operate and manage our business. These systems are complex and are frequently updated as technology improves, and may include 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, and update our information technology infrastructure or any failure in the operation of this infrastructure could harm our business.

We intend to move our headquarters and may face disruption and additional costs.

We have entered into a lease to relocate our corporate headquarters in 2019. In connection with the relocation, we expect to incur additional expenses, including those related to moving and exit costs, tenant improvements and associated expenses not covered by the landlord, as well as furniture and equipment for the new corporate headquarters. The relocation could result in 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, which 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 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, or that 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 and 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 try 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 with applicable regulations. Noncompliance could result in our marketing and distribution of contaminated, defective or dangerous products which could subject us to liabilities and 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.

Obtaining and maintaining our 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 lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

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

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; our 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 manufacture or other problems that could unexpectedly compromise information security. The continued occurrence of high-profile data breaches provides evidence of an external environment increasingly hostile to information security, and the secure processing, maintenance and transmission of information is 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, our training of employees and vendors on data security, our vendor security requirements and other practices we follow 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, which could adversely affect our business, revenues and competitive position.

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 (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.

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 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.

We had incurred significant operating losses since inception through 2014. As of December 31, 2017, we had an accumulated deficit of approximately $26.8 million and as of December 31, 2018, we had retained earnings of approximately $86.5 million. Substantially all of our operating losses in prior years resulted from 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.

Our prior losses have had an adverse effect on our stockholders' equity and cash position. While we anticipate maintaining profitability in 2019 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. Furthermore, since the completion of our initial public offering in May 2012, we have incurred additional costs associated with operating as a public company, including those associated with Section 404 of the Sarbanes-Oxley Act of 2002 (SOX) concerning financial controls over financial reporting.

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

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

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 additional 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.

We may not be able to maintain or increase profitability.

Our ability to remain profitable depends upon our ability to generate 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 grow demand for our products and defend against potential generic competition, and successfully develop and commercialize our product candidates.

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 from approved products, our license agreements, the amount of and timing for 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.

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 the 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 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 devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit group and 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 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 control 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.

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 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, 2018, we had U.S. Federal net operating loss carryforwards of approximately $20.6 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 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.

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, 2018, we had outstanding 52,316,583 shares of common stock, of which approximately 1,929,645 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, 2018, we had outstanding options to purchase 3,916,963 shares of common stock that, if exercised, would result in these additional shares becoming

available for sale. Approximately 5% 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 2,776,656 and 154,834 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 any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. 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 and may impair our ability to enter into strategic partnerships or acquire companies or products, product candidates or technologies by using our shares of common stock as consideration.

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

As of December 31, 2018, we had issued options to purchase 3,916,963 shares of common stock outstanding, with exercise prices ranging from $2.56 to $58.15 per share and a weighted average exercise price of $19.98 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.

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;

- Status of our ongoing patent infringement law suits;

- 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.

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 will 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, 2018, 3,916,963 shares of our common stock were reserved for future issuance upon the exercise of outstanding options, 2,776,656 shares were reserved for future issuance under our 2012 Equity Incentive Plan and 154,834 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 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 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 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 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 or removing 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, 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 into 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, which 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 by paying the conversion value in cash up to the principal amount being converted and any excess in shares, we are be 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 issued 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 and 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 purchase 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 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 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 prices 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.

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 expenses related to intangible assets;
- difficulties in the assimilation of the operations, technologies, services and products of the acquired companies; and
- diversion of management's attention from our other business activities.
- 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; 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal executive offices are located at 1550 East Gude Drive, Rockville, Maryland 20850, where we occupy approximately 44,500 square feet of laboratory and office space. Our lease term expires in April 30, 2020, with an option for a five-year extension. We also lease approximately 20,530 square feet of office space in an adjacent building to our existing office space located at 1500 East Gude Drive, Rockville, MD 20850, with a co-terminus lease term date of April 30, 2020. Effective January 31, 2019, we entered into a lease for approximately 136,016 square feet for the Company's new headquarters to be located at 9715 and 9717 Key West Avenue, Rockville, Maryland. 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 are subject to various claims, charges and litigation. We may be required to file infringement claims against third parties for the infringement of

our patents. We have filed such claims for infringement of the Orange Book patents listed for our product Oxtellar XR.

Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc., et al., C.A. No. 15-369 (RMB)(JS) (D.N.J.)

Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc., et al., Appeal No. 2017-2513 (Fed. Cir.)

We received a Paragraph IV Notice Letter against United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930 from generic drug maker TWi Pharmaceuticals, Inc. on December 9, 2014. On January 16, 2015, we filed a lawsuit against TWi Pharmaceuticals, Inc. and TWi International LLC (d/b/a TWi Pharmaceuticals USA) (collectively TWi) alleging infringement of United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleged, inter alia, that TWi infringed our Oxtellar XR patents by submitting to the FDA an ANDA seeking to market a generic version of Oxtellar XR prior to the expiration of our patents. On February 13, 2015, TWi answered the Complaint and denied the substantive allegations of the Complaint. TWi also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity of United States Patent Nos. 7,722,898 and 7,910,131. On March 20, 2015, we filed our Reply, denying the substantive allegations of those Counterclaims. A four-day bench trial was held between April 3 and April 6, 2017. On August 15, 2017, the Court issued an opinion and order finding that: (i) TWi's ANDA products infringe United States Patent Nos. 7,722,898, 7,910,131, and 8,821,930; and (ii) United States Patent Nos. 7,722,898, 7,910,131, and 8,821,930 are not invalid. The Court entered a final judgment on August 28, 2017: (i) enjoining the FDA from approving TWi's ANDA before the expiration date of United States Patent Nos. 7,722,898, 7,910,131, and 8,821,930; and (ii) enjoining TWi from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, TWi's ANDA products until the expiration of United States Patent Nos. 7,722,898, 7,910,131, and 8,821,930. On August 31, 2017, TWi filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit. On September 6, 2018, the United States Court of Appeals for the Federal Circuit affirmed the District Court's Final Judgment. The Federal Circuit's mandate issued on October 16, 2018.

Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc., et al., C.A. No. 17-2164 (RMB)(JS) (D.N.J.)

We received a second Paragraph IV Notice Letter against United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, 8,821,930, 9,119,791, 9,351,975, and 9,370,525 from generic drug maker TWi Pharmaceuticals, Inc. on February 16, 2017. On March 31, 2017, we filed a lawsuit against TWi Pharmaceuticals, Inc. and TWi International LLC alleging infringement of United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, 8,821,930, 9,119,791, 9,351,975, and 9,370,525. TWi filed a motion to dismiss Supernus's March 31, 2017 Complaint on May 10, 2017. On May 19, 2017, the Court "administratively terminate[d] this matter pending this Court's decision in the First TWi Action [concerning United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930]." As of the date of this filing, Civil Action No. 17-2164 (RMB)(JS) (D.N.J.) remains administratively terminated.

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.

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

	High	Low
2018		
First Quarter	$ 48.65	$ 34.90
Second Quarter	$ 61.25	$ 43.53
Third Quarter	$ 59.75	$ 41.80
Fourth Quarter	$ 51.38	$ 30.05
2017		
First Quarter	$ 32.00	$ 23.10
Second Quarter	$ 44.95	$ 29.55
Third Quarter	$ 50.05	$ 36.16
Fourth Quarter	$ 43.25	$ 33.30

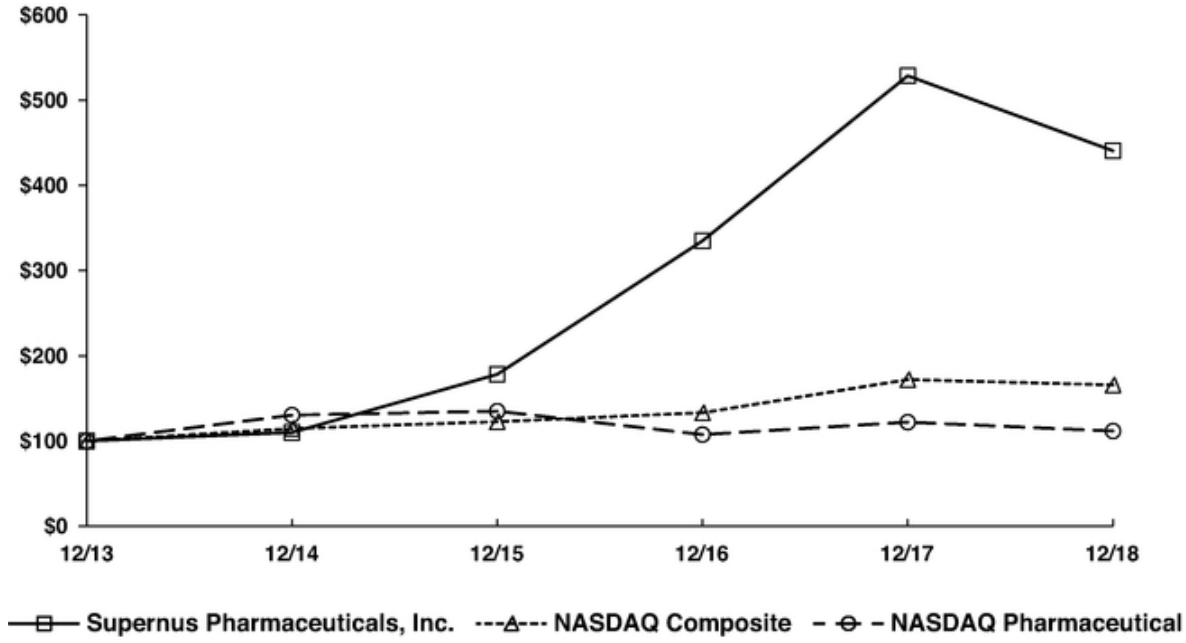
On December 31, 2018, the closing price of our common stock on The NASDAQ Global Market was $33.22 per share. As of December 31, 2018, we had 20 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who 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.

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.

During the three months ended December 31, 2018, the Company granted options to employees to purchase an aggregate of 20,100 shares of common stock at an exercise price of $37.20 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.

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 May 1, 2012 and ending December 31, 2018. 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.

COMPARISON OF 5 YEARS CUMULATIVE TOTAL RETURN*
Among Supernus Pharmaceuticals, Inc., the NASDAQ Composite Index
and the NASDAQ Pharmaceutical Index



* $100 invested on 12/31/13 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, 2013	$ 100.00	$ 100.00	$ 100.00
December 31, 2014	110.08	114.62	130.42
December 31, 2015	178.25	122.81	135.08
December 31, 2016	334.88	133.19	107.58
December 31, 2017	528.51	172.11	122.18
December 31, 2018	440.58	165.84	111.73

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, 2018, 2017 and 2016 and balance sheet data as of December 31, 2018 and 2017 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, 2015 and 2014 and the balance sheet data as of December 31, 2016, 2015 and 2014 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.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Earnings

(in thousands, except share and per share data)

	Years Ended December 31,				
	2018	2017	2016	2015	2014
Revenue					
Net product sales	$ 399,871	$ 294,097	$ 210,078	$ 143,526	$ 89,571
Royalty revenue	8,276	6,367	4,686	3,038	633
Licensing revenue	750	1,774	239	901	2,474
Total revenue	408,897	302,238	215,003	147,465	92,678
Costs and expenses					
Cost of product sales	15,356	15,215	11,986	8,423	5,758
Research and development	89,209	49,577	42,791	29,135	19,586
Selling, general and administrative	159,888	137,905	106,010	89,063	72,612
Total costs and expenses	264,453	202,697	160,787	126,621	97,956
Operating earnings (loss)	144,444	99,541	54,216	20,844	(5,278)
Other income (expense)					
Interest income	13,843	2,864	1,467	681	387
Interest expense	(13,840)	(134)	(543)	(1,229)	(4,963)
Interest expense on non-recourse liability related to sale of future royalties	(4,271)	(1,434)	(4,548)	(3,541)	(658)
Changes in fair value of derivative liabilities	—	76	448	193	2,809
Loss on extinguishment of debt	—	(295)	(671)	(2,338)	(2,592)
Total other income (expense)	(4,268)	1,077	(3,847)	(6,234)	(5,017)
Earnings (loss) before income tax	140,176	100,618	50,369	14,610	(10,295)
Income tax expense (benefit)	29,183	43,334	(40,852)	666	630
Net earnings (loss)	110,993	57,284	91,221	13,944	(10,925)
Earnings (loss) per share:					
Basic	$ 2.13	$ 1.13	$ 1.84	$ 0.29	$ (0.26)
Diluted	$ 2.05	$ 1.08	$ 1.76	$ 0.28	$ (0.26)
Weighted-average shares outstanding:					
Basic	51,989,824	50,756,603	49,472,434	47,485,258	42,260,896
Diluted	54,098,872	53,301,150	51,708,983	51,160,380	42,260,896

