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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, 2020

or

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER: 001-35518

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware			**20-2590184**
(State or other jurisdiction of incorporation or organization)			(I.R.S. Employer Identification Number)
9715 Key West Avenue	**Rockville**	**MD**	**20850**
(Address of Principal Executive Offices)			(zip code)

(301) 838-2500

(Registrant's telephone number, including area code)

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

TITLE OF EACH CLASS:	**Outstanding at February 28, 2021**	**Trading Symbol**	**NAME OF EACH EXCHANGE ON WHICH REGISTERED:**
Common Stock, $0.001 Par Value	52,923,107	SUPN	NASDAQ Stock Market LLC

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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

As of June 30, 2020, the aggregate market value of the common stock held by non-affiliates of the registrant based on the closing price of the common stock on the NASDAQ Global Market was $1,205,174,821.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2021 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 2020 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, 2020

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

We are the owner/licensee 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®", “Xadago®”, “Myobloc®”, “Apokyn®”, "NeuroBloc®", and the registered Supernus Pharmaceuticals logo.

All trademarks or trade names referred to in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933 that involve risks and uncertainties. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Annual Report other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans, and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "seek," "anticipate," "should," "could," "would," "potential," or the negative of those terms and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking.

These forward-looking statements include expectations regarding the Company's recent and future interactions and communications with the FDA concerning the New Drug Applications (NDA) for SPN-812 and SPN-830, the outcome of any additional device testing associated with the SPN-830 NDA submission, the potential approval of the NDAs for SPN-812, currently under review, and SPN-830 following resubmission, the planned submission to the FDA of a Supplemental New Drug Application for SPN-812 in adults, and the potential benefits and commercialization of SPN-812 and SPN-830. In addition to the factors mentioned in this annual report, such risks and uncertainties include, but are not limited to, the Company's ability to sustain and increase its profitability; the Company's ability to raise sufficient capital to fully implement its corporate strategy; the implementation of the Company's corporate strategy, including the successful identification and implementation of business development opportunities; the Company's future financial performance and projected expenditures; the Company's product research and development activities, including the timing and progress of the Company's clinical trials, and projected expenditures; completion of the purchase price allocation for the Company's acquisition of USWM Enterprises, LLC; the Company's ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its products and product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the early entry into the market of generic equivalents to all the Company's approved products; the Company's ability to develop successful product formulations that are accepted by patients, physicians, and payors; availability of potential funding sources; the Company's ability to meet its staffing needs; the Company's ability to comply with the Corporate Integrity Agreement and other risk factors set forth from time to time in the Company's filings with the Securities and Exchange Commission made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended.

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) is a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. Our diverse neuroscience portfolio includes approved treatments for epilepsy, migraine, hypomobility in Parkinson's Disease (PD), cervical dystonia, and chronic sialorrhea. We are developing a broad range of novel CNS product candidates, including new potential treatments for attention-deficit hyperactivity disorder (ADHD), hypomobility in PD, epilepsy, depression, and rare CNS disorders.

The Company was incorporated in Delaware, commenced operations in 2005, became publicly traded in 2012, and is listed on the NASDAQ Stock Exchange under the ticker symbol SUPN. Our principal executive offices are located in Rockville, Maryland. Our extensive expertise in product development has been built over the past 25 years: initially as a stand-alone development organization; then, as a United States (U.S.) subsidiary of Shire Plc (Shire, a subsidiary of Takeda Pharmaceutical Company Ltd.); then upon our acquisition of substantially all of the assets of Shire Laboratories, Inc. in 2005, as Supernus Pharmaceuticals.

On April 21, 2020, we entered into a Development and Option Agreement (Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor). Under the terms of the Development Agreement, the Company and Navitor will jointly conduct a Phase II clinical program for NV-5138 (mTORC1 activator) (SPN-820) in treatment-resistant depression (TRD).

On April 28, 2020, we entered into a Sale and Purchase Agreement with US WorldMeds Partners, LLC to acquire the CNS portfolio of USWM Enterprises, LLC (USWM Enterprises) (USWM Acquisition). With the acquisition completed on June 9, 2020, we added three established commercial products, APOKYN, XADAGO, and MYOBLOC, and a product candidate in late-stage development, SPN-830 (apomorphine infusion pump), to our portfolio.

Our Strategy

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

- *Drive growth and profitability.* We will continue to drive the revenue growth of our commercial products by continuing to dedicate sales and marketing resources.
- *Advance our current pipeline toward commercialization.* We have a portfolio of early to late-stage product candidates. We continue to advance our late-stage product candidates, SPN-812 (viloxazine hydrochloride) for treatment of ADHD and SPN-830 (apomorphine infusion pump) for treatment of hypomobility in PD, to regulatory approval and commercialization.
- *Target strategic business development opportunities.* We are actively exploring a broad range of strategic opportunities that fit well with our strong presence in CNS. These include in-licensing products and entering into co-promotion partnerships, which are synergistic with our sales force call point for our commercial products and product candidates. We are also exploring co-development partnerships for our pipeline products and growth opportunities through value creation and transformative merger and acquisition transactions.
- *Continue to grow our pipeline.* We plan to continue to evaluate and develop additional CNS product candidates through our internal research development efforts that we believe have significant commercial potential.

Commercial Products

The table below summarizes our portfolio of commercial products.

Trokendi XR

Trokendi XR is the first once-daily extended release topiramate product indicated for the treatment of epilepsy in the U.S. market. In 2013, we launched Trokendi XR for the treatment of epilepsy. In April 2017, we launched Trokendi XR for the prophylaxis of migraine headaches in adults and adolescents.

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

Pursuant to the U.S. Food and Drug Administration's (FDA) 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 for patients aged two years to less than six years of age.

Oxtellar XR

Oxtellar XR is the first once-daily extended release oxcarbazepine product indicated for the treatment of epilepsy in the U.S. market. In 2013, we launched Oxtellar XR for adjunctive therapy in the treatment of partial seizures in adults and children 6 to 17 years of age. In January 2019, we launched Oxtellar XR for monotherapy treatment of partial onset epilepsy seizures in adults and children 6 to 17 years of age.

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

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

APOKYN

APOKYN (apomorphine hydrochloride injection) is a product indicated for the acute, intermittent treatment of hypomobility or "off" episodes ("end-of-dose wearing off" and unpredictable "on-off" episodes) in patients with advanced PD. APOKYN’s adjustable dose subcutaneous injection pen is designed to quickly and reliably reverse the effects of oral levodopa wearing off in patients with inadequately controlled PD. Patients taking APOKYN saw 95% of "off" episodes reversed, with improvement beginning as quickly as 10 minutes post-dosing in clinical studies. With the alternative of immobility and limited function, we believe the rapid and reliable reduction of "off" episode symptoms is of utmost importance to patients.

XADAGO

XADAGO (safinamide) is a once-daily product indicated as adjunctive treatment to levodopa/carbidopa in patients with PD who are experiencing “off” episodes. XADAGO is a monoamine oxidase B (MAO-B) inhibitor that works by blocking the catabolism of dopamine, which is believed to result in an increase in dopamine levels, and therefore a subsequent increase in dopaminergic activity in the brain.

In March 2017, XADAGO received FDA approval. In the XADAGO clinical trials, patients experienced more beneficial “on” time, a time when Parkinson’s symptoms are reduced, without troublesome uncontrolled involuntary movement (dyskinesia), compared to those receiving a placebo. The increase in “on” time was accompanied by a reduction in “off” time and better scores on a measure of motor function assessed during “on” time than before treatment.

MYOBLOC

MYOBLOC (rimabotulinumtoxinB) is a product indicated for the treatment of cervical dystonia and sialorrhea in adults, and it is the only Type B toxin available on the market. Based on clinical studies, MYOBLOC injections offer patients struggling with painful cervical dystonia symptoms relief as early as two weeks after injection, with the duration of effect of between 12-16 weeks. In sialorrhea, patients generally experienced symptom relief for up to three months post-dosing in well-controlled studies. In well controlled studies, injections of MYOBLOC have been shown to reduce the unstimulated salivary flow rate (USFR) by 0.3g/minute compared to placebo. MYOBLOC must be administered by a physician.