	Years Ended December 31,				
	2018	2017	2016	2015	2014
			(in thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents and marketable securities	$ 356,018	$ 140,040	$ 90,121	$ 62,190	$ 74,336
Long term marketable securities	418,798	133,638	75,410	55,009	19,816
Working capital	332,134	105,451	70,662	49,012	80,603
Total assets	977,811	424,464	309,568	188,626	136,784
Convertible notes, net of discount	329,462	—	4,165	7,085	26,223
Non-recourse liability related to sale of future royalties	24,758	26,541	30,390	30,528	30,025
Retained earnings (accumulated deficit)	86,492	(26,823)	(84,288)	(175,509)	(189,453)
Total stockholders' equity	453,023	267,480	191,755	88,007	40,699

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 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. In 2013, we launched Oxtellar XR (extended-release oxcarbazepine) and Trokendi XR (extended-release topiramate), our two novel treatments for epilepsy. In April 2017, we launched Trokendi XR for the prophylaxis of migraine headache in adults and adolescents. In December 2018, the FDA approved the Company's supplemental new drug application (sNDA) for Oxtellar XR to include monotherapy treatment of partial onset seizures of epilepsy in adults and in children 6 to 17 years of age. Since 2013, we have significantly grown our net product sales, and have become profitable.

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

We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies, products, and product candidates. We currently have U.S. patents covering Oxtellar XR and U.S. patents covering Trokendi XR, with the patents expiring no earlier than 2027 for each product. See Part I, Item I—Business, *Intellectual Property and Exclusivity*, for a complete description of our intellectual property position and Part I, Item 3—*Legal Proceedings* for additional information.

Product Prescriptions

We expect the number of prescriptions filled for Oxtellar XR and Trokendi XR to continue to increase through 2019 and in subsequent years. Data from IQVIA (formerly Intercontinental Marketing Services (IMS)) shows that 786,411 total prescriptions were filled for both of these drugs during the year ended December 31, 2018, which is 29% higher than the 609,184 prescriptions reported for the year ended December 31, 2017.

Since the 2017 migraine launch, Trokendi XR has shown robust acceleration in prescription growth. For the year ended December 31, 2018, total prescriptions for Trokendi XR increased by 161,810, or 34%, as compared to 2017. For the fourth quarter of 2018, total prescriptions for Trokendi XR increased by 25,519, or 18%, as compared to the fourth quarter of 2017.

For the year ended December 31, 2018, total prescriptions for Oxtellar XR increased by 15,417, or 12%, as compared to 2017. For the fourth quarter of 2018, total prescriptions for Oxtellar XR increased by 34,782, or approximately 13%, as compared to the fourth quarter of 2017.

Net product sales for the year ended December 31, 2018 totaled $399.9 million, an increase of $105.8 million, or approximately 36%, over the $294.1 million for 2017. Net product sales for the fourth quarter of 2018 were $113.5 million, compared to net product sales of approximately $86.3 million for the same quarter last year, an increase of approximately 32%.

Operating earnings for the year ended December 31, 2018 totaled $144.4 million compared to operating earnings of $99.5 million in 2017, an increase of approximately $44.9 million or 45%.

Net product sales and operating earnings for both the fourth quarter and year ended December 31, 2018 were favorably impacted by approximately $10 million due to higher wholesaler/distributor and pharmacy inventory levels in the fourth quarter of 2018. We expect that wholesaler and pharmacy channel inventory levels will revert to historical 2018 levels, thereby affecting 2019 net product sales by approximately$10 million.

Patents

In years prior to 2018, we received several Paragraph IV Notice Letters concerning Oxtellar XR and Trokendi XR from various third-parties. (See Part I, Item 3—*Legal Proceedings* for additional information.) We received no such letters in 2018.

Product Candidates

SPN-812 (viloxazine hydrochloride)

SPN-812 is being developed as a novel non-stimulant treatment for ADHD. We initiated four Phase III clinical trials for SPN-812 in September 2017. The program consists of four three-arm, placebo-controlled trials: P301 and P303 trials in patients 6-11 years old and P302 and P304 trials in patients 12-17 years old.

In December 2018, we announced positive topline results from P301, P302 and P303, meeting the primary efficacy endpoint in each of the three trials. Results of the second adolescent Phase III trial, P304, are expected by the end of the first quarter of 2019. We expect to submit a new drug application (NDA) for SPN-812 in the second half of 2019, and to launch it, pending FDA approval, in the second half of 2020.

SPN-810 (molindone hydrochloride)

SPN-810 is being developed as a novel treatment for impulsive aggression (IA) in children who have attention deficit hyperactivity disorder (ADHD). One of our Phase III clinical trials (P301) was conducted under a Special Protocol Assessment (SPA) with the FDA, using a novel measurement scale, developed by us. Under the SPA, an interim analysis was conducted in the P301 trial. The purpose of the interim analysis was to assess the efficacy of the doses being tested and allow for optimization of the trial design of both trials. The interim analysis was completed and as a result we discontinued the 18 mg dose arm. Moving forward, all patients in each of the two trials are randomized to either the 36 mg dose arm or placebo, with the second Phase III trial, also conducted in children, using the same design and novel measurement scale.

The first Phase III trial (P301) has reached its original enrollment target with data originally scheduled to be released in the first quarter of 2019. However, given that the data readout from the second trial (P302) is now expected in the second half of 2019, we have decided to keep enrolling in the P301 trial until data from both trials can be released concurrently instead of sequentially. We believe this change in the plan has no impact on the timing of the NDA filing. The completion of the second Phase III trial (P302) and the generation of data from the adolescent patient population (P503) are now rate-limiting for the NDA filing. We expect to submit a NDA for SPN-810 in the second half of 2020, and to launch it, pending FDA approval, in the second half of 2021.

In addition, patient enrollment began in December 2018 in a Phase III trial for SPN-810 (P503) treating IA in adolescents who have ADHD.

SPN-817 (huperzine A)

SPN-817 will utilize a novel synthetic form of huperzine A, whose mechanism of action includes potent acetyl cholinesterase inhibition with pharmacological activities in CNS conditions such as epilepsy. SPN-817 will have new chemical entity status (NCE) in the U.S. market. SPN-817 represents a novel mechanism of action for an anticonvulsant. Development will initially focus on the drug's anticonvulsant activity that has been demonstrated in preclinical models for partial seizures and Dravet Syndrome.

We plan on studying SPN-817 initially in severe pediatric epilepsy disorders. A Phase I proof-of-concept trial is currently underway, using a non-synthetic form of huperzine A in adult patients with refractory complex partial seizures to study the safety and pharmacokinetics profile of a new extended release formulation.

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 new drug application (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. It 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)

We continue to progress our plans to initiate pivotal Phase III studies for the treatment of bipolar disorder in the second half of 2019. If approved, this would represent the first approval for treatment of bipolar patients with oxcarbazepine in the U.S. Recently, we completed certain activities, including market research and claims database analysis on the use of oxcarbazepine in bipolar patients. We will be using information generated from these activities to finalize plans for the pivotal Phase III trials.

We expect to incur significant research and development expenses related to the continued development of each of our product candidates from 2019 through FDA approval or until the program terminates.

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 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

Revenue from product sales is recognized when control of our products is transferred to our customers, who are primarily pharmaceutical wholesalers and distributors. Net product sales are based on gross revenue from product shipments to our customers, and are recorded net of various forms of variable consideration, including estimated rebates, discounts, allowances, and an estimated liability for 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—Financial Statements and Supplementary Data, Note 2, *Revenue from Product Sales* of the Notes to Consolidated Financial Statements.

Research and Development Expenses and Related Accrued Clinical Expenses

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee-related expenses, including: salaries and benefits; share-based compensation expense; expenses incurred under agreements with clinical research organizations (CROs), fees paid to investigators who are participating in our clinical trials, consultants and other vendors that assist in the conduct of the Company's clinical trials; the cost of acquiring and manufacturing clinical trial materials; the cost of manufacturing materials used in process validation, to the extent that those materials are manufactured prior to receiving regulatory approval for those products and are not expected to be sold commercially; facilities costs that do not have an alternative future use; related depreciation and other allocated expenses; license fees for and milestone payments related to in-licensed products and technologies; and costs associated with animal testing activities and regulatory approvals. Assets acquired that are used for research and development and have no future alternative use are expensed as in-process research and development.

Clinical trials are inherently complex and often involve multiple service providers. Because billing for services often lags by a substantial period of time, we often are required to estimate and accrue a significant portion of our clinical expenses. This process involves reviewing open contracts and communicating with our subject matter expert personnel and the appropriate service provider personnel to identify services that have been performed on our behalf but for which no invoice has been received. We accrue for the estimated but unbilled services performed and the associated cost incurred as of the end of the calendar quarter.

Payments to service providers can either be based on hourly rates for service or based on performance driven milestones. When accruing clinical 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. To the maximum extent possible, we work with each service provider to obtain an estimate for incurred but unbilled services as of the end of the calendar quarter, including estimates for payments to site investigators.

We work diligently to minimize, if not eliminate, estimates based solely on company generated calculations. If the service provider underestimates or overestimates the cost associated with a trial or service at any given point in time, adjustments to research and development expenses may be necessary in the current or subsequent periods. Historically, our estimated accrued clinical expenses have closely approximated the actual expenses incurred.

Results of Operations

Comparison of the year ended December 31, 2018 and December 31, 2017

	Years Ended December 31,		Increase/ (decrease)
	2018	2017	
		(in thousands)	
Revenue			
Net product sales	$ 399,871	$ 294,097	$ 105,774
Royalty revenue	8,276	6,367	1,909
Licensing revenue	750	1,774	(1,024)
Total revenue	408,897	302,238	
Costs and expenses			
Cost of product sales	15,356	15,215	141
Research and development	89,209	49,577	39,632
Selling, general and administrative	159,888	137,905	21,983
Total costs and expenses	264,453	202,697	
Operating earnings	144,444	99,541	
Other income (expense)			
Interest income	13,843	2,864	10,979
Interest expense	(13,840)	(134)	13,706
Interest expense on non-recourse liability related to sale of future royalties	(4,271)	(1,434)	2,837
Changes in fair value of derivative liabilities	—	76	(76)
Loss on extinguishment of debt	—	(295)	(295)
Total other income (expense)	(4,268)	1,077	
Earnings before income taxes	140,176	100,618	
Income tax expense	29,183	43,334	(14,151)
Net earnings	$ 110,993	$ 57,284	

Net Product Sales. The increase in net product sales from 2017 to 2018 was primarily driven by increased prescription volume generated by the launch of the migraine indication for Trokendi XR in April 2017. In addition, fourth quarter 2018 net product sales were favorably impacted by approximately $10 million due to an increase in inventory levels at wholesalers/distributors and pharmacies. Price increases in 2018 also contributed to the increase in net product sales, offset by increases in gross to net deductions.

The table below lists our net product sales by product, in thousands:

	Net Product Sales Years Ended December 31,		Change in Net Product Sales (%)
	2018	2017	
Trokendi XR	$ 315,295	$ 226,518	39%
Oxtellar XR	84,576	67,579	25%
Total	$ 399,871	$ 294,097	36%

Trokendi XR net product sales grew 39% for the year ended December 31, 2018 compared to the same period last year primarily due to increased prescription volume. Total prescriptions for Trokendi XR increased by 34% for the year ended December 31, 2018 as compared to 2017. This increase in

prescriptions and the aforementioned increase in inventory levels at wholesalers/distributors and pharmacies in the fourth quarter of 2018 accounted for the majority of the total increase in net product sales for Trokendi XR. The difference between the volume growth and the related net product sales increase is generally due to price increases, offset by changes in revenue related allowances.

Oxtellar XR net product sales grew 25% for the year ended December 31, 2018 compared to the same period in 2017 primarily due to increased prescription volume and the aforementioned increase in inventory levels at wholesalers/distributors and pharmacies in the fourth quarter of 2018. Total prescriptions for Oxtellar XR increased by 12% for the year ended December 31, 2018 as compared to 2017. The difference between the volume growth and the related net product sales increase is generally due to price increases, offset by changes in revenue related allowances.

Royalty Revenue. Royalty revenue includes royalty from net product sales of Shire Plc's product, Mydayis, and non-cash royalty revenue consequent to the Healthcare Royalty Partners III, L.P. (HC Royalty) agreement, wherein HC Royalty receives royalty otherwise payable to us from sale of United Therapeutic's product, Orenitram. Non-cash royalty revenue for the years ended December 31, 2018 and 2017 were $5.9 million and $5.3 million, respectively. The increase is primarily due to increased sales of Orenitram.

Licensing Revenue. Licensing revenue includes milestone revenue for the years ended December 31, 2018 and 2017 were $0.75 million and $1.5 million, respectively. The decrease from prior year is primarily due to the adoption of the new revenue recognition standard, Accounting Standards Codification (ASC) 606, which resulted in accelerated amortization of previously deferred up-front license revenue. The impact of the adoption was recorded as an adjustment to the opening balance of accumulated deficit in 2018.

Cost of Product Sales. Cost of product sales for the years ended December 31, 2018 and 2017 were $15.4 million and $15.2 million, respectively. The year over year increase of $0.2 million is attributable primarily to higher unit volume partially offset by manufacturing efficiencies.

Research and Development Expense. Research and development (R&D) expenses for the year ended December 31, 2018 were $89.2 million as compared to $49.6 million an increase of $39.6 million. This increase was primarily due to the ongoing four Phase III clinical trials for SPN-812, ongoing patient recruitment for the Phase III trials for SPN-810, the open label extension trials for both SPN-810 and SPN-812, and approximately $14 million charge related to the Biscayne acquisition.

Selling, General, and Administrative Expense (SG&A). The table below shows the comparison of selling and marketing and general and administrative expenses for the years ended December 31, 2018 and 2017:

	Selling, General and Administrative Expense Years Ended December 31,		
	2018	2017	Change (%)
	(in thousands)		
Selling and Marketing	$ 121,645	$ 104,072	17%
General and Administrative	38,243	33,833	13%
Total	$ 159,888	$ 137,905	16%

Selling and Marketing. Selling and marketing expenses increased by approximately $17.6 million for the year ended December 31, 2018 as compared to 2017. Approximately $6.4 million of the increase was due to increased compensation, benefits and other employee-related expenses associated with increased headcount in our field sales force. In addition, approximately $10.4 million of the increase was due to

increased expenses for promotional and marketing programs, speaker programs and consulting services to support our commercial products, including the launch of the monotherapy indication for Oxtellar XR.

General and Administrative. General and administrative expenses (G&A) increased by $4.4 million for the year ended December 31, 2018, as compared to 2017. Of this total, approximately $1.5 million relates to increased stock based compensation expense and approximately $2.6 million of increased compensation, benefits and other employee-related expenses associated with increased administrative headcount.

Interest Income. For the years ended December 31, 2018 and 2017, we recognized approximately $13.8 million and $2.9 million, respectively, of interest income earned on our cash, cash equivalents and marketable securities. The increase is primarily attributable to an increase in cash, cash equivalents and marketable securities holdings from the net proceeds from the issuance of $402.5 million of 0.625% Convertible Senior Notes due 2023 (2023 Notes).

Interest Expense. For the years ended December 31, 2018 and 2017, interest expense were approximately $13.8 million and $134,000, respectively. The increase of approximately $13.7 million was entirely due to the interest on the 2023 Notes issued in March 2018. Approximately $11.8 million was non-cash interest expense from the amortization of deferred financing costs and debt discount on the 2023 Notes, and the remainder was cash interest expense.

Interest Expense on Non-recourse Liability Related to Sale of Future Royalties. For the years ended December 31, 2018 and 2017, non-cash interest expense related to our non-recourse royalty liability was $4.3 million and $1.4 million, respectively. The increase of $2.9 million in non-cash expense was primarily due to an expected increase in the Orenitram sales forecast as a result of a favorable settlement of patent litigation for United Therapeutics Corporation (United Therapeutics).

Loss on Extinguishment of Debt. There were no 2023 Notes converted for the year ended December 31, 2018. For the year ended December 31, 2017, we recognized a non-cash loss on extinguishment of debt of approximately $295,000 related to the conversion of $4.6 million aggregate principal amount of our 7.5% Convertible Senior Secured Notes due 2019 (2019 Notes).

Income Tax. For the year ended December 31, 2018, we recorded $29.2 million of income tax expense, a decrease of $14.1 million as compared to the year ended December 31, 2017. The decrease in income tax expense is primarily due to a decrease in the effective income tax rate, from 43% in 2017 to 21% in 2018. The decrease in the effective income tax rate was primarily due to the reduction of the statutory U.S. corporate income tax rate from 35% to 21% as a result of the Tax Cuts and Jobs Act (Job Act) passed on December 22, 2017, coupled with the tax benefit from the exercise of employee stock options in 2018.

Net Earnings. Net earnings for the year ended December 31, 2018 were $111.0 million, compared to net earnings of $57.3 million for the year ended December 31, 2017, an increase of $53.7 million. This increase was primarily due to the revenue generated from our two commercial products, Trokendi XR and Oxtellar XR, partially offset by increased R&D and SG&A spending.

Comparison of the year ended December 31, 2017 and December 31, 2016

	Year Ended December 31,		Increase/ (decrease)
	2017	2016	
	(in thousands)		
Revenue			
Net product sales	$ 294,097	$ 210,078	$ 84,019
Royalty revenue	6,367	4,686	1,681
Licensing revenue	1,774	239	1,535
Total revenue	302,238	215,003	
Costs and expenses			
Cost of product sales	15,215	11,986	3,229
Research and development	49,577	42,791	6,786
Selling, general and administrative	137,905	106,010	31,895
Total costs and expenses	202,697	160,787	
Operating earnings	99,541	54,216	
Other income (expense)			
Interest income	2,864	1,467	1,397
Interest expense	(134)	(543)	(409)
Interest expense on non-recourse liability related to sale of future royalties	(1,434)	(4,548)	(3,114)
Changes in fair value of derivative liabilities	76	448	(372)
Loss on extinguishment of debt	(295)	(671)	(376)
Total other income (expense)	1,077	(3,847)	
Earnings before income taxes	100,618	50,369	
Income tax expense (benefit)	43,334	(40,852)	84,186
Net earnings	$ 57,284	$ 91,221	

Net Product Sales. The increase in net product sales from 2016 to 2017 was primarily driven by increased prescription volume generated by the launch of the migraine indication for Trokendi XR in April 2017. Price increases in 2017 and 2016 also contributed to the increase in net product sales, offset by increases in gross to net deductions.

The table below lists our net product sales by product, in thousands:

	Net Product Sales Years Ended December 31,		Change in Net Product Sales (%)
	2017	2016	
	(in thousands)		
Trokendi XR	$ 226,518	$ 158,384	43%
Oxtellar XR	67,579	51,694	31%
Total	$ 294,097	$ 210,078	40%

Royalty Revenue. Royalty revenue for the years ended December 31, 2017 and 2016 was $6.4 million and $4.7 million, respectively. Royalty revenue includes non-cash royalty from the HC Royalty agreement and royalty from collaboration partners. The increase, $1.7 million, is primarily due to royalty earned from collaboration partners.

Licensing Revenue. Total licensing revenue for the years ended December 31, 2017 and 2016 was $1.8 million and $0.2 million, respectively. The increase, $1.6 million, is primarily due to milestone revenue received during the year.

Cost of Product Sales. Cost of product sales during the year ended December 31, 2017 was $15.2 million, an increase of $3.2 million or 27%, as compared to $12.0 million for the year ended December 31, 2016. The year over year increase is attributable primarily to increased unit volume.

Research and Development Expense. R&D expenses during the year ended December 31, 2017 were $49.6 million as compared to $42.8 million in 2016, an increase of $6.8 million or 16%. This increase was due to ongoing patient recruitment for Phase III trials for SPN-810 and commencement of the four Phase III trials for SPN-812.

Selling, General, and Administrative Expense. The table below shows the comparison of selling and marketing and general and administrative expenses for the years ended December 31, 2017 and 2016:

	Selling, General and Administrative Expense Years Ended December 31,		
	2017	2016	Change (%)
	(in thousands)		
Selling and Marketing	$ 104,072	$ 79,997	30%
General and Administrative	33,833	26,013	30%
Total	$ 137,905	$ 106,010	30%

Selling and Marketing. The increase in selling and marketing expenses, approximately $24.1 million for the year ended December 31, 2017 as compared to 2016, was primarily the result of an increase in workforce headcount to support for our commercial products, coupled with development, production, and execution of promotional and marketing programs to support the launch of the migraine indication for Trokendi XR in April 2017. Of this total, approximately $9.2 million is due to increased compensation, benefits and other employee-related expenses associated with increased headcount in our field sales force. Approximately $13.2 million was due to increased expenses for marketing programs, speaker programs, and consulting services to support the launch of the migraine indication for Trokendi XR in 2017.

General and Administrative. G&A increased by $7.8 million for the year ended December 31, 2017 as compared to 2016. Approximately $5.6 million of this increase was attributable to increased patent amortization expense.

Interest Income. For the years ended December 31, 2017 and 2016, we recognized $2.9 million and $1.5 million, respectively, of interest income earned on our cash, cash equivalents and marketable securities. The increase was primarily attributable to an increase in cash, cash equivalents and marketable securities holdings year over year from cash generated by operations.

Interest Expense. Interest expense was $0.1 million for the year ended December 31, 2017 as compared to $0.5 million for the year ended December 31, 2016. The decrease of $0.4 million was primarily due to a decrease in the principal amount of our outstanding 2019 Notes. As of July 2017, all Notes were converted and were no longer outstanding. For the year ended December 31, 2017, a total of $4.6 million aggregate principal amount of Notes and related accrued interest were converted into 0.9 million shares of common stock.

Interest Expense on Non-recourse Liability Related to Sale of Future Royalties. Non-cash interest expense related to our non-recourse royalty liability was $1.4 million during the year ended December 31, 2017 as compared to $4.5 million for 2016. The decrease of $3.1 million for this non-cash expense item was primarily due to a reduction in the forecast of future sales of Orenitram.

Changes in Fair Value of Derivative Liability. During the year ended December 31, 2017, we recognized a non-cash gain of $76,000 related to a change in the estimated fair value of the interest make-whole derivative liability related to the Notes. For the year ended December 31, 2016, we recognized a non-cash gain of $0.4 million related to a change in the estimated fair value of the interest make-whole derivative liability related to the Notes. The "make-whole fundamental change" provision, as defined in the Indenture governing the Notes, expired in May 2017.

Loss on Extinguishment of Debt. For the year ended December 31, 2017, we recognized a non-cash loss on extinguishment of debt of $0.3 million related to the conversion of $4.6 million aggregate principal amount of the Notes. For the year ended December 31, 2016, we recognized a non-cash loss on extinguishment of debt of $0.7 million related to the conversion of $3.9 million aggregate principal amount of Notes.

Income Tax. For the year ended December 31, 2017, we recorded $43.3 million of income tax expense, an increase of $84.2 million from the prior year. This increase was driven by the release of all of our valuation allowance on deferred tax assets of $56.0 million in 2016. The 2017 tax provision also included the effect of the write-down of $9.7 million of deferred tax assets to reflect the estimated impact of the Tax Act, effective January 1, 2018. The Tax Act decreased the U.S. statutory corporate income tax rate from 35% to 21%, among other things.