MYOBLOC was first approved by the FDA in 2000 for the treatment of adults with cervical dystonia. In August 2019, the FDA approved a supplemental Biologics License Application (sBLA) for MYOBLOC for the treatment of chronic sialorrhea in adults. Pursuant to the FDA's approval of MYOBLOC for the treatment of chronic sialorrhea in adults, we will be conducting a clinical program under a Special Protocol Assessment from the FDA, which will address post-marketing commitments and potentially provide expanded indications for MYOBLOC.

We market rimabotulinumtoxinB in select European countries under the trade name NeuroBloc. In addition, our collaboration partner Eisai has been marketing rimabotulinumtoxinB in Japan since 2013 under the trade name NerBloc.

Research and Development

We are developing a pipeline of novel CNS product candidates for the treatment of various CNS conditions. The table below summarizes our product candidates.

Product Candidate	Indication	Development	NDA
SPN-812	Pediatric ADHD		Under Review [1]
SPN-812	Adult ADHD	Positive Phase III Data announced in December 2020	sNDA planned for 2H 2021 [2]
SPN-817	Severe Epilepsy	Phase I	
SPN-820	Depression	Phase I	
SPN-830	Continuous prevention of “off” episodes in PD patients		NDA resubmission planned post FDA discussions [3]
MYOBLOC	Neurological Disorders	Phase IV	

[1] SPN-812 NDA was assigned a Prescription Drug User Fee Act (PDUFA) target action date in early April 2021.
[2] Assumes approval of the SPN-812 NDA.
[3] SPN-830 Refusal to File (RTF) letter received from FDA in November 2020.

We have devoted and continue to devote significant resources to research and development activities. We expect to incur significant expenses as we continue developing each of our product candidates through FDA approval or until the program terminates; and expanding product indications for approved products and intellectual property portfolio.

SPN-812 (extended release viloxazine hydrochloride)

SPN-812 is a novel non-stimulant product being developed for the treatment of ADHD in children and adults. It has a mechanism of action which can be described as multimodal. We believe SPN-812 could be well-differentiated compared to other non-stimulant treatments due to its different pharmacological and pharmacokinetic profile. The active ingredient in SPN-812, viloxazine hydrochloride, has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant, albeit at much higher dosage levels. Viloxazine hydrochloride will have a new chemical entity (NCE) status in the U.S.

SPN-812 for the treatment of ADHD in pediatric patients

The Phase III pivotal program for SPN-812 for the treatment of ADHD in pediatric patients with ADHD consisted of four three-arm, placebo-controlled trials: P301 and P303 trials in patients 6 to 11 years old; and P302 and P304 trials in patients 12 to 17 years old. We announced positive topline results from the pediatric trials (P301 and P303) and the first adolescent trial (P302) in December 2018. Results of the second adolescent Phase III trial (P304) were released in March of 2019. Refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2019, for the results of the previously completed Phase III trials in patients 6 to 11 years old and patients 12 to 17 years old.

In January 2020, the FDA accepted for review the NDA for SPN-812 for the treatment of ADHD in pediatric patients 6 to 17 years of age and assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 8, 2020. In November 2020, the FDA issued a Complete Response Letter (CRL) regarding the NDA for SPN-812. The CRL indicated that the review cycle for the SPN-812 NDA was complete but was not ready for approval in its present form. The primary issue cited in the CRL relates to our in-house laboratory that conducts analytical testing, which recently moved to a new location. No clinical safety or efficacy issues were identified during the review.

In January 2021, we met with the FDA in a Type A meeting to discuss the CRL and the requirements for the NDA resubmission. In February 2021, we resubmitted the SPN-812 NDA and removed the reference to our in-house laboratory, and addressed other contents of the CRL. The FDA notified us that the NDA resubmission is a Class I resubmission with a PDUFA target action date in early April 2021.

We are preparing for the commercial launch of SPN-812 for the treatment of ADHD in pediatric patients, which is expected in the second quarter of 2021, if approved by the FDA.

SPN-812 for the treatment of ADHD in Adult patients

We initiated a Phase III program of SPN-812 for the treatment of ADHD in adult patients in the third quarter of 2019.

In December. 2020, we announced positive topline results from the P306 Phase III study of SPN-812 for the treatment of ADHD in adult patients. A total of 374 adult patients were randomized across placebo and a daily dose of SPN-812 starting with 200mg with flexible dose administration up to 600mg. At a daily dose of up to 600mg, the trial met the primary endpoint with statistical significance (p=0.0040) compared to placebo in improving the symptoms of ADHD from baseline to end of the study as measured by the Adult ADHD Investigator Rating Scale (AISRS). Patients receiving SPN-812 had a -15.5 point change from baseline in the primary endpoint compared to -11.7 for placebo at week 6 (p=0.0040).

In addition to meeting the primary efficacy endpoint, the Phase III study met the key secondary efficacy endpoint with statistical significance (p=0.0023) in the change from baseline of the Clinical Global Impression – Severity of Illness (CGI-S) Scale at week 6. The active dose was well tolerated. Patients who completed the study were offered the opportunity to continue into an ongoing open-label safety extension study.

At the end of the P306 study, SPN-812 reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the AISRS with p-values of 0.0380 and 0.0015, respectively.

Assuming approval for SPN-812 for the treatment of ADHD in pediatric patients, we plan to submit a supplemental NDA (sNDA) to the FDA for SPN-812 for the treatment of ADHD in adult patients in the second half of 2021.

SPN-830 (Apomorphine Infusion Pump)

SPN-830 is a late-stage drug/device combination product candidate for the treatment of continuous prevention of “off” episodes in PD patients. If approved, it would be the only continuous infusion of apomorphine available in the U.S. and an important step for PD patients that would have otherwise been candidates for potentially invasive surgical procedures, such as deep brain stimulation. Continuous infusion may also limit some of the side effects of a subcutaneous injection of apomorphine.

Results from the Phase III randomized Toledo study of SPN-830 for the continuous treatment of motor fluctuations (“on-off” episodes) in PD patients were published in The Lancet Neurology in 2018. The primary endpoint demonstrated that SPN-830 resulted in a 2.47 hours per day reduction in “off” time compared to placebo (0.58); p= 0.0025. Regina Katzenschlager et al. The Lancet Neurology. 2018;Vol 17(9):749-759.

In September 2020, we submitted an NDA to the FDA for SPN-830 for the continuous treatment of motor fluctuations (“on-off” episodes) in PD patients. In November 2020, we received a Refusal to File (RTF) letter from the FDA that stated the NDA was not sufficiently complete to permit a substantive review. In the RTF letter, the FDA requested certain documents and reports to be submitted in support of the application. We believe additional testing of the device will be necessary to support the SPN-830 NDA resubmission.

We have engaged in discussions with the FDA regarding the SPN-830 filing and expect to have ongoing future interactions with the FDA. We have scheduled a Type A meeting with the FDA in March 2021 to discuss the full contents of the RTF letter and clarify the steps required for the resubmission of the SPN-830 NDA. We plan to provide updates on the NDA status once we have agreed on the path forward for the program.

SPN-817 (huperzine A)

SPN-817 represents a novel mechanism of action (MOA) for an anticonvulsant. SPN-817 is a novel synthetic form of huperzine A, whose mechanism of action includes potent acetylcholinesterase inhibition, with pharmacological activities in CNS conditions such as epilepsy. The development will initially focus on the drug's anticonvulsant activity, which has been shown in preclinical models to be effective for the treatment of partial seizures and Dravet Syndrome. SPN-817 is in clinical development and has received Orphan Drug designation for both Dravet Syndrome and Lennox-Gastaut Syndrome from the FDA.

We plan on initially studying SPN-817 in severe epilepsy disorders. A Phase I, proof-of-concept trial is currently underway outside of the U.S. in adult patients with refractory complex partial seizures. We are studying the safety and pharmacokinetic profile of a new extended release formulation of non-synthetic SPN-817 (huperzine A). We are focused on completing and optimizing the synthesis process of the synthetic drug as well as developing a novel dosage form. Given the potency of SPN-817 (huperzine A), a novel extended release oral dosage form is critical to the success of this program because initial studies with the immediate release formulations of non-synthetic SPN-817 (huperzine A) have shown serious dose-limiting, side effects.

A pre-IND meeting with the FDA is planned for 2021 to enable a Dravet Syndrome Phase II study.