Net Earnings. Net earnings for the year ended December 31, 2017 was $57.3 million, compared to net earnings of $91.2 million for 2016, a decrease of $33.9 million. This decrease was primarily due to the increase in R&D and SG&A spending in 2017, the increase in income tax expense as a result of the elimination of valuation allowance against deferred tax assets in 2016, and the impact of the Tax Act.

Liquidity and Capital Resources

We believe our increasing levels of net product sales will be sufficient to finance our operations in 2019 and in subsequent years, including increased R&D expenses, increased expenses to support our commercial products and expenses to support pre-launch activities in anticipation of launching our product candidates. We expect to incur increased R&D expenses to support the development of our product candidates. We expect our SG&A expenses to continue to increase for the foreseeable future, as we continue to invest in the commercialization of Trokendi XR and Oxtellar XR along with completing pre-launch activities for SPN-812 and SPN-810, and in areas such as regulatory compliance, finance, management of our intellectual property portfolio, information technology systems and personnel, in each case, commensurate with the growth of our business.

Our working capital at December 31, 2018 was $332.1 million, an increase of $226.6 million compared to our working capital of $105.5 million at December 31, 2017. In addition, our long term marketable securities at December 31, 2018 were $418.8 million, an increase of $285.2 million as compared to $133.6 million at December 31, 2017. This increase is primarily attributable to the net proceeds generated by the issuance of the 2023 Notes.

Our stockholders' equity increased by $185.5 million for the year ended December 31, 2018, primarily as a result of net earnings of $111.0 million, coupled with option exercises, share-based compensation and the issuance of the 2023 Notes and warrants as described above. These increases were partially offset by the purchase of convertible note hedges, as described below.

On March 14, 2018, we issued $402.5 million in aggregate principal amount of 2023 Notes pursuant to an indenture, dated as of March 19, 2018 (the Indenture) between us and Wilmington Trust, National Association, as trustee. The Indenture includes customary terms and covenants, including certain events of default after which the 2023 Notes may be immediately due and payable. Interest on the 2023 Notes, at an annual rate of 0.625%, is payable semi-annually in arrears, on April 1 and October 1 of each year.

As of December 31, 2018, the outstanding aggregate principal amount of 2023 Notes was $402.5 million. We will settle conversions of the 2023 Notes by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our 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 adjustments specified in the Indenture. We may not redeem the 2023 Notes at our option before maturity.

We also entered into separately negotiated convertible note hedge transactions (collectively, the Convertible Note Hedge Transactions). The Convertible Note Hedge Transactions cover the number of shares of our common stock underlying the 2023 Notes. Concurrently with entering into the Convertible Note Hedge Transactions on each such date, we also entered into separate, privately negotiated warrant transactions (collectively, the Warrant Transactions) whereby we sold warrants to purchase up to the same number of shares of our common stock. The Convertible Note Hedge Transactions and the Warrant Transactions are separate contracts entered into by the Company. The Convertible Note Hedge Transactions are expected to generally 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 we are required to make in excess of the principal amount of converted Notes, as the case may be. Although intended to partially offset the cost of the purchased Convertible Note Hedge Transactions, the Warrant Transactions could have a dilutive effect with respect to our common stock to the extent that the market price per share of our common stock, as measured under the terms of the Warrant Transactions, exceeds the strike price of the warrants, or $80.9063 per share of the Company's common stock.

We achieved positive cash flow and profitability from operations in each quarter of 2018 and 2017. While we expect continued profitability in 2019 and in subsequent years as we continue to increase sales, we anticipate there may be significant variability from quarter to quarter in our level of profitability.

Cash Flows

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

	Years Ended December 31,		
	2018	2017	Change
Net cash provided by (used in):			
Operating activities	$ 128,986	$ 114,640	$ 14,346
Investing activities	(413,480)	(86,415)	(327,065)
Financing activities	376,438	5,681	370,757
Net increase in cash and cash equivalents	$ 91,944	$ 33,906	$ 58,038

Operating Activities

Net cash provided by operating activities is comprised of two components: cash provided by operating earnings and cash provided by changes in working capital.

Results for the years ended December 31, 2018 and 2017 are summarized below, in thousands:

	Years Ended December 31,		
	2018	2017	Change
Cash provided by operating earnings	$ 133,720	$ 90,930	$ 42,790
Cash (used in) provided by working capital	(4,734)	23,710	(28,444)
Net cash provided by operating activities	$ 128,986	$ 114,640	$ 14,346

The increase in net cash provided by operating activities is primarily driven by increased revenue generated from product sales of Trokendi XR and Oxtellar XR.

The changes in certain operating assets and liabilities are, in thousands:

	Years Ended December 31,		
	2018	2017	Explanation of Change
(Increase) Decrease in:			
Accounts receivable	$ (35,856)	$ (24,059)	Increased product sales and higher wholesaler and pharmacy inventory levels in the fourth quarter of 2018 offset by timing of cash collections
Inventory	(9,355)	497	Increased inventory volume to support increased product demand.
Prepaid expenses, other current assets and other non-current assets	(2,367)	(3,566)	Timing differences related to prepayment of drug regulatory fees and income tax payments; progress of clinical trials.
Increase (Decrease) in:			
Accounts payable and accrued expenses	6,854	2,268	Timing of vendor payments.
Accrued sales deductions	38,720	26,400	Increased accrued sales deductions due to increased product sales and higher wholesaler and pharmacy inventory levels in the fourth quarter of 2018
Income taxes payable	(3,561)	15,931	Timing of income tax payments.
Other	831	6,239	Increased accrual for uncertain tax position in 2017 related to alternative minimum tax and state nexus; timing of bonus compensation payments
	$ (4,734)	$ 23,710	

Investing Activities

We invest excess cash in marketable securities in accordance with our investment policy. Marketable securities consist of investments which mature in four years or less, including U.S. Treasury and various

government agency debt securities, municipal bonds, and investment grade securities in industrial and financial institutions. Fluctuations in investing activities between periods relate exclusively to the timing of marketable securities purchases and the related maturities of these securities.

Net cash used in investing activities for the year ended December 31, 2018 of $413.5 million primarily relates to net purchases of marketable securities of $411.8 million. Net cash used in investing activities for the year ended December 31, 2017 of $86.4 million included net purchases of marketable securities of $73.2 million, patent defense costs of approximately $11.2 million and property and equipment purchases of approximately $2.0 million.

Financing Activities

Net cash provided by financing activities totaled $376.4 million and $5.7 million for the years ended December 31, 2018 and 2017, respectively. Cash was generated from issuance of the 2023 Notes and common stock due to stock option exercises.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2018, except as noted below, in thousands:

Contractual Obligations	Fiscal Year 2019	Fiscal Year 2020 - Fiscal Year 2021	Fiscal Year 2022 - Fiscal Year 2023	Thereafter	Total
2023 Convertible Notes	$ —	$ —	$ 402,500	$ —	$ 402,500
Interest on 2023 Convertible Notes[(1)]	2,516	5,031	3,145	—	10,692
Operating Leases[(2)]	3,400	4,120	6	1	7,527
Purchase Obligations[(3)]	203,318	2,410	110	—	205,838
Total[(4)]	$ 209,234	$ 11,561	$ 405,761	$ 1	$ 626,557

(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 current headquarters office and laboratory space as of December 31, 2018.

(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, 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) This table does not include contingent milestones that we may be required to pay to the former Biscayne security holders after the closing of the merger and upon achievement of these milestones. The additional contingent milestone payments include (i) payments of up to approximately $73 million, contingent on achieving certain development milestones with respect to certain pharmaceutical intellectual property assets held by Biscayne prior to the Merger; and (ii) payments of up to approximately $95 million, contingent on achieving certain sales milestones with respect to the marketing of products developed from such assets. We will also pay a low single digit royalty on net product sales to the former security holders of Biscayne and any applicable royalties to third parties for the use of in-licensed intellectual property. The maximum combined royalty that we will pay to all parties is approximately 12%, depending on the

intellectual property covering the marketed product and applicable tiered sales levels. This table does not include any of these milestones and royalty payments, as the timing and likelihood of such payments are not known.

(6) As of December 31, 2018, 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 $24.8 million at December 31, 2018 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 will have no impact on our liquidity at any time. The non-recourse liability has not been included in the table above.

We have obtained exclusive licenses from third parties for proprietary rights to support the product candidates in our psychiatry portfolio. We have two license agreements with Afecta Pharmaceuticals, Inc. (Afecta) pursuant to which we obtained exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810. We may pay up to $0.3 million upon the achievement of certain milestones. If a product candidate is successfully developed and commercialized, we will be obligated to pay royalties at a low single digit percentage of worldwide net product sales.

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 of 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 or liquidity risk. Our exposure to market risk is confined to investments in cash, cash equivalents, marketable securities and long term marketable securities. As of December 31, 2018, we had unrestricted cash, cash equivalents, marketable securities and long term marketable securities of $774.8 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash, cash equivalents, marketable securities and long term marketable securities and because we generally hold these securities to maturity, we do

not believe that an increase in market rates would have any significant impact on the realizable value of our investments.

In connection with the 2023 Notes, we have separately entered into the 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 of the purchased Convertible Note Hedge Transactions, respectively. We do not have any currency or other derivative financial instruments other than the outstanding warrants to purchase common stock and the convertible note hedges.

We may contract with CROs and investigational sites globally. Currently, we have one ongoing trial for SPN-817 outside the United States, and no clinical trials for our other product candidates 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, 2018 and December 31, 2017, substantially all of our total liabilities were denominated in the U.S. dollar.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our consolidated results of operations for the years ended December 31, 2018 and 2017.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Supernus Pharmaceuticals, Inc.
Consolidated Financial Statements
Years ended December 31, 2018, 2017 and 2016

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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, 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, 2018, 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 March 1, 2019 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.

/s/ KPMG LLP

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

Baltimore, Maryland
March 1, 2019

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, 2018, 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, 2018, 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, 2018 and 2017, 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, 2018, and the related notes (collectively, the consolidated financial statements), and our report dated March 1, 2019 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's 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
March 1, 2019

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 192,248	$ 100,304
Marketable securities	163,770	39,736
Accounts receivable, net	102,922	65,586
Inventories, net	25,659	16,304
Prepaid expenses and other current assets	8,888	6,521
Total current assets	493,487	228,451
Long term marketable securities	418,798	133,638
Property and equipment, net	4,095	5,124
Intangible assets, net	31,368	36,019
Deferred income taxes	29,683	20,843
Other assets	380	389
Total assets	$ 977,811	$ 424,464
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,195	$ 6,844
Accrued sales deductions	107,063	68,343
Accrued expenses	36,535	27,305
Income taxes payable	12,377	15,938
Non-recourse liability related to sale of future royalties, current portion	2,183	4,283
Deferred licensing revenue	—	287
Total current liabilities	161,353	123,000
Deferred licensing revenue, net of current portion	—	1,149
Convertible notes, net	329,462	—
Non-recourse liability related to sale of future royalties, long term	22,575	22,258
Other non-current liabilities	11,398	10,577
Total liabilities	524,788	156,984
Stockholders' equity		
Common stock, $0.001 par value, 130,000,000 shares authorized at December 31, 2018 and December 31, 2017; 52,316,583 and 51,314,850 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	52	51
Additional paid-in capital	369,637	294,999
Accumulated other comprehensive loss, net of tax	(3,158)	(747)
Retained earnings (accumulated deficit)	86,492	(26,823)
Total stockholders' equity	453,023	267,480
Total liabilities and stockholders' equity	$ 977,811	$ 424,464

See accompanying notes to consolidated financial statements.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Earnings

(in thousands, except share and per share data)

	Years Ended December 31,		
	2018	2017	2016
Revenue			
Net product sales	$ 399,871	$ 294,097	$ 210,078
Royalty revenue	8,276	6,367	4,686
Licensing revenue	750	1,774	239
Total revenue	408,897	302,238	215,003
Costs and expenses			
Cost of product sales	15,356	15,215	11,986
Research and development	89,209	49,577	42,791
Selling, general and administrative	159,888	137,905	106,010
Total costs and expenses	264,453	202,697	160,787
Operating earnings	144,444	99,541	54,216
Other income (expense)			
Interest income	13,843	2,864	1,467
Interest expense	(13,840)	(134)	(543)
Interest expense on non-recourse liability related to sale of future royalties	(4,271)	(1,434)	(4,548)
Changes in fair value of derivative liabilities	—	76	448
Loss on extinguishment of debt	—	(295)	(671)
Total other income (expense)	(4,268)	1,077	(3,847)
Earnings before income taxes	140,176	100,618	50,369
Income tax expense (benefit)	29,183	43,334	(40,852)
Net earnings	$ 110,993	$ 57,284	$ 91,221
Earnings per share:			
Basic	$ 2.13	$ 1.13	$ 1.84
Diluted	$ 2.05	$ 1.08	$ 1.76
Weighted-average shares outstanding:			
Basic	51,989,824	50,756,603	49,472,434
Diluted	54,098,872	53,301,150	51,708,983

See accompanying notes to consolidated financial statements.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Earnings

(in thousands)

	Years Ended December 31,		
	2018	2017	2016
Net earnings	$ 110,993	$ 57,284	91,221
Other comprehensive earnings (loss):			
Unrealized (loss) gain on marketable securities, net of tax	(2,411)	(613)	354
Other comprehensive earnings (loss)	(2,411)	(613)	354
Comprehensive earnings	$ 108,582	$ 56,671	$ 91,575

See accompanying notes to consolidated financial statements.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity

(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, 2015	49,004,674	$ 49	$ 263,955	$ (488)	$ (175,509)	$ 88,007
Share-based compensation	—	—	5,926	—	—	5,926
Issuance of employee stock purchase plan shares	109,244	—	1,494	—	—	1,494
Exercise of stock options	85,694	—	557	—	—	557
Equity issued on conversion of convertible notes	771,655	1	4,161	—	—	4,162
Net earnings	—	—	—	—	91,221	91,221
Unrealized gain on marketable securities, net of tax	—	—	—	354	—	354
Other	—	—	34	—	—	34
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 at 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 at 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

See accompanying notes to consolidated financial statements.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities			
Net earnings	$ 110,993	$ 57,284	$ 91,221
Adjustments to reconcile net earnings to net cash provided by operating activities:			
Loss on extinguishment of debt	—	295	671
Change in fair value of derivative liability	—	(76)	(448)
Realized gains/losses on sales of securities	8	—	—
Depreciation and amortization	7,063	8,132	2,399
Amortization of deferred financing costs and debt discount	11,848	50	278
Amortization of premium/discount on marketable securities	(1,673)	(563)	242
Non-cash interest expense on non-recourse liability related to sale of future royalties	4,271	1,434	4,548
Non-cash royalty revenue	(5,914)	(5,283)	(4,686)
Share-based compensation expense	11,291	8,433	5,926
Deferred income tax (benefit) provision	(4,167)	21,224	(41,787)
Changes in operating assets and liabilities:			
Accounts receivable	(35,856)	(24,059)	(15,619)
Inventories	(9,355)	497	(4,214)
Prepaid expenses and other current assets	(2,367)	(3,566)	2,306
Accounts payable	(3,578)	(620)	3,470
Accrued sales deductions	38,720	26,400	15,149
Accrued expenses	10,432	2,888	7,539
Income taxes payable	(3,561)	15,931	7
Deferred licensing revenue	—	(274)	144
Other non-current liabilities	831	6,513	(334)
Net cash provided by operating activities	128,986	114,640	66,812
Cash flows from investing activities			
Purchases of marketable securities	(491,654)	(101,889)	(47,364)
Sales and maturities of marketable securities	79,827	28,657	31,824
Purchases of property and equipment	(844)	(2,029)	(1,603)
Deferred legal fees	(809)	(11,154)	(18,821)
Net cash used in investing activities	(413,480)	(86,415)	(35,964)
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	11,582	5,681	2,052
Net cash provided by financing activities	376,438	5,681	2,052
Net change in cash and cash equivalents	91,944	33,906	32,900
Cash and cash equivalents at beginning of year	100,304	66,398	33,498
Cash and cash equivalents at end of period	$ 192,248	$ 100,304	$ 66,398
Supplemental cash flow information:			
Cash paid for interest on convertible notes	$ 1,342	$ 134	$ 493
Cash paid for Biscayne acquisition	$ 15,000	$ —	$ —
Income taxes paid	$ 34,772	$ 1,588	$ —
Non-cash investing and financing activity:			
Conversion of convertible notes and interest make-whole	$ —	$ 4,548	$ 4,162
Deferred legal fees included in accounts payable and accrued expenses	$ 250	$ 521	$ 5,122
Unsettled purchase of marketable securities included in accrued expenses	$ —	$ 1,004	$ —

See accompanying notes to consolidated financial statements.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

Years ended December 31, 2018, 2017 and 2016

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 treatment of epilepsy. The Company has several proprietary product candidates in clinical development that address the CNS market.

The Company launched Oxtellar XR and Trokendi XR in 2013 for the treatment of epilepsy and launched Trokendi XR for the prophylaxis of migraine headache in adolescents and adults in April 2017.

On October 4, 2018, the Company acquired Biscayne Neurotherapeutics, Inc. (Biscayne). Supernus obtained worldwide rights, excluding certain markets in Asia where rights have been out-licensed, to Biscayne's product candidate, hurpezine A, that is in Phase I clinical development. This product candidate has received an Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of Dravet Syndrome, a severe form of childhood epilepsy. Supernus obtained rights to all the product candidate's underlying and related intellectual property (IP). (See Note 18.)

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., and Biscayne Neurotherapeutics, Inc. and its wholly-owned subsidiary, Biscayne Neurotherapeutics Australia Pty Ltd, collectively referred to herein as "Supernus" or "the Company." All significant intercompany transactions and balances have been eliminated in consolidation. The financial results of Biscayne have been included in the consolidated financial statements from date of acquisition.

The Company has its principal business in the U.S. and operates in one operating segment.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, as well as related disclosure of contingent assets and liabilities. Actual results could differ materially from the Company's estimates. To the extent that there are material differences between these estimates and actual results, the Company's financial condition or operating results will be affected. The Company bases its estimates on: historical experience; various forecasts; information received from its service providers; and other assumptions that the Company believes are reasonable under the circumstances. The Company evaluates the methodology employed and the judgment and assumptions used in its estimates on an ongoing basis.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

2. Summary of Significant Accounting Policies (Continued)

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 government, 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 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.

Declines in value judged to be other-than-temporary, if any, are included in 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.

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. Realized gains and losses are also included in interest income and are determined using the specific identification method for determining the cost of securities sold.

Accounts Receivable, Net

Accounts receivable are reported on the consolidated balance sheets at outstanding amounts due from customers, less an allowance for doubtful accounts and sales discounts and 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 generally less than one year.

The Company recorded approximately $0.1 million, zero and $0.4 million for doubtful accounts for the years ended December 31, 2018, 2017 and 2016, respectively. There was no receivable write-off recorded for the years ended December 31, 2018, 2017 and 2016.

The Company recorded an allowance of approximately $11.5 million and $8.9 million for expected sales discounts and allowances related to prompt pay discounts and contractual fee for service arrangements to pharmaceutical wholesalers and distributors, as of December 31, 2018 and December 31, 2017, respectively.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

2. Summary of Significant Accounting Policies (Continued)

Concentration of Credit Risk

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

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 insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, these bear minimal default risk.

The following table includes the Company's customers, who are pharmaceutical wholesalers and distributors, that represent more than 10% of total net product sales for the years ended December 31, 2018, 2017 and 2016.

	Years Ended December 31,		
	2018	2017	2016
Customer A	33%	30%	29%
Customer B	33%	30%	30%
Customer C	32%	37%	37%
	98%	97%	96%

The following table includes each major customer that represented more than 10% of accounts receivable, net as of December 31, 2018 and 2017:

	December 31,	
	2018	2017
Customer A	46%	46%
Customer B	24%	22%
Customer C	27%	28%
	97%	96%

Inventories

Inventories, which are recorded at the lower of cost or net realizable value, include materials, labor and other direct and indirect costs and are valued using the first-in, first-out method. The Company typically capitalizes inventories produced in preparation for commercial launches when the related product candidates have received regulatory approval and it is probable that the related costs will be recoverable through the commercial sale of the product.

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

2. Summary of Significant Accounting Policies (Continued)

Trokendi XR. Patent defense costs will be charged to expense in the event of an unsuccessful outcome of the litigation. Patents 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. The carrying value of the patents is assessed for impairment annually during the fourth quarter of each year, or more frequently if impairment indicators exist.

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 to determine whether the asset's value is recoverable. Evaluating for impairment requires judgment, including the estimation of future cash flows, future growth rates and profitability, and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in market conditions could affect impairment analyses and require 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.

Deferred Financing Costs

Deferred financing costs were incurred by the Company in connection with the Company's sale 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.

Preclinical Study and Clinical Trial Accruals

The Company estimates preclinical study 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 conduct activities on our behalf. In recording service fees, the Company estimates the time period over which the related services will be performed and compares the level of effort expended through the end of each period to the cumulative expenses recorded and payments made for such services. As appropriate, the Company accrues additional service fees or defers any non-refundable advance payments until the related services are performed. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust its accrued expenses or deferred advance payments accordingly. If the Company later determines that it no longer expects the services associated with a nonrefundable advance payment to be rendered, the remaining portion of that advance payment will be charged to expense in the period in which such determination is made.

Revenue Recognition

In accordance with ASC 606, "*Revenue from Contracts with Customers,"* the Company recognizes revenue when control of promised goods or services is transferred to the Company's customers in an

2. Summary of Significant Accounting Policies (Continued)

amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. (See Note 17 for disaggregation of revenue by nature.) The Company does not adjust revenue for effects of significant financing component for contracts where the Company expects the period between the transfer of the goods or service and collection to be less than one year.

Incremental costs for obtaining a contract include only those costs that the Company would not have incurred if the contract had not been obtained; e.g., sales commissions. As a practical expedient, the Company expenses incremental costs in obtaining a contract if the expected amortization period of the contract would have been a year or less, or if the amount is immaterial. These costs are recorded in *Selling, general and administrative expenses* in the consolidated statement of earnings. Costs to fulfill a contract are expensed as incurred and recorded in *Cost of product sales* in the consolidated statement of earnings. There were no contract assets or liabilities recorded as of January 1, 2018 or December 31, 2018.

Revenue from Product Sales

The Company's products are distributed through a third party fulfillment center. The Company's customers purchase product to fulfill orders from retail pharmacy chains and independent pharmacies of varying size and buying power. The Company's customers take control of the products, including title and ownership, upon physical receipt of these products at their facilities.

The Company recognizes gross revenue when its products are shipped from its fulfillment center to its customers, who are primarily pharmaceutical wholesalers and distributors and the customers take control of the products. Product sales are recorded net of various forms of variable consideration, including estimated rebates, discounts, allowances, and an estimated liability for product returns (collectively, "sales deductions").

Variability in the net transaction price for the Company's products primarily arises from sales deductions, which require significant judgment. The Company considers: historical experience; current contract prices under applicable programs; unbilled claims; processing time lags; and inventory levels in the distribution channel in arriving at these estimates. The Company adjusts its estimates of revenue at the earlier of 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 estimates, the Company adjusts these estimates. These adjustments could materially affect net product sales and earnings in the period that such variances become known.

Sales Deductions

Sales deductions are primarily comprised of rebates, product returns and sales discounts and allowances. The Company records product sales net of the following sales deductions:

- *Rebates:* Rebates are discounts which the Company pays under either private sector or public sector health care programs. Public sector rebate programs encompass: Medicaid Drug Rebate Programs; Medicare Coverage Gap Programs; and programs covering public health service institutions and government entities that purchase drugs under the Federal Supply Schedule,

2. Summary of Significant Accounting Policies (Continued)

encompassing all federal employees and agencies. 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 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.