SPN-820 (NV-5138)

SPN-820 is a first-in-class, orally active small molecule that directly activates brain mTORC1 (mechanistic target of rapamycin complex 1), a gatekeeper of cellular metabolism and renewal. SPN-820 binds to and modulates sestrin, which senses amino acid availability in the brain, a potent natural activator of mTORC1. This complex may be suppressed in people suffering from depression. A Phase I trial demonstrated early proof of concept in which a single dose of SPN-820 showed a rapid and sustained improvement in core symptoms, with favorable safety and tolerability in patients with treatment resistant depression. We believe the novel MOA in depression may improve symptoms of depression in patients who have failed other agents.

Complex 1 of the mechanistic target of rapamycin (mTORC1) activity governs the pace and ability of the cell to synthesize protein and other cellular components. Increased mTORC1 activity contributes to a broad array of aging diseases by increasing protein misfolding and driving cellular stress, inflammation, and fibrosis. In other disease states such as severe depression, inadequate mTORC1 activity contributes to disease pathology by limiting energy utilization and protein synthesis, leading to impaired function. Multiple preclinical studies have shown that mTORC1 activation is required for the efficacy of many rapid-acting antidepressant compounds, including but not limited to modulators of the N-methyl-D-aspartic-acid (NMDA)-mediated signaling pathway like ketamine.

Development activities are ongoing, including a multiple-ascending dose study in healthy volunteers, with the goal of initiating a Phase II clinical program in treatment-resistant depression by the end of 2021.

Market Overview

Epilepsy

Epilepsy is a complex neurological disorder characterized by the 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.

Adherence with drug treatment regimens is critically important to achieving effective control for patients with epilepsy. Non-adherence 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, particularly Trokendi XR and Oxtellar XR, may offer important advantages in the treatment of epilepsy. The release profiles of extended release products can produce more consistent and steadier plasma concentrations as compared to immediate release products, potentially resulting in fewer side effects, better tolerability, fewer emergency room visits, improved efficacy, and fewer breakthrough seizures. Extended release products may help patients improve adherence and, consequently, help patients enjoy a better quality of life.

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

Migraine

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. The World Health Organization categorizes migraine as one of the most disabling medical illnesses worldwide. The American Research Foundation categorizes migraine as the third most prevalent illness in the world, and nearly 1 in 4 U.S. households includes someone with migraines. Migraine is estimated to affect over 39 million individuals in the U.S.

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

Parkinson's Disease

Parkinson's Disease is a progressive neurological disorder that is characterized by a loss of dopamine producing neurons in certain regions of the brain, causing symptoms like tremor, slowness of movement, stiffness, loss of balance, and lack of coordination. PD is the second most common progressive neurodegenerative disorder, affecting 1-2% of individuals 65 years and older. Patients with PD can also be affected with psychological symptoms such as anxiety, depression, aggression, and problems with cognition and memory. As the disease progresses, some patients may lose the ability to independently perform the tasks of daily living.

PD patients are frequently prescribed levodopa to help replace dopamine, which is reduced in the brain. However, motor disabilities as a result of levodopa wearing off remain a significant problem for over half of PD patients. Patients in an "off" state, including those whose last dose of oral levodopa has worn off and whose next oral dose has not yet begun to take effect, can suffer from reduced coordination or mobility for several hours per day.

In well-controlled clinical studies, APOKYN injections were effective in treating "off" periods, as measured by the motor function subset of the Unified Parkinson's Disease Rating Scale (UPDRS). For patients for whom oral levodopa will not sufficiently control "off" periods, the Company has commercialized APOKYN, delivered via an injection pen. For patients who experience significant "off" time each day, the Company has developed a product candidate as a continuous infusion pump (SPN-830) to deliver apomorphine subcutaneously. The infusion may reduce the variability in motor symptoms of PD and offer improved tolerability versus the acute injection route. For patients not ready to try parenteral therapy, oral MAO-B inhibitors, such as XADAGO, may provide a decrease in "off" time of up to one hour per day when combined with appropriate levodopa therapy.

Cervical Dystonia

Cervical dystonia, also known as spasmodic torticollis, is a condition characterized by involuntary muscle contractions in the neck, which cause the head to twist uncontrollably into an abnormal, often painful position. It is a rare disorder, most often presenting in middle age, whose symptoms begin gradually, worsen, and then plateau over a period of months. Estimates of the

prevalence of cervical dystonia vary considerably, from 20 to 4,100 per million individuals. Injections of botulinum toxin into affected neck muscles can create temporary relief from symptoms.

In well controlled studies, botulinum toxins like MYOBLOC have been shown to improve symptoms as measured on the Toronto Western Spasmodic Torticollis Rating Scale, including pain.

Sialorrhea

Sialorrhea can occur in conjunction with several neurologic disorders, such as amyotrophic lateral sclerosis (ALS), cerebral palsy (CP), PD, or as a side effect of some medications. It is characterized by overactive salivary glands. In adults, PD is the most common cause of sialorrhea, with 70%–80% of PD patients experiencing symptoms. In 30%–80% of schizophrenic patients taking clozapine, sialorrhea is evident. In addition to being embarrassing, complications of sialorrhea include aspiration, infection, skin breakdown, and bad odor.

ADHD

ADHD is a CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children, and an estimated 3% to 5% of adults in the U.S. An estimated 50% of children with ADHD continue to meet the criteria for ADHD into adolescence.

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

Competition

We are engaged in segments of the pharmaceutical industry that are highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations are commercializing or pursuing the development of products for the same molecule, compound, or diseases that we are currently pursuing or may target in the future.

Migraine and Epilepsy Competition

Trokendi XR competes with all immediate release and extended release topiramate products, including Topamax, Qudexy XR, and their related generic products. For example, in February 2021, Glenmark Pharmaceuticals Limited (Glenmark) received final approval by the FDA for topiramate extended release capsules, the generic version of Qudexy XR capsules of Upsher-Smith Laboratories.

Trokendi XR also competes with other products used for the prevention of migraine headaches. Most notably, this includes anti-CGRPs (calcitonin gene related peptide), which is a new class of products introduced in 2018; Botox; beta-blockers; valproic acid; and amitriptyline.

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. Many medications are used to treat epilepsy, including topiramate, oxcarbazepine, acetazolamide, brivaracetam, carbamazepine, clobazam, lacosamide, phenytoin, valproic acid, lamotrigine, gabapentin, levetiracetam phenobarbital, and zonisamide.

Parkinson's Disease Competition

The most commonly prescribed medicine for PD is levodopa (L-dopa). Carbidopa may be used along with levodopa to improve its efficacy and reduce the amount of levodopa needed to control PD symptoms. There are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's patients, including various levodopa preparations, dopamine agonists, MAO-B inhibitors, and others.

APOKYN is given as needed as an adjunct to levodopa/carbidopa therapy in PD patients who experience "off" episodes. It competes with all apomorphine hydrochloride products, including KYNMOBI. It also competes with other PRN therapies such as Inbrija, and other adjunctive therapies, including NOURIANZ.

XADAGO competes with other MAO-B inhibitors used to treat "off" episodes in PD, including rasagiline (AZILECT) and selegiline (Zelapar and EMSAM).

APOKYN and XADAGO also compete with other products for the treatment of PD, both branded and generic, including levodopa products.

Sialorrhea and Cervical Dystonia Competition

MYOBLOC is the only available botulinum toxin B, whereas other available toxins are type A. MYOBLOC competes with type A toxins such as Botox, Dysport, and Xeomin. MYOBLOC also competes with oral agents used to treat cervical dystonia, including generic baclofen, anticholinergics, benzodiazepines, and tetrabenazine.

MYOBLOC competes with Xeomin (incobotulinumtoxinA) for the treatment of sialorrhea in adults. Other pharmacologic treatments used to treat sialorrhea include generic glycopyrrolate tablets as well as behavior modification.

ADHD Competition

ADHD medications prescribed to both children and adults are broadly categorized as stimulants and non-stimulants. Stimulants for ADHD include amphetamine, methylphenidate, amphetamine, dexmethylphenidate, methylphenidate. Non-stimulant treatments for ADHD include atomoxetine, guanfacine, and clonidine. Stimulants and non-stimulants may be prescribed together for some ADHD patients.

Sales and Marketing

We market our products through our own sales force in the U.S. and seek strategic collaborations with other pharmaceutical companies to commercialize our products outside of the U.S. We have a commercial sales and marketing organization in the U.S. to support sales of our commercial products. As a result of the USWM Acquisition, we acquired an experienced commercial team, which includes a proven sales force and a medical organization with expertise and focus on serving movement disorder specialists and other specialized health care providers in the U.S. that will continue to commercially promote APOKYN, MYOBLOC, and XADAGO. We believe our current sales force of over 240 sales representatives is effectively targeting healthcare providers, primarily neurologists, to support and grow our current commercial products. Simultaneously promoting our neurology products allows us to leverage our commercial infrastructure and gain efficiencies in operations.

Assuming we obtain FDA approval for SPN-812, we anticipate expanding our existing sales force to market the commercial product to the relevant physician audience of psychiatrists, pediatricians, and primary care physicians.

Customers

The majority of our product sales are to pharmaceutical wholesalers, specialty pharmacies, and distributors who, in turn, sell our products to pharmacies, hospitals, and other customers, including federal and state entities. The majority of sales of Oxtellar XR, Trokendi XR, XADAGO, and MYOBLOC are made to wholesalers and distributors. In addition, MYOBLOC is available for direct purchase by physicians and hospitals. The majority of sales of APOKYN are made to specialty pharmacies.

Each of our three major customers, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation, individually accounted for more than 25% of our total product revenue in 2020 and collectively accounted for more than 85% of our total product revenue in 2020.

Manufacturing

We currently depend on third-party commercial manufacturing organizations (CMOs) for all manufacturing operations, including the production of raw materials, dosage form product, and product packaging. This encompasses products for commercial use, as well as some products for preclinical and clinical research. We do not own or operate manufacturing facilities for the production of any of our product candidates beyond that used in Phase II clinical trials, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently employ internal resources to manage our manufacturing contractors.

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

APOKYN is manufactured for the U.S. market by our licensing partner, Britannia. Britannia, a subsidiary of Stada Arzneimittel AG, also supplies injectable apomorphine to the European market under the brand name Apo-go. MYOBLOC is manufactured and packaged by Merz GmbH & Co. KGaA (Merz). Under the contract manufacturing agreement with Merz for the manufacture and supply of MYOBLOC, the Company has an annual minimum purchase requirement of MYOBLOC amounting to an estimated €3.0 million. XADAGO is provided to us as a finished product by Zambon S.p.A. (Zambon).

Refer to Part I, Item 1A—*Risk Factors* for risks associated with manufacturing and supply of our products and product candidates.

Our Proprietary Technology Platforms

We have a successful track record of developing and launching novel products by applying proprietary formulation technologies to known drugs to improve their side effect profile or improve patient adherence. 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 novel, customized product profiles designed to enhance efficacy, reduce the frequency of dosing to improve patient adherence and improve tolerability. Our technologies have been used to create ten commercial products, including our products: Trokendi XR and Oxtellar XR; Adderall XR (developed for Shire); Intuniv (developed for Shire); Mydayis (developed for Shire); and Orenitram (developed for United Therapeutics Corporation); as well as our product candidate SPN-812.

We are also engaged in generating and assessing NCEs. These NCEs are generated by leveraging our expertise in structure function relationships in active molecules. Our NCEs are being assessed in preclinical pharmacology models for CNS activity and are advancing through Investigational New Drug application (IND), enabling toxicology studies to support potential future clinical investigation.

Intellectual Property and Exclusivity

Overview

We continue to build our intellectual property portfolio to provide protection for our technologies, products, and product candidates. We seek patent protection, where appropriate, both in the U.S. and internationally for 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, proprietary knowledge, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology or products. We cannot be sure that any patents, if granted, will sustain a legal challenge.

Patent Portfolio

Our commercial products covered by active patents include Trokendi XR, Oxtellar, XR, and XADAGO. We own all of the issued patents for Trokendi XR and Oxtellar XR, as well as the pending U.S. patent applications for Oxtellar XR. We have a license from Zambon for the U.S. patents that cover XADAGO.

Trokendi XR

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

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

Oxtellar XR

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

The Company is currently in litigation with Apotex concerning Oxtellar XR. For more information, refer to Part I, Item 3—*Legal Proceedings* in this annual Report on Form 10-K.

XADAGO

As an NCE, XADAGO is under the 5 year FDA exclusivity period that expires on March 21, 2022. The patent portfolio covering XADAGO has three U.S. patents licensed from Zambon. Two of these patents will expire no earlier than 2027, and one will expire no earlier than 2028.

SPN-812 (extended release viloxazine hydrochloride)

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

SPN-817 (huperzine A)

We have two U.S. patents licensed from Harvard University covering the method of treating seizures to potentially cover our SPN-817 development program. Additionally, we have filed patent applications in the U.S., Canada, Japan, China, Australia, Europe, and Mexico for various extended release formulations of huperzine A.

SPN-817 has received Orphan Drug designation for both Dravet Syndrome and Lennox-Gastaut Syndrome from the FDA.

SPN-820 (NV-5138)

Under the terms of the April 2020 Development Agreement with Navitor, we have an exclusive option to license or acquire NV-5138 in all world territories, prior to initiation of the Phase III clinical program.

SPN-830 (Apomorphine Infusion Pump)

Our SPN-830 development program is potentially eligible to receive the Orphan Drug Designation in the U.S. If such designation is granted by the FDA, SPN-830 would receive 7 years of U.S. exclusivity from the time of approval by the FDA.

U.S. Patent Application Process

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

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

In evaluating the patentability of a claimed invention, the filing date of a non-provisional patent application is used by the USPTO to determine what information constitutes prior art. If certain requirements are satisfied, a non-provisional patent

application can claim the benefit of the filing date of a previously filed provisional patent application. In such an instance, the filing date accorded to the provisional patent application may supersede information that otherwise could preclude the patentability of an invention.

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

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

Other Intellectual Property Rights

We seek trademark protection in the U.S. and internationally, where available and when appropriate. We have filed for trademark protection for several marks, which we use in connection with our pharmaceutical research and development collaborations as well as with our products. We are the owner/licensee of various U.S. federal trademark registrations (®) and registration applications (TM), 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®", “XADAGO®”, “MYOBLOC®”, “APOKYN®”, "NeuroBloc®", 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 a 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. See Part I, Item 3—*Legal Proceedings*. Litigation to enforce our own patent rights is subject to uncertainties that cannot be quantified in advance. In the event of an adverse outcome in litigation, we could be prevented from commercializing a product or precluded from using certain aspects of our technology platforms. This could have a material adverse effect on our business. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part; on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize products or use technologies that are similar to ours and then compete directly with us, without compensation to us. In addition, third parties could allege that our products infringe their intellectual property rights and pursue legal action against the Company. See Part I, Item 1A—*Risk Factors* for risk factors related to intellectual property.

Collaborations and Licensing Arrangements

We obtained exclusive licenses from third parties for proprietary rights to support our product candidates. Under these license agreements, we may be required to pay certain amounts upon the achievement of defined milestones. If these products are ultimately commercialized, we are also obligated to pay royalties to third parties, computed as a percentage of net product sales, for each respective product under a license agreement.

APOKYN and SPN-830 (Apomorphine Infusion Pump)

In January 2016, we entered into an Amended and Restated Distribution, Development, Commercialization, and Supply Agreement with Britannia that grants us certain intellectual property and product rights in relation to APOKYN, including the right to use and market APOKYN in the United States (Territory). Additionally, under the agreement, Britannia retains certain intellectual property and product rights in relation to APOKYN, including the right to use and market APOKYN in the rest of the world, excluding the United States. Under the Agreement, Britannia has an obligation to supply us with APOKYN for our marketing and sale of the product.

Under the agreement, we are obligated to make royalty payments to Britannia based upon U.S. net sales, adjusted for other product related costs for APOKYN, SPN-830 and any other commercial products jointly developed under the agreement. Based on this formula, the effective royalty rate is in the mid-thirties percent of U.S. net product sales. The parties have also agreed to a cost sharing arrangement for the development of new products beyond APOKYN. Under the agreement, we are obligated to pay more than half of the related costs associated with the development of SPN-830 or other new products that are commercialized solely in the Territory. For costs associated with new products that are commercialized both inside and outside the Territory, we are obligated to pay less than half of related costs.

We have agreed to use commercially reasonable efforts to develop and commercialize products under the agreement. The initial 15 year term of the agreement is subject to automatic renewal periods unless canceled by either party. Either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other.