Rebates are owed upon dispensing product to a patient; i.e., filling a prescription. Our accrual balance consists of 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 accrual for known or estimated prior quarters' unpaid rebates to cover prescriptions dispensed in past quarters. Third, the accrual balance includes an estimate for rebates that will be owed for prescriptions filled in future quarters; i.e., for product which has been sold to our customers, and which resides either as wholesaler/distributor inventory, or is held as inventory at pharmacies. This product will be used prospectively to fill prescriptions.

Because the period from the date on which the prescription is filled to the date the Company receives and pays the invoice varies, the Company's estimates of expected rebate claims vary by program and by type of customer. For each of its products, the Company bases its estimates of expected rebate claims using 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 contractual agreements; prospective changes in co-pay assistance programs; and anticipated changes in program utilization rates (i.e., patient participation rates).

The sensitivity of the Company's estimates can vary by program and by type of customer. If actual rebates vary from estimated amounts, the Company may need to adjust the balances of such rebates to reflect actual expenditures with respect to these programs. These changes could materially affect net product sales and earnings in the period of adjustment. 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) as a reduction to gross product sales and an increase in *Accrued Sales Deductions* in current liabilities.

- *Returns:* Sales 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 the return of product that is damaged or defective when shipped from its warehouse. In addition, 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 are destroyed.

  The Company estimates liability for returns based on the actual returns experience for its two commercial products, in conjunction with industry return experience for similar products; i.e., ambient temperature storage for oral formulations. Because the Company's products have not reached maturity, the return rate of its products has and is expected to continue to vary. The

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

2. Summary of Significant Accounting Policies (Continued)

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 Sales Deductions* in current liabilities.

The Company's estimated liability for product returns is also affected by price increases. The Company's products have a shelf life of 36 to 48 months from date of manufacture. Because of the extended shelf life and its return policy, there typically is a significant time lag between the time at which the product is sold and when the Company issues credit on expired product. The Company's policy permits product returns to be processed at current wholesaler price rather than historical price. Therefore, price increase(s) taken during the current period increases the provision for product returns and therefore affects its estimated liability for product returns for both sales made in the current period as well as sales made in prior periods. Accordingly, the Company may have to adjust its estimates, favorably or unfavorably, which would have an effect on product sales and earnings in the period of adjustment.

- *Sales discounts and allowances*: Distributors and wholesalers of pharmaceutical products are generally offered various forms of consideration, including allowances, service fees and prompt payment discounts, as consideration for distributing 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, they 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 reduction to *Accounts Receivable*.

  Customer orders are generally fulfilled within a few days of receipt, resulting in minimal order backlog. Open purchase orders for products from customers are expected to be fulfilled within the next twelve months. 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., which involve the right to use the Company's intellectual property as a functional license. These agreements generally include an up-front license fee and ongoing milestone payments upon the achievement of specific events. These agreements may also require minimum royalty payments based on in-country sales of products developed from the applicable intellectual property.

Up-front license fees are recognized once the license has been delivered to the customer.

Milestones are a form of variable consideration that are recognized when either the underlying events have been achieved (event-based milestone) or the sales-based targets have been met by the collaborative partner (sales-based milestone). Both types of milestone payments are non-refundable. The Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. This can involve management's judgment that includes assessing factors that are outside of the Company's influence,

2. Summary of Significant Accounting Policies (Continued)

such as: likelihood of regulatory success; availability of third party information; and expected duration of time until achievement of event. These factors are evaluated based on the specific facts and circumstances. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price.

Event-based milestones are recognized in the period that the related event, such as regulatory approval, occurs. Milestone payments 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 development activities of a third-party, are not considered probable of being achieved until the specified event occurs. Sales-based milestones are recognized as revenue when the target is achieved. Revenue is recognized from the satisfaction of performance obligations in the amount billable to the customer.

Revenue associated with future milestones will be recognized when the related event occurs or 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 non-cash royalty revenue for royalty amounts earned pursuant to a royalty agreement with United Therapeutics Corporation that involves 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 16). Accordingly, the Company records non-cash royalty revenue based on estimated product sales of Orenitram by United Therapeutics that result in Royalty payments made from United Therapeutics to HC Royalty in connection with these agreements.

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

There are no guaranteed minimum amounts owed to the Company related to royalty revenue agreements.

Cost of Product Sales

The cost of product sales consists primarily of materials, third-party manufacturing costs, freight and distribution costs, allocation of labor, quality control and assurance, and other manufacturing overhead costs.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist primarily of: employee-related expenses, including salaries and benefits; share-based compensation expense; expenses incurred under agreements with CROs; fees paid to clinical investigators who are participating in our clinical trials; fees paid to consultants and other vendors that assist in the conduct of the Company's clinical trials; the cost of acquiring and manufacturing clinical trial materials; the cost

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

2. Summary of Significant Accounting Policies (Continued)

of manufacturing materials used in process validation, but only to the extent that those materials are manufactured prior to receiving regulatory approval and are not expected to be sold commercially; facilities costs that do not have an alternative future use; related depreciation and other allocated expenses; license fees for, and milestone payments related to, in-licensed products and technologies; and costs associated with animal testing activities and regulatory approvals. Assets acquired that are used for research and development and have no future alternative use are expensed as in-process research and development.

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 $43.3 million, $33.8 million and $21.9 million in advertising costs for the years ended December 31, 2018, 2017 and 2016, respectively. These expenses are recorded in *Selling, general and administrative expenses* in the consolidated statement of earnings.

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. The Company uses the Black-Scholes option-pricing model in calculating the grant date fair value of option awards. 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 was determined based on observable market prices of the Company's common stock.

Expected Volatility—Volatility is a measure of the amount by which a variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company has identified several public entities of similar size, complexity, and stage of development. Accordingly, historical volatility has been estimated using the volatility of the stock of these companies, as well as taking into consideration the Company's actual volatility since our IPO in 2012. As the Company's historical experience is not sufficient to calculate volatility for the option grants, the Company will continue to use the guideline peer group volatility information until the historical volatility of its own common stock is sufficiently mature on its own to measure expected volatility for future option grants.

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 that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years. The Company determines 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.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

2. Summary of Significant Accounting Policies (Continued)

Over time, management will track actual experience with the option term, so that estimates will approximate actual experience.

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

Expected Forfeiture Rate—Prior to 2017, the forfeiture rate was the estimated percentage of options granted that were anticipated to be forfeited or canceled before becoming fully vested. Following the Company's adoption of ASU 2016-09, "*Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,"* at January 1, 2017, forfeitures are accounted for as they occur.

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 in 2018

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, "*Revenue from Contracts with Customers,*" and has subsequently issued a number of amendments to ASU 2014-09. ASU 2014-09 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.

On January 1, 2018, the Company adopted 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.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

2. Summary of Significant Accounting Policies (Continued)

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

	December 31, 2017 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 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.

In May 2017, the FASB issued ASU 2017-09, "*Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting,*" which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of a change in terms or conditions. ASU 2017-09 is effective after December 15, 2017 for all annual periods, and interim periods within those annual periods, with early adoption permitted. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, "*Classification of Certain Cash Receipts and Cash Payments*." The standard eliminates diversity in the practice of how certain cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective after December 15, 2017 for annual reporting periods and interim periods therein. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, "*Business Combination (Topic 805): Clarifying the Definition of a Business*," which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business. The guidance requires that if substantially all of the fair value of gross assets acquired or disposed of is concentrated in a single asset or group of similar identifiable assets, the assets would not represent a business. The guidance also clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. The Company adopted the new standard on

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

2. Summary of Significant Accounting Policies (Continued)

January 1, 2018 and will apply the new guidance prospectively to transactions occurring after adoption, including the Biscayne acquisition (see Note 18).

In August 2018, the U.S. Securities and Exchange Commission (SEC) adopted the final rule under SEC Release No. 33-10532, *"Disclosure Update and Simplification."* This final rule amends certain disclosure requirements that are redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. The final rule is effective for all filings made on or after November 5, 2018. The SEC staff clarified that the first presentation of the changes in shareholders' equity may be included in the first Form 10-Q for the quarter that begins after the effective date of the amendments. The adoption of the final rule did not have a material impact on the Company's consolidated financial statements. The Company will change its presentation of statement of shareholders' equity in the first quarter of 2019.

New Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*" and its related amendments (the New Lease Standard). The New Lease Standard requires a lessee to recognize a right-of-use asset and a lease liability on the balance sheet. The New Lease Standard is effective after December 15, 2018 for fiscal years, and interim periods within those years. The Company will adopt this ASU on January 1, 2019 using the modified retrospective approach transition method. The adoption will result in an immaterial cumulative adjustment to retained earnings at the beginning of the adoption period. Results for reporting periods beginning after January 1, 2019 will be presented under the New Lease Standard while prior period amounts are not adjusted and continue to be reported in accordance with ASC 840, "*Leases*." Hence, this will result in a balance sheet presentation that will not be comparable to the prior period in the first year of adoption. The Company expects to elect certain practical expedients permitted under the transition guidance.

The adoption of this ASU will result in the recognition of right-of-use assets and lease liabilities of approximately $4.0 million. The New Lease Standard is also expected to result in enhanced quantitative and qualitative lease-related disclosures. The Company does not expect the New Lease Standard to have a material impact on the consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*, which requires credit losses on financial assets measured at amortized cost basis to be presented at the net amount expected to be collected, not 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 standard is effective after December 15, 2019, for interim and annual periods within those years, with early adoption permitted. The Company is currently assessing the impact of this new standard. The Company does not expect it to have a material impact.

The Company has evaluated all other ASUs issued through the date the consolidated financials 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.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

3. Fair Value of Financial Instruments

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. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal or most advantageous market for the asset or liability. Accordingly, fair value is determined based on a hypothetical transaction at the measurement date, considered from the perspective of a market participant rather than from a reporting entity's perspective.

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

- Level 1—Inputs are unadjusted quoted prices that the Company has the ability to access at the measurement date for identical assets traded in active markets.
- Level 2—Inputs are quoted prices for similar assets and liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability (interest rates, yield curves, etc.). Inputs are derived principally from or corroborated by observable market data or by correlation or other means (market corroborated inputs).
- Level 3—Unobservable inputs that reflect the Company's own assumptions, based on the best information available, including the Company's own data.

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

		Fair Value Measurements as of December 31, 2018 Using		
	Total Fair Value at December 31, 2018	Quoted Prices in Active Markets for Indentical Assests (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 192,248	$ 192,248	$ —	$ —
Marketable securities				
Corporate debt securities	163,770	245	163,525	—
Long term marketable securities:				
Corporate debt securities	415,650	445	415,205	—
Government debt securities	3,148	—	3,148	—
Other non-current assets:				
Marketable securities—restricted (SERP)	326	1	325	—
Total assets at fair value	$ 775,142	$ 192,939	$ 582,203	$ —

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

3. Fair Value of Financial Instruments (Continued)

		Fair Value Measurements as of December 31, 2017 Using		
	Total Fair Value at December 31, 2017	Quoted Prices in Active Markets for Indentical Assests (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 100,304	$ 100,304	$ —	$ —
Marketable securities				
Corporate debt securities	39,736	2,118	37,618	—
Long term marketable securities:				
Corporate debt securities	132,477	448	132,029	—
Government debt securities	1,161	—	1,161	—
Other non-current assets:				
Marketable securities—restricted (SERP)	335	—	335	—
Total assets at fair value	$ 274,013	$ 102,870	$ 171,143	$ —

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

Level 2 assets include the SERP (Supplemental Executive Retirement Plan) assets, commercial paper and investment grade corporate and government debt securities and other fixed income securities. 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. The fair value of the restricted marketable securities is included within other non-current assets in the consolidated balance sheets.