XADAGO

In February 2016, we entered into a License and Distribution Agreement and a Supply Agreement with Zambon. Under the License and Distribution Agreement, we are the exclusive distributor of XADAGO in the U.S. and we are prohibited from selling or distributing in the U.S. any product that competes with XADAGO. We are also required to spend certain annual amounts on educational, marketing, and promotional activities for XADAGO through 2022 and cooperate with Zambon concerning such activities.

Zambon is eligible to receive up to $30 million in future payments upon the achievement of sales-based milestones, which are based upon specified annual net product sales of XADAGO in the U.S. During the term of the License and Distribution Agreement, we are also obligated to pay a high single digit royalty on net product sales of XADAGO in the U.S. In the event that XADAGO annual net sales exceed the specified U.S. annual net product sales thresholds, the royalty percent increases and could go as high as the mid-teens.

Under the Supply Agreement, we must purchase from Zambon and Zambon must provide to us all XADAGO finished products for the U.S. market.

We have agreed to use commercially reasonable efforts to develop and commercialize XADAGO under the agreement. Either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other.

MYOBLOC

In May 2004, we entered into an asset purchase agreement with Elan Pharmaceuticals (Elan agreement), now a subsidiary of Perrigo Company (Perrigo). Under the Elan agreement, we own the worldwide rights to MYOBLOC and pay a low double digit royalty to Perrigo based on U.S. annual net sales of MYOBLOC. If MYOBLOC is approved in the U.S. for cosmetic use, Perrigo is eligible to receive a $4 million future payment and the royalty rate will become subject to certain reductions based on cosmetic use net sales. Under a settlement agreement between Perrigo and Allergan, certain amounts of the royalty are owed to Allergan. We also have the right under the Elan agreement to make use of, develop and offer for sale worldwide products containing Botulinum Toxin Type B. The Elan agreement may not be terminated for convenience.

We also have an agreement with Elan and Eisai related to the marketing and distribution of NerBloc in Japan by Eisai. We also have the right under the agreement to make use of, develop and offer for sale in Japan human pharmaceutical drugs

containing Botulinum Toxin Type B. This agreement will terminate upon certain conditions relating to Perrigo's patent rights and the commercial launch of products with respect to cervical dystonia and indications other than cervical dystonia.

We have a contract manufacturing agreement with Merz Pharma GmbH & Co. KGaA (Merz) for the manufacture and supply of MYOBLOC, NeuroBloc and NerBloc (Merz Agreement). Pursuant to the Merz Agreement, Merz is required to provide a dedicated manufacturing facility including a stand-alone building, dedicated clean room suites, dedicated manufacturing and purification equipment, and filling and packaging production lines (collectively, the manufacturing facility) to manufacture finished products. The Merz Agreement will expire in July 2027, unless the Company and Merz mutually agree to extend the term. The Merz Agreement may not be terminated for convenience. Under the terms of the Merz Agreement, the Company is required to purchase a minimum quantity of finished products on an annual basis. This minimum purchase requirement represents the in-substance fixed contract consideration associated with the dedicated manufacturing facility. The Company has an annual minimum purchase quantity requirement of finished products amounting to an estimated €3.0 million.

SPN-817 (huperzine A)

In September 2018, the Company entered into a merger agreement to acquire Biscayne Neurotherapeutics (Biscayne), a privately-held company developing a novel treatment for epilepsy (SPN-817). Through this agreement, we obtained worldwide rights, excluding certain markets in Asia where rights have been previously out-licensed, to SPN-817. SPN-817 has received Orphan Drug designation from the FDA for the treatment of Dravet Syndrome, a severe form of childhood epilepsy and Lennox-Gastaut Syndrome. We may be obligated to pay up to $73 million to the prior Biscayne security holders if certain development milestones are achieved. In addition, we may be obligated to pay up to $95 million if certain sales milestones are achieved. In addition, we will be obligated to pay a low single digit royalty on net sales to the prior Biscayne security holders and any applicable royalties to third parties for the use of in-licensed IP. The maximum combined royalty we will pay to all parties on net product sales is approximately 12%, depending on the IP covering the commercial product and the applicable tiered sales levels.

SPN-820 (NV-5138)

In April 2020, we entered into a Development and Option Agreement with Navitor to collaborate on a clinical development program for NV-5138 (SPN-820), Navitor's mTORC1 activator. Under the terms of the agreement, the Company and Navitor will jointly conduct a Phase II clinical program in TRD. We will pay the costs of Phase II development up to $50 million, plus certain costs associated with nonclinical development and formulation. In addition, Navitor has granted the Company an exclusive option to license or acquire NV-5138 in all world territories, prior to initiation of the Phase III clinical program. We paid Navitor a one time, nonrefundable, and non-creditable fee of $10 million for the option to acquire or license NV-5138 (SPN-820) and made a $15 million equity investment representing approximately 13% ownership in Navitor. There are certain additional payment amounts that could be incurred by the Company. These costs are contingent upon Navitor and the Company achieving defined development milestones.

Total payments, exclusive of royalty payments on net sales of NV-5138 and development costs under the agreement, have the potential to reach $410 million to $475 million, which includes the upfront payment of $25 million paid in 2020, an additional license or acquisition fee depending on whether the Company ultimately licenses or acquires NV-5138, and subsequent clinical, regulatory and sales milestone payments. We also will have the first right of refusal for any compound with a similar MOA on mTORC1 as NV-5138 in the central nervous system.

See Part II, Item 9, Financial Statements and Supplementary Data, Note 12, *Investments in Unconsolidated VIEs*, in the Notes to the Consolidated Financial Statements.

Rune HealthCare Limited

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

United Therapeutics

We have a license agreement with United Therapeutics Corporation to use one of our proprietary technologies in an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension, and other indications. United Therapeutics Corporation launched Orenitram (treprostinil) in 2014, which triggered a $2 million milestone payment to the Company. In the third quarter of 2014, we received a cash payment of $30 million from HealthCare Royalty Partners III, L.P.'s (HC Royalty), for the purchase of certain of our rights under our license agreement with United Therapeutics

Corporation related to the commercialization of Orenitram. This is a non-recourse liability for which we have no obligation to make any cash payments to HC Royalty, under any circumstances. Ownership of the royalty rights will return to us if/when a certain cumulative threshold payment to HC Royalty is reached.

We are entitled to receive milestones and royalties for the use of this formulation in indications other than arterial hypertension.

Stendhal

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

Takeda Pharmaceuticals Company Ltd.

The Company has entered into a licensing agreement with Takeda Pharmaceuticals Company Ltd. (Takeda) under which Takeda received the right to use the Company's intellectual property as a functional license. The Company is eligible to receive royalties under this agreement based on net product sales of Takeda's product, Mydayis.

Confidential Information and Inventions Assignment Agreements

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

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

Government Regulation

U.S. Drug Development Process

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

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

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

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

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

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

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

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

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

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

U.S. FDA Review and Approval Processes

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

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

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

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

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

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

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

New Drug Application

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

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

Section 505(b)(2) NDAs often provide an alternative path to FDA approval for new or improved formulations or new uses of previously approved products. For a Section 505(b)(2) application, the FDA permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. The FDA permits the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies or clinical trials demonstrating safety and effectiveness. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The Section 505(b)(2) regulatory approval process is designed to allow for potentially expedited, lower cost and lower risk regulatory approval, based on previously established safety, efficacy, and manufacturing information on a drug which has been already approved by the FDA for the same or a different indication.

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

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

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

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

By its very nature, a Section 505(b)(1) NDA submission carries a higher degree of regulatory approval risk than a Section 505(b)(2) NDA submission. In addition, a requirement for more extensive testing and development can adversely impact our ability to compete with alternative products that arrive on the market sooner than our product candidate. Further, the time and financial resources required to obtain FDA approval could substantially and materially increase.

Review and Approval of Combination Products

Products comprised of separate components (e.g., a drug and a device; a biologic and a device; a drug and a biologic; or a drug, device, and a biologic) are known as “combination products.” Such products often raise regulatory, policy, and review management challenges because they integrate components that are regulated under different types of regulatory requirements and by different FDA Centers, namely, Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER) (each a "Center"). Differences in regulatory pathways for each component can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees, and post-approval modifications.

The FDA's Office of Combination Products (OCP) determines which Center will have primary jurisdiction (the “Lead Center”) for the combination product based on the combination product’s “primary mode of action” (PMOA). A mode of action is the means by which a product achieves an intended therapeutic effect or action. The PMOA is the mode of action that provides the most important therapeutic action of the combination product or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. The Lead Center has primary responsibility for the review and regulation of a combination product; however, a second Center is often involved in the review process, especially to provide input regarding the “secondary” component(s). In most instances, the Lead Center applies its usual regulatory pathway. For example, a drug-device combination product assigned to CDER will typically be reviewed under an NDA, while a drug-device combination product assigned to CDRH is typically reviewed through a 510(k), Premarket Approval Application (PMA), or de novo reclassification request.

Often it is difficult for OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which Center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product. A sponsor may use a voluntary formal process, known as a Request for Designation, when the product classification is unclear or in dispute to obtain a binding decision as to which center will regulate the combination product. If the sponsor objects to that decision, it may request that the agency reconsider that decision.

Combination products are subject to application User Fees based on the type of application submitted for the product's premarket approval or clearance. For example, a combination product for which an NDA is submitted is subject to the NDA fee under the Prescription Drug User Fee Act. Likewise, a combination product for which a PMA is submitted is subject to the PMA fee under the Medical Device User Fee and Modernization Act.

Since a combination product incorporates two or more components with different regulatory requirements, a combination product manufacturer must comply with all cGMP and Quality System (QS) Regulation/Medical Device Good Manufacturing Practices (QSR) requirements that apply to each component. The FDA has issued a combination product cGMP regulation, along with final guidance, describing two approaches a combination product manufacturer may follow to demonstrate compliance. Under these two options, the manufacturer demonstrates compliance with:

- All cGMP regulations applicable to each separate regulated component included in the combination product; or

- Either the drug cGMPs or the QSR, as well as with specified provisions from the other of these two sets of requirements (also called the "streamlined approach").

Pediatric Information

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

Orphan Drug Designation

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

Priority Review

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

Fast Track Designation

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

Post-approval Regulatory Requirements

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

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

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

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

Patent Term Restoration and Marketing Exclusivity

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

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

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

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

Other Regulatory Requirements

In March 2019, MDD US Operations, LLC (formerly US WorldMeds, LLC) and its subsidiary, Solstice Neurosciences, LLC (US) (collectively, the MDD Subsidiaries), each of which is now subsidiaries of the Company, entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. Under the CIA, the MDD Subsidiaries agreed to pay $17.5 million to resolve U.S. Department of Justice allegations that they violated the False Claims Act by paying kickbacks to induce the use of APOKYN and MYOBLOC (collectively, the MDD Products). The fine was paid by the MDD Subsidiaries prior to the closing of the USWM Acquisition.

As a consequence of the USWM Acquisition, and under the terms of the CIA, the Company has assumed the extensive obligations of the MDD Subsidiaries concerning the ongoing maintenance of an effective compliance and disclosure program to promote compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs and with the statutes, regulations and written directives of the FDA. The CIA has a term of five years, ending in March 2024, and imposes material burdens on the Company, its officers and directors to take actions designed to insure compliance with applicable healthcare laws, including requirements to maintain specific compliance positions within the Company, to report any non-compliance with the terms of the agreement, to submit annual reports to the Office of Inspector General of the U.S. Department of Health and Human Services and to have prepared an annual audit by an Independent Review Organization. The CIA sets forth potentially substantial stipulated monetary penalties for non-compliance with the terms of the agreement. In addition, the Company may be excluded from federally funded healthcare programs for a material breach of the CIA.

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

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

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

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

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

Pharmaceutical Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our products and product candidates for which we obtain regulatory approval. Sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers, and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor’s decision to provide

coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the U.S. government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Federal, state, and local governments in the U.S. continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals, such as the product candidates that we are developing.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act (ACA), substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the pharmaceutical industry.

The marketability of any drug candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased, and we expect will continue to increase the pressure on pharmaceutical drug pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Environmental Matters

We believe that our operations comply in all material respects with applicable laws and regulations concerning environmental protection.

Human Capital

Our success begins and ends with our people. Our solid progress to date reflects the talent and hard work of all of our employees. We consider the intellectual capital of our employees to be an essential driver of our business and key to our future prospects. Attracting, developing, and retaining talented people in technical, marketing, sales, research, and other positions is crucial to executing our strategy and our ability to compete effectively. As of December 31, 2020, we employed 563 full-time employees in the U.S. None of our employees is represented by a labor union. We consider relations with our employees to be good.

Talent Acquisition, Retention and Development

Our key human capital objectives are to attract, retain and develop the highest quality talent. We employ various human resource programs in support of these objectives. Our ability to recruit and retain such talent depends on a number of factors, including compensation and benefits, talent development and career opportunities, and the work environment.

We attract and reward our employees by providing market competitive compensation and benefit practices, including incentives and recognition plans that extend to all levels in our organization. To that end, we offer a comprehensive total rewards program aimed at health, home-life, and financial needs of our employees. Our total rewards package includes market-competitive pay, broad-based stock grants, bonuses, healthcare benefits, retirement savings plans, paid time off and family leave, and an Employee Assistance Program, and mental health services.

We are committed to the safety, health, and security of our employees. We believe a hazard-free environment is critical for the success of our business. Throughout our operations, we strive to ensure that all our employees have access to safe workplaces that allow them to succeed in their jobs. Importantly during 2020, our experience and continuing focus on workplace safety has enabled us to preserve business continuity without sacrificing our commitment to keeping our colleagues and workplace visitors safe during the COVID-19 pandemic.

Inclusion and Diversity

We place a strong value on collaboration, inclusion, and diversity, and we believe that working together leads to better outcomes for our customers. This extends to the way we treat each other as team members. We strive to create an environment where innovative ideas can flourish by demonstrating respect for each other and valuing the diverse opinions, backgrounds, and

viewpoints of employees. We believe a diverse and inclusive workplace results in business growth and encourages increased innovation, retention of talent, and a more engaged workforce.

In recent years we have been named to a number of best company lists, including the 2021 Forbes Best Small Companies list and the 2020 Best of Rockville – Pharmaceutical Companies list.

Other Information

We are listed on the NASDAQ Stock Exchange under the ticker symbol SUPN. Our principal executive offices are located at 9715 Key West Ave., Rockville, Maryland, 20850. Our website address is *www.supernus.com*.

We make available free of charge on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as well as proxy statements, and, from time to time, other documents, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the U.S. Securities and Exchange Commission (SEC). Through a link on the Investor Relations portion of our website, you can access our filings with the SEC. Information contained on our website is not a part of this Annual Report on Form 10-K.

The SEC also maintains a website at www.sec.gov that contains reports, proxy, and other information statements, and other information regarding issuers, including us, that file electronically with the SEC.

References to our website and the SEC's website in this report are provided as a convenience and do not constitute, and should not be viewed as, incorporation by reference of the information contained on, or available through, such websites. Such information should not be considered a part of this report unless otherwise expressly incorporated by reference in this report.

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 the results of our operations. In this eventuality, the market price of our common stock may decline, and you could lose part or all of your investment.

RISK FACTORS SUMMARY

We are subject to a variety of risks and uncertainties, including risks related to our industry and business, risks related to our finances and capital requirements, risks related to securities markets and investment in our stock, and certain general risks, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in this "Risk Factors" section.

Risks Related to Our Industry and Business

- We are dependent on the commercial success of our products in the U.S.
- If other versions of extended or controlled release oxcarbazepine or topiramate, or other products including generics containing apomorphine hydrochloride for the treatment of Parkinson's Disease, are approved and successfully commercialized, our business could be materially harmed.
- We are subject to uncertainty relating to payment or managed care reimbursement policies, which, if not favorable for our products or product candidates, could hinder or prevent our commercial success.
- We depend on wholesalers, distributors, and specialty pharmacies for the retail distribution of our products. If we lose any of our significant wholesaler, distributor, or specialty pharmacy accounts, our business could be harmed.
- Final marketing approval of any of our product candidates or approval of 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.
- If we fail to produce our products and product candidates in the volumes that we require on a timely basis or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our products and product candidates, or be required to withdraw our products from the market.