The carrying value, face value and estimated fair value of the 2023 Notes were approximately $329.5 million, $402.5 million and $375.8 million, respectively, as of December 31, 2018. The fair value was estimated based on actual trade information as well as quoted prices provided by bond traders and are characterized within Level 2 of the fair value hierarchy.

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 marketable securities held by the Company were as follows, in thousands of dollars:

At December 31, 2018:

Available for Sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate and government debt securities	$ 586,726	55	(4,213)	$ 582,568

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

3. Fair Value of Financial Instruments (Continued)

At December 31, 2017:

Available for Sale	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate and government debt securities	$ 174,235	48	(909)	$ 173,374

The contractual maturities of the unrestricted available for sale marketable securities held by the Company were as follows, in thousands of dollars:

	December 31, 2018
Less Than 1 Year	$ 163,770
1 year to 2 years	166,482
2 year to 3 years	163,687
3 years to 4 years	88,629
Greater Than 4 Years	—
Total	$ 582,568

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

4. Inventories

Inventories consist of the following, in thousands of dollars:

	December 31, 2018	December 31, 2017
Raw materials	$ 5,742	$ 2,995
Work in process	7,275	8,873
Finished goods	12,642	4,436
	$ 25,659	$ 16,304

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

5. Property and Equipment

Property and equipment consist of the following, in thousands of dollars:

	December 31, 2018	December 31, 2017
Lab equipment and furniture	$ 8,995	$ 8,331
Leasehold improvements	2,731	2,731
Software	2,181	2,004
Computer equipment	1,313	1,226
Construction-in-progress	94	178
	15,314	14,470
Less accumulated depreciation and amortization	(11,219)	(9,346)
	$ 4,095	$ 5,124

Depreciation and amortization expense on property and equipment was approximately $1.9 million, $1.2 million, and $1.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

No indicators of impairment were identified.

6. Intangible Assets

Intangible assets consist of patent defense costs, which are legal fees incurred in conjunction with defending patents for Oxtellar XR and Trokendi XR. We amortize those 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, in thousands of dollars:

	Weighted-Average Life	December 31, 2018	December 31, 2017
Capitalized patent defense costs	4.00 - 8.25 years	$ 44,724	$ 44,185
Less accumulated amortization		(13,356)	(8,166)
		$ 31,368	$ 36,019

In March 2017, the Company entered into two settlements with several companies related to Trokendi XR patent litigation, which effectively reduced the remaining life of the Trokendi XR patents. The remaining unamortized aggregate capitalized patent defense costs for Trokendi XR have subsequently been amortized over the reduced remaining useful life of the patents at issue, or January 1, 2023. This is the date the Company is obligated under the settlements to grant a non-exclusive license to the patents at issue.

Amortization expense on intangible assets was approximately $5.2 million, $6.9 million and $1.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Anticipated annual amortization expense on intangible assets for each of the next four years from, 2019 to 2022, is approximately $5.2 million per year. Anticipated annual amortization expense on intangible assets for the fifth year, 2023, is approximately $2.5 million.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

6. Intangible Assets (Continued)

No indicators of impairment were identified.

7. Accrued Expenses

Accrued expenses are comprised of the following, in thousands of dollars:

	December 31, 2018	December 31, 2017
Accrued clinical trial and clinical supply costs	$ 14,034	$ 6,996
Accrued compensation	13,546	10,279
Accrued professional fees	3,706	2,890
Accrued interest expense	650	—
Accrued product costs	38	726
Other accrued expenses	4,561	6,414
	$ 36,535	$ 27,305

8. Accrued Sales Deductions

Accrued sales deductions are comprised of the following, in thousands of dollars:

	December 31, 2018	December 31, 2017
Accrued rebates	$ 85,003	$ 49,460
Accrued product returns	22,060	18,883
	$ 107,063	$ 68,343

9. Convertible Senior Secured Notes

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 additional 2023 Notes on the same terms and conditions, which the Initial Purchasers exercised in full on March 15, 2018.

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.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

9. Convertible Senior Secured Notes (Continued)

The Company will pay interest on the 2023 Notes 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. The 2023 Notes will be structurally subordinated to all future indebtedness and other liabilities, including trade payables.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

9. Convertible Senior Secured Notes (Continued)

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 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 and 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 generally 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 are intended 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.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

9. Convertible Senior Secured Notes (Continued)

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 $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 remaining $8.4 million is recorded as deferred costs and is being amortized to interest expense over the contractual term of the 2023 Notes.

The liability component of the 2023 Notes consisted of the following, in thousands of dollars:

	December 31, 2018
Principal amount of the 2023 Notes	$ 402,500
Debt discount	(76,434)
Deferred financing costs	(8,452)
Accretion of debt discount and deferred financing costs	11,848
December 31, 2018 carrying value	$ 329,462

No 2023 Notes were converted as of December 31, 2018.

10. Stockholders' Equity

Common Stock

The holders of our common stock are entitled to one vote for each share of common stock held.

11. Share-Based Compensation

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 at 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 ten year contractual terms.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

11. Share-Based Compensation (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 will be 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 expense was as follows, in thousands of dollars:

	Years Ended December 31,		
	2018	2017	2016
Research and development	$ 1,943	$ 1,387	$ 1,107
Selling, general and administrative	9,348	7,046	4,819
Total	$ 11,291	$ 8,433	$ 5,926

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

	Years Ended December 31,		
	2018	2017	2016
Fair value of common stock	$37.20 - $58.15	$25.30 - $41.00	$12.98 - $22.80
Expected volatility	57.95% - 60.56%	53.61% - 60.60%	60.89% - 64.54%
Dividend yield	0%	0%	0%
Expected term	6.25 years	6.25 years	6.25 years
Risk-free interest rate	2.69% - 2.85%	1.90% - 2.18%	1.14% - 2.15%
Expected forfeiture rate	0%	0%	5%

As of December 31, 2018 and 2017, total unrecognized compensation expense was approximately $22.4 million and $17.6 million, respectively, which the Company expects to recognize over a weighted-average period of 2.65 years and 2.8 years, respectively.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

11. Share-Based Compensation (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, 2016	3,644,088	$ 10.25	7.59	$ 54,673
Granted	1,130,155	$ 26.57		
Exercised	(407,477)	$ 9.31		$ 12,822
Forfeited	(86,096)	$ 17.24		
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
As of December 31, 2018:				
Vested and expected to vest	3,916,963	$ 19.98	7.10	$ 57,220
Exercisable	1,889,947	$ 12.47	5.96	$ 39,447

The weighted-average grant-date fair value of options which were granted for the years ended December 31, 2018, 2017 and 2016 was $23.43, $14.35 and $7.66 per share, respectively.

The total fair value of the underlying common stock related to shares that vested during the years ended December 31, 2018, 2017, and 2016 was approximately $8.3 million, $5.4 million and $3.9 million, respectively.

12. Earnings per Share

Basic earnings per share is calculated using the weighted-average number of common shares outstanding. Diluted earnings per share is calculated using the weighted-average number of common shares, as per the treasury stock method under the dilutive effect of the Company's stock option grants, SAR, warrants, ESPP awards and the 2023 Notes, as determined.

The following common stock equivalents were excluded in the calculation of diluted earnings per share because their inclusion would be anti-dilutive, as applied to the earnings from continuing operations, and as applicable to common stockholders, for the years ended December 31, 2018, 2017 and 2016:

	Years Ended December 31,		
	2018	2017	2016
Warrants to purchase common stock	3,949,743	—	—
Convertible notes	87,215	—	—
Convertible notes hedges	87	—	—
Stock options, SAR and ESPP awards	199,982	40,009	22,944

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

12. Earnings per Share (Continued)

The following table sets forth the computation of basic and diluted net earnings per share for the years ended December 31, 2018, 2017 and 2016, in thousands of dollars, except share and per share amounts:

	Years Ended December 31,		
	2018	2017	2016
Numerator, in thousands:			
Net earnings used for calculation of basic EPS	$ 110,993	$ 57,284	$ 91,221
Interest expense on convertible debt	—	134	543
Changes in fair value of derivative liabilities	—	(76)	(448)
Loss on extinguishment of debt	—	295	671
Loss on extinguishment of outstanding debt, as if converted	—	(321)	(1,182)
Total adjustments	—	32	(416)
Net earnings used for calculation of diluted EPS	$ 110,993	$ 57,316	$ 90,805
Denominator:			
Weighted average shares outstanding, basic	51,989,824	50,756,603	49,472,434
Effect of dilutive potential common shares:			
Shares underlying Convertible Senior Notes	—	285,257	1,222,363
Shares issuable to settle interest make-whole derivatives	—	7,012	71,537
Stock options and SAR	2,109,048	2,252,278	942,649
Total dilutive potential common shares	2,109,048	2,544,547	2,236,549
Weighted average shares outstanding, diluted	54,098,872	53,301,150	51,708,983
Net earings per share, basic	$ 2.13	$ 1.13	1.84
Net earnings per share, diluted	$ 2.05	$ 1.08	1.76

13. Income Taxes

The summary of the income tax expense (benefit) for the years ended December 31, 2018, 2017 and 2016 is as follows, in thousands of dollars:

	Years Ended December 31,		
	2018	2017	2016
Current			
Federal	$ 26,772	$ 18,288	$ 544
State	5,621	3,822	78
Deferred			
Federal	(2,450)	21,493	(39,898)
State	(760)	(269)	(1,576)
Total	$ 29,183	$ 43,334	$ (40,852)

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

13. Income Taxes (Continued)

A reconciliation of income tax expense at the U.S. Federal statutory income tax rate to provision for income taxes at the Company's effective tax rate is as follows, in thousands of dollars:

	Years Ended December 31,		
	2018	2017	2016
Income tax expense computed at U.S. Federal statutory income tax rate[1]	$ 29,437	$ 35,217	$ 17,629
State income taxes	3,674	2,714	(1,523)
Permanent items[3]	(2,196)	(2,311)	715
Research and development credits	(3,199)	(2,196)	(1,902)
Uncertain income tax position	716	(1,137)	143
Effect of rate changes[2]	—	9,694	—
Change in valuation allowance[4]	—	—	(56,019)
Other	751	1,353	105
Income tax expense (benefit)	$ 29,183	$ 43,334	$ (40,852)

(1) Includes the effect of the Tax Cuts and Jobs Act, which lowered the U.S. corporate income tax rate from 35 percent to 21 percent effective January 1, 2018.

(2) Relates to the remeasurement of existing deferred taxes as a result of the change to the U.S. corporate income tax rate. The impact was a reduction in value of deferred taxes.

(3) Primarily relates to tax benefit from the exercise of employee stock options.

(4) Reduction in the 2016 valuation allowances was attributable to profitable results of operations.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

13. Income Taxes (Continued)

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

	As of December 31,	
	2018	2017
Deferred tax assets:		
Convertible bond hedge	$ 21,412	$ —
Accrued sales deductions	13,205	8,449
Accrued compensation and stock based compensation	8,218	7,090
Non-recourse liability related to sale of future royalties	5,571	6,377
Research and development credit carryforwards	3,817	3,795
Amortization	3,289	2,073
Net operating loss carryforwards	2,900	5,072
Deferred rent	125	211
Inventory	499	480
Alternative Minimum Tax (AMT) credit	978	1,613
Other	1,143	645
Total deferred tax assets	61,157	35,805
Less: valuation allowance	(9)	—
Deferred tax asset, net of valuation allowance	61,148	35,805
Deferred tax liability:		
Debt discount on 2023 Notes	(17,568)	—
Infringement legal costs	(10,697)	(10,557)
Depreciation	(236)	(264)
Section 481(a)	(2,964)	(4,141)
Net deferred tax assets	$ 29,683	$ 20,843

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. The use of the Company's U.S. Federal and State NOL carryforwards and research and development credits are restricted in annual use due to changes in the Company's ownership. The Company's state NOLs have a similar limitations on the use of NOLs. 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.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

13. Income Taxes (Continued)

As of December 31, 2018, the U.S. Federal and state NOL carryforwards amounted to approximately $20.6 million and $9.2 million, respectively, and will expire in various years beginning in 2033. For the year ended December 31, 2018, the Company utilized NOLs of approximately $18.4 million and expects the remaining $20.6 million of Federal NOL carryforwards to become available in the future years.