- If we do not obtain marketing exclusivity for our product candidates, our business may suffer.
- We depend on collaborators to work with us to develop, manufacture and commercialize their and our products and product candidates.
- We rely on and will continue to rely on outsourcing arrangements for certain of our critical activities, including clinical research of our product candidates, manufacture of our compounds and product candidates beyond Phase II clinical trials, and the manufacture of our commercial products.
- Delays or failures in the completion of clinical development of our product candidates would increase our costs, delay, or limit our ability to generate revenues.
- If we fail to comply with healthcare regulations, we could face substantial penalties. Our business, operations, and financial condition could be adversely affected.
- We could be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming, distracting, and ultimately unsuccessful.
- Limitations on our patent rights relating to our products and product candidates may limit our ability to prevent third parties from competing against us.
- The Company’s financial condition and results of operations for the fiscal year 2021 and beyond may be materially and adversely affected by the ongoing COVID-19 outbreak.
- Compliance with the terms and conditions of our Corporate Integrity Agreement requires significant resources and management time and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.

Risks Related to Our Finances and Capital Requirements

- 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.
- We have and may further expand our business through acquisitions of new product lines or businesses, which exposes us to various risks, including difficulties in integrating acquisitions. Our recent acquisition poses certain incremental risks to the Company.
- Any impairment in the value of our intangible assets, including goodwill, would negatively affect our operating results and total capitalization.

Risks Related to Securities Markets and Investment in Our Stock

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

General Risk Factors

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

Risks Related to Our Industry and Business

We are dependent on the commercial success of our products in the U.S.

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

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

- Defend our patents, intellectual property, and products from the competition, both branded and generic;
- Maintain commercial manufacturing arrangements with third-party manufacturers;
- Produce, through a validated process, sufficiently large quantities of our products to meet demand;
- Continue to maintain a wide variety of internal sales, distribution, and marketing capabilities, sufficient to sustain and grow revenue;
- Continue to maintain and grow widespread acceptance of our products from physicians, health care payors, patients, pharmacists, and the medical community;
- Properly price and obtain adequate reimbursement coverage of these products by governmental authorities, private health insurers, managed care organizations, and other third-party payors;
- Maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety, and other post-market requirements;
- Obtain approval from the FDA to expand the labeling of our approved products for additional indications;
- Adequately protect against and effectively respond to any claims by holders of patents and other IP rights alleging that our products infringe their rights; and
- Adequately protect against and effectively respond to any unanticipated adverse effects or unfavorable publicity that develops with respect to our products, as well as respond to the emergence of new or existing competitive products, which may be proven to be more clinically effective and cost-effective.

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

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

Our ability to increase market acceptance of any of our products or to gain market acceptance of approved product candidates among physicians, patients, health care payors, and the medical community will depend on a number of factors, including:

- Acceptable evidence of safety and efficacy;
- Relative convenience and ease of administration;
- Prevalence, nature, and severity of any adverse side effects;

- Availability of alternative treatments, including branded and generic products; and
- Pricing and cost effectiveness.

Further, our products are subject to continual review by the FDA. We cannot provide assurance that newly discovered or reported safety issues would not arise. With the use of any marketed drug by a broader patient population, serious adverse events may occur from time to time that initially does not appear to be related to the drug itself. Any safety issues could cause us to suspend or to cease marketing of our approved products; cause us to modify how we market our approved products; subject us to substantial liabilities; and adversely affect our revenues and financial condition. In the event of a withdrawal of any of our products from the market, our revenues would decline significantly, and our business would be seriously harmed and could fail.

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

If other versions of extended or controlled release oxcarbazepine or topiramate, or other products including generics containing apomorphine hydrochloride, are approved and successfully commercialized, our business could be materially harmed.

Third parties have and in the future may receive approval to manufacture and market their own versions of extended release oxcarbazepine or topiramate in the U.S. For example, Upsher-Smith launched Qudexy XR (extended release topiramate) and a branded generic version of Qudexy XR in 2014. Upsher Smith also entered into a settlement with a generic company to launch a generic to Qudexy XR in 2020 and a separate settlement with Glenmark to enter the market at a date that is unknown to us. In February 2021, Glenmark entered the U.S. market with its own therapeutically equivalent generic products to Qudexy XR. The entry of new generic products could adversely impact the sales or prescriptions for Trokendi XR or could result in an earlier than anticipated entry of generics to compete with Trokendi XR. We have the right to defend our products against third parties who may infringe or are infringing our patents.

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

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

In addition, third parties have and in the future may receive approval to manufacture and market their own products, including generics containing apomorphine hydrochloride for the treatment of Parkinson’s Disease in the U.S. For example, Acorda Therapeutics, Inc. launched Inbrija, an inhalable form of levodopa in 2019 and Sunovion Pharmaceuticals, Inc.’s (Sunovion, a subsidiary of Sumitomo Dainippon Pharma Co. Ltd) launched KYNMOBI, a sublingual film formulation of apomorphine hydrocholoride, in 2020. The success of these products and the entry of new products could adversely impact the sales of prescriptions for APOKYN.

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

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

Our ability, or our collaborators' ability, to successfully commercialize our products and product candidates, including SPN-812 and SPN-830, 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 require that drug products be approved for marketing by the FDA. Third-party payors are increasingly challenging the effectiveness of and prices charged for medical products and services. Government authorities and third-party payors have attempted to control costs, in some instances, by limiting coverage, by limiting the amount of reimbursement for particular medications, or by encouraging the use of lower-cost generic products.

We cannot be sure that reimbursement will be available for any of the products that we develop and, if reimbursement is available, the level of reimbursement. Moreover, that level of reimbursement may change over time as a result of requests from payors for higher levels of fees. Reduced or partial payment, or reduced reimbursement coverage, could make our products or product candidates, including Oxtellar XR, Trokendi XR, and APOKYN, 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, Trokendi XR, and APOKYN, in determining whether to approve reimbursement for such products or product candidates and to what extent they will provide reimbursement. Moreover, they will consider the efficacy and cost effectiveness of comparable or competitive products, including generic products, in making reimbursement decisions for our products. Because each third-party payor individually approves payment or reimbursement, obtaining these approvals can be a time consuming and expensive process, requiring us to provide scientific or clinical support for the use of each of our products or product candidates separately to each third-party payor. In some cases, it could take months or years before a particular private insurer or managed care organization reviews a particular product. Prior to that time, reimbursement may be negligible. We may ultimately be unsuccessful in obtaining coverage. In addition, our competitors may have more extensive existing business relationships with third-party payors that could adversely impact the coverage for our products.

Our business would be materially and adversely affected if we do not receive reimbursement for our products or product candidates from private insurers in a timely fashion or on a satisfactory basis. Our products and product candidates may not be considered cost-effective, and coverage and reimbursement may not be available or economically 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.

Moreover, increasing efforts by governmental and third-party payors in the U.S. to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products. As a result, they may not cover or provide adequate reimbursement for our products or product candidates.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislative initiatives designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under the Medicare program, to review the relationship between pricing and manufacturer patient programs, and to reform government reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, additional cost containment initiatives, and additional legislative changes.

In some foreign jurisdictions, particularly Canada and Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take 6 to 12 months, or longer, after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought, or to obtain pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products or product candidates, if approved, to other available therapies. If reimbursement for our products or product candidates is unavailable in any country in which reimbursement is sought or is limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed and unprofitable.

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

We expect these challenges to continue and to potentially intensify in 2021 and following years, as political pressures mount, and healthcare payors, including government-controlled health authorities, insurance companies, and managed care organizations, step up initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generic products and impose overall price cuts. Such pressures could have a material adverse impact on our business, financial condition, and results of operations, as well as on our reputation.

We depend on wholesalers, distributors, and specialty pharmacies for the retail distribution of our products. If we lose any of our significant wholesaler, distributor, or specialty pharmacy accounts, our business could be harmed.

The majority of the sales of Oxtellar XR, Trokendi XR, XADAGO, and MYOBLOC are made to wholesalers and distributors who, in turn, sell our products to pharmacies, hospitals, and other customers. The majority of sales of APOKYN are made to specialty pharmacies, including Accredo Health Group, Inc. and Caremark LLC. For the year ended December 31, 2020, three wholesale pharmaceutical distributors, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation, each individually accounted for more than 25% of our total revenue from sales of our commercial products and collectively accounted for more than 85% of our total revenue from sales of these products in 2020. For the year ended December 31, 2020, the two specialty pharmacies, Accredo Health Group, Inc. and Caremark LLC, accounted for more than 35% individually and more than 80% collectively of the total revenue from sales of APOKYN.

The loss of any of these wholesale pharmaceutical distributors or wholesale and specialty pharmacy accounts, or a material reduction in their purchases, could have a material adverse effect on our business, results of operations, financial condition, and prospects. In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. This distribution network has undergone and may continue to undergo significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market.