As of December 31, 2018, the Company has available research and development credit carryforwards of approximately $4.2 million, which will become available in 2020 and will expire, if unused, starting in 2026.

Due to NOL and research and development credit carryforwards, all U.S. Federal and state income tax returns filed by the Company are subject to examination by the taxing jurisdictions.

The Company accounts for uncertain income tax positions pursuant to the guidance in FASB 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 can't 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, in thousands of dollars:

	Years Ended December 31,		
	2018	2017	2016
Balance as of January 1	$ 8,859	$ 9,299	$ 9,341
Gross increases related to current year tax positions	1,108	1,178	662
Gross decreases related to current year tax positions	—	—	(169)
Gross increases related to prior year tax positions	—	947	—
Gross decreases related to prior year tax positions	(484)	—	(375)
Lapse of statute of limitations	(635)	—	—
Change in tax rates	—	(2,565)	(160)
Balance as of December 31	$ 8,848	$ 8,859	$ 9,299

As of December 31, 2018, 2017 and 2016, the Company recorded $0.6 million of tax benefit, zero and $0.5 million of current tax expense on setting up an uncertain tax position related to the AMT. The $0.6 million current tax benefit was caused by the expiration of statute of limitation on 2014 AMT. The Company also recorded a $0.3 million expense on setting up an uncertain tax position related to 2018 research and development tax credit. The Company does not anticipate a significant increase or decrease in the uncertain income tax benefits within the next 12 months.

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (Tax Act), resulting in significant modifications to existing law. The Tax Act, among other things, lowered the U.S. corporate income tax rate from 35 percent to 21 percent effective January 1, 2018. The Tax Act also enhanced and extended through 2026 the option to claim accelerated depreciation on qualified property and expanded limitations on the deductibility of executive compensation. As of December 31, 2018, the Company has completed the accounting for all of the enactment date income tax effects of the Tax Act and

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

13. Income Taxes (Continued)

determined that no adjustments are need to be recognized to the provisional amounts recorded at December 31, 2017.

14. Commitments and Contingencies

Operating Leases

The Company has concurrent leases for office and lab space that extend through April 2020. The Company may elect to extend the term of the leases for an additional five-year term. The leases provide for a tenant improvement allowance of approximately $2.1 million in aggregate. As of December 31, 2018, $0.4 million is available for tenant improvements.

Rent expense for the leased facilities and leased vehicles for the years ended December 31, 2018, 2017 and 2016 was approximately, $3.6 million, $2.7 million and $2.7 million, respectively.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2018 are as follows, in thousands of dollars:

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

On February 27, 2018, the Company and Rockside-700 LLC (Rockside) entered into a Lease Agreement (the Lease) for the Company's new headquarters to be located at 700 Quince Orchard Road, Gaithersburg, Maryland. On December 13, 2018 (the Termination Date), the Company and Rockside terminated the Lease. As of the Termination Date, the term of the Lease had not commenced and the Company had not occupied the building. The Company has not incurred any material termination penalties in connection with termination of the Lease.

Product Licenses

The Company has obtained exclusive licenses from third parties for proprietary rights to support the product candidates in the Company's psychiatry portfolio. Under license agreements with Afecta Pharmaceuticals, Inc. (Afecta), the Company has exclusive worldwide rights to selected product candidates, including an exclusive license to SPN-810 (molindone hydrochloride). We may pay up to $0.3 million upon the achievement of certain milestones, none of which is owed as of December 31, 2018. The Company is obligated to pay royalties to Afecta at a low single digit percentage of worldwide net product sales.

The Company has also entered into a purchase and sale agreement with Rune HealthCare Limited (Rune), where the Company obtained the exclusive worldwide rights to a product concept from Rune. There are no future milestone payments due to Rune under this agreement. If the Company receives approval to market and sell any products based on the Rune product concept, for SPN-809 (viloxazine

14. Commitments and Contingencies (Continued)

hydrochloride), the Company is obligated to pay royalties to Rune at a low single digit percentage of worldwide net product sales.

15. 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 $2.1 million, $1.8 million, and $1.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

16. Royalty Agreements

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. The Company will retain full ownership of the royalty rights if and when a certain cumulative payment threshold is reached per the terms of the agreement. The Company recorded a non-recourse liability related to this transaction, and amortizes this amount as non-cash royalty revenue. Revenue recognition is based on estimated net product sales by United Therapeutics of Orenitram that result in payments made from United Therapeutics to HC Royalty.

The Company also recognizes non-cash interest expense related to this liability and accrues at an effective interest rate. That rate is determined based on projections of HC Royalty's rate of return. The Company recognized non-cash interest expense of $4.3 million, $1.4 million and $4.5 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

17. Disaggregated Revenues

The following tables summarize the disaggregation of revenue by nature:

	Years Ended December 31,		
	2018	2017	2016
		(in thousands)	
Net Product Sales:			
Trokendi XR	$ 315,295	$ 226,518	$ 158,384
Oxtellar XR	84,576	67,579	51,694
Total Net Product Sales	399,871	294,097	210,078
Royalty Revenues	8,276	6,367	4,686
Licensing Revenue	750	1,774	239
Total Revenues	$ 408,897	$ 302,238	$ 215,003

The Company recognized non-cash royalty revenue of $5.9 million, $5.3 million and $4.7 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Licensing revenue included $0.75 million and $1.5 million of milestone revenue for the years ended December 31, 2018 and 2017, respectively. No milestone revenue was recorded during the year ended December 31, 2016.

For the year ended December 31, 2018, revenue recognized from performance obligations related to prior periods (for example, due to changes in transaction price) was not material in the aggregate to Net Product Sales, License Revenue and Royalty Revenue.

18. Acquisitions

Biscayne Acquisition

On October 4, 2018, the Company acquired Biscayne, a privately-held company developing a novel treatment for epilepsy. The Company obtained worldwide rights, excluding certain markets in Asia where rights have been out-licensed, to Biscayne's product candidate, huperzine A (SPN-817). Huperzine A is in clinical development and has received an Orphan Drug designation from the U.S. Food and Drug Administration for the treatment of Dravet Syndrome, a severe form of childhood epilepsy.

The Company made an upfront cash payment of $15 million as of the acquisition date. Upon the achievement of certain specified development and sales milestones, The Company may be required to make additional cash payments to the former Biscayne security holders. These additional payments include: (i) payments of up to approximately $73 million, contingent on the Company achieving certain development milestones by utilizing the acquired pharmaceutical intellectual property assets and (ii) payments of up to approximately $95 million, contingent on the Company achieving certain net product sales milestones with respect to the marketing of products developed from such assets. The Company will also pay a low single digit royalty on net sales to the former security holders of Biscayne, and any applicable royalties to third parties for the use of in-licensed intellectual property. The maximum combined royalty the Company will pay to all parties is approximately 12%, depending on the intellectual property covering the marketed product and applicable tiered net product sales levels.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

18. Acquisitions (Continued)

As a result of the acquisition, the Company added SPN-817 to its product development pipeline. The Company plans on studying SPN-817 initially in severe pediatric epilepsy disorders such as Dravet Syndrome.

In accordance with ASU 2017-01, the acquisition of Biscayne was accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in a single asset, SPN-817. Net assets acquired included the in-process research and development asset, SPN-817, which is in early Phase I clinical development for the treatment of Dravet Syndrome, and deferred tax assets from net operating loss carryovers. Due to the stage of development of this asset, significant development risk remains. It is not yet probable that there is future economic benefit from this asset. Absent successful clinical results and regulatory approval for the asset, there is no alternative future use associated with SPN-817. Accordingly, approximately $14 million of the $15 million cash payment was recorded as research and development expense in the consolidated statement of earnings at the time of acquisition, as SPN-817 has not yet reached technological feasibility. The Company also recorded approximately $1 million related to the deferred tax assets acquired.

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

Quarterly financial information for fiscal 2018 and 2017 are presented in the following table, in thousands of dollars, except per share data:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2018				
Revenue	$ 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
Net earnings per share, basic	0.51	0.59	0.54	0.50
Net earnings per share, diluted	0.49	0.57	0.52	0.48
2017				
Revenue	$ 57,576	$ 75,829	$ 80,398	$ 88,435
Total costs and expenses	40,788	49,762	58,056	54,091
Operating earnings	16,788	26,067	22,342	34,344
Net earnings	10,297	17,368	15,961	13,658
Net earnings per share, basic	0.21	0.34	0.31	0.27
Net earnings per share, diluted	0.19	0.32	0.29	0.26

20. Subsequent Event

The Company has 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 lease commences upon Landlord tendering possession of the Premises. The term of this lease commenced on February 1, 2019 (the Commencement Date) and shall continue until April 30, 2034, unless earlier terminated in accordance with the terms of the Lease (the Lease Term).

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2018, 2017 and 2016

20. Subsequent Event (Continued)

Fixed rent with respect to the Premises shall commence on the Commencement Date. The initial fixed rental rate is approximately $195,000 per month for the first 12 months, which rate 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 and its pro rata share of any operating expenses and real estate taxes.

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, 2018, 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, 2018.

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, 2018 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, 2018.

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, 2018. Their responsibility is to evaluate whether internal controls over financial reporting was designed and operating effectively. KPMG issued an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2018 which is 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, 2018. 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, 2018, 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 2019 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2018.

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 2019 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2018.

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 2019 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2018.

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, 2018:

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	3,916,963	$ 19.98	2,776,656
Equity compensation plans not approved by security holders	—	—	—
Total	3,916,963	$ 19.98	2,776,656

(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 2019 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2018.

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 2019 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2018.

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, 2018 and 2017 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).

Exhibit Number	Description
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).
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).

Exhibit Number	Description
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).
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 2019 (incorporated by reference to Item 5.02 of the Form 8-K filed on February 26, 2019, 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).

Exhibit Number	Description
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).
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).

Exhibit Number	Description
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).
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).
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
31.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).

Exhibit Number	Description
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 INS**	XBRL Instance Document.
101 SCH**	XBRL Taxonomy Extension Schema Documents.
101 CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101 DEF**	XBRL Taxonomy Extension Definition Linkbase Document.
101 LAB**	XBRL Taxonomy Extension Label/Linkbase Document.
101 PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.

† 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: March 1, 2019

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)	March 1, 2019
/s/ GREGORY S. PATRICK	Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2019
/s/ CHARLES W. NEWHALL, III.	Director and Chairman of the Board	March 1, 2019
/s/ CARROLEE BARLOW, M.D., PH.D.	Director	March 1, 2019
/s/ GEORGES GEMAYEL	Director	March 1, 2019
/s/ FREDERICK M. HUDSON	Director	March 1, 2019
/s/ JOHN M. SIEBERT, PH.D.	Director	March 1, 2019

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EXHIBIT 21

SUBSIDIARIES OF SUPERNUS PHARMACUTICALS, INC.

Name of Subsidiaries	Jurisdiction of Organization
Supernus Europe Ltd.	United Kingdom
Biscayne Neurotherapeutics, Inc.	Delaware
Biscayne Neurotherapeutics Australia Pty Ltd.	Australia

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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 March 1, 2019, with respect to the consolidated balance sheets of Supernus Pharmaceuticals, Inc. and subsidiaries as of December 31, 2018 and 2017, 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, 2018, and the related notes (collectively, the "consolidated financial statements"), and the effectiveness of internal control over financial reporting as of December 31, 2018, which reports appear in the December 31, 2018 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
March 1, 2019

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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: March 1, 2019

By: /s/ JACK A. KHATTAR

Jack A. Khattar
President and Chief Executive Officer

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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: March 1, 2019

By: /s/ GREGORY S. PATRICK

Gregory S. Patrick
Vice President and Chief Financial Officer

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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, 2018 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: March 1, 2019

By: /s/ JACK A. KHATTAR

Jack A. Khattar
President and Chief Executive Officer

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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, 2018 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: March 1, 2019

By: /s/ GREGORY S. PATRICK

Gregory S. Patrick
Vice President and Chief Financial Officer

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