Consolidation of drug wholesalers has increased. This may result in increased competition 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.

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

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

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

We plan on building or expanding our sales and marketing capabilities in the U.S. to commercialize our product candidates if approved. This will require investing significant amounts of financial and management resources. If we are unable to establish and maintain adequate sales and marketing capabilities for our product candidates or do so in a timely manner, we may not be able to generate sufficient product revenues from our product candidates to be profitable. The cost of establishing and maintaining such marketing and sales capabilities may not be economically justifiable in light of the revenues generated by any of our product candidates.

Final marketing approval of any of our product candidates or approval of 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.

We are dependent on obtaining regulatory approval of our product candidates and approval for additional indications for existing products. Our business depends on successful clinical development; i.e., successful completion of clinical trials and

completion of requisite manufacturing information. 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 market in any foreign jurisdiction until we receive approval from the requisite authority. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity, and novelty of the product, and requires the expenditure of substantial resources. We cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates. We cannot, therefore, predict the timing of any future revenues from these product candidates.

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

- Could reject or delay the marketing application for an NCE;
- Could determine that we cannot rely on Section 505(b)(2) for any approval of our product candidates;
- Could determine that the information provided by us was inadequate, contained clinical deficiencies, or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for a specific indication;
- May not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S.;
- May find the clinical and other benefits of our product candidates do not outweigh their safety risks;
- May disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies, and/or clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our trials; the outcome and measurement scale used in the trials; or the clinical protocols whether with or without a special protocol assessment process;
- May determine that we have identified the wrong reference listed drug or drugs, or that approval of our Section 505(b)(2) application of our product candidate is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;
- May identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of raw materials, including the active pharmaceutical ingredient (API) or formulated product used in our product candidates, wherein those deficiencies may result in an 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 their approval policies or adopt new regulations;
- May not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates or may approve them with warnings and precautions that could limit the acceptance of our product candidates and their commercial success; or
- May not approve the addition of new indications to the label of our existing products.

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

Notwithstanding the approval of many products by the FDA pursuant to Sections 505(b)(1) and 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Any failure to obtain regulatory approval of our product candidates would eliminate our ability to generate revenues for that candidate. Any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming. We may not be able to obtain these clearances or approvals on a timely basis, if at all. The FDA exercises significant discretion over the regulation of combination products, including drug and device components in a combination product.

The FDA could in the future require additional regulation under the medical device provisions of the FDCA. We must comply with the QSR, which sets forth the FDA's cGMP, requirements for medical devices, and other applicable government regulations and corresponding foreign standards for drug cGMPs. If we fail to comply with these regulations, it could have a material adverse effect on our business and financial condition.

In November 2020, we received a CRL from the FDA regarding the NDA for SPN-812. The FDA issued the CRL to indicate that the review cycle for the application was complete and that the application was not ready for approval in its present form. The FDA cited that the primary issue relates to our in-house laboratory that conducts analytical testing, which recently moved to a new location. In January 2021, we met with the FDA in a Type A meeting to discuss the CRL and the requirements for the NDA resubmission. In February 2021, we resubmitted the SPN-812 NDA and removed the reference to our in-house laboratory, and addressed other contents of the CRL. The FDA notified us that the NDA resubmission is a Class I resubmission with a PDUFA target action date in early April 2021.

After the expected approval for SPN-812 for one indication, additional indications may be submitted using the Section 505(b)(2) regulatory pathway. The FDA may not approve our filing under Section 505(b)(2) for SPN-812 for other indication(s), and therefore we would be required to submit a full NDA filing. In such a case, the time and financial resources required to obtain approval could also significantly increase.

In addition, we intend to complete the development of an infusion-pump delivery system containing apomorphine (SPN-830) and have submitted the NDA for SPN-830 to the FDA in September 2020. We received a refusal to file letter from the FDA and are seeking guidance from the FDA to clarify the steps required for the resubmission of the NDA for SPN-830. We are investing significant amounts of resources into the continued development of the infusion-pump delivery system. If we are unable to gain FDA approval for the infusion-pump delivery system or are unable to successfully commercialize the infusion-pump delivery system, we may not be able to generate revenue from the infusion-pump delivery system to justify the cost of invested company resources. In addition, as discussed further below, failure to gain FDA approval could have an adverse effect on the infusion-pump product's commercial potential or could require additional costly studies.

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

We do not currently own or operate manufacturing facilities for the commercial production of any of our products or our product candidates, nor do we have plans to develop our own manufacturing operations at a commercial scale in the foreseeable future. We currently depend on third-party CMOs in various countries for the supply of API for our products and product candidates, including drug substances for our preclinical research and clinical trials. For Trokendi XR, Oxtellar XR, MYOBLOC, XADAGO, and APOKYN, 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.

There is a risk that supplies of our products or product candidates may be significantly delayed by or may become unavailable as a result of manufacturing, equipment, process, or business-related issues affecting our suppliers. Any future curtailment in the availability of raw materials or finished goods 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. For example, as it relates to SPN-812, we may encounter additional manufacturing and supply-chain risks due to the regulatory and political structure of Switzerland or as a result of the international relationship between Switzerland and the U.S. We may also encounter similar risks with the other products and product candidates where raw materials or finished goods are purchased from suppliers outside the U.S., such as the case for example for SPN-830 where the supplier for the infusion pump device is based in Italy and for APOKYN, XADAGO and MYOBLOC where the API manufacturer and finished goods supplier, respectively, are in Europe.

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 the production of their products. These problems can adversely affect production costs and yields, quality control, the stability of the product and quality assurance testing, as well as compliance with federal, state, and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain or maintain FDA approval and to market our products and product candidates, respectively, would be jeopardized. In addition, any delay or interruption in producing clinical trial supplies could delay or prohibit the completion of our clinical trials, increase the costs

associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new trials at the significant additional expense or to terminate a trial.

Manufacturers of pharmaceutical products need to comply with cGMP requirements and other requirements 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 other FDA and similar foreign regulatory requirements. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for such product candidates or to successfully commercialize such products. We may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical development, regulatory submissions, approvals, or commercialization of our product candidates, entail higher costs, or result in our being unable to effectively commercialize our product candidates. Furthermore, if we fail to obtain the required commercial quantities on a timely basis from our suppliers and at commercially reasonable prices, we may be unable to meet the demand for our approved products or may not be able to sell our products profitably.

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

Under the Hatch-Waxman Amendments, three years of marketing exclusivity may be granted for the approval of NDAs and sNDAs, including Section 505(b)(2) applications, for, among other things, new indications, dosage forms, routes of administration, strengths, or for a new use of an existing drug. If the clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application, the FDA may grant exclusivity for the product, sometimes referred to as clinical investigation exclusivity. This prevents the FDA from approving an application under Section 505(b)(2) for the same conditions of use for new clinical investigations prior to the expiration of three years from the date of approval. Such exclusivity, however, would not prevent the approval of another application if the applicant submits a full NDA and has conducted its own adequate, well-controlled clinical trials, demonstrating safety and efficacy. It would not prevent approval of a generic product or Section 505(b)(2) product that did not incorporate the exclusivity-protected changes of the approved drug product.

Under the Hatch-Waxman Amendments, newly-approved drugs and indications may also benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Amendments provide five-year marketing exclusivity to the first applicant to gain the approval of an NDA for an NCE. This would be the case if the FDA had not previously approved any other drug containing the same API or active moiety, which is the molecule responsible for the action of the drug substance. Although protection under the Hatch-Waxman Amendments will not prevent the submission or approval of another full NDA, such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness.

While the FDA granted a three-year marketing exclusivity period for Oxtellar XR, it did not grant a similar marketing exclusivity period for Trokendi XR.

If we are unable to obtain marketing exclusivity for our subsequent product candidates, then our competitors may obtain approval for competing products more easily than if we had such marketing exclusivity. In such an event, our future revenues could be reduced, possibly materially.

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

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug, which can be cited by potential competitors in support of approval of an ANDA. FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use or labeling, as our product or product candidate and that the generic product is bioequivalent to our product. Bioequivalence implies that a product is absorbed in the body at the same rate and to the same extent as our product or product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market. Companies that produce generic equivalents are generally able to offer their products at significantly lower prices. Thus, regardless of the regulatory approval pathway, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product through both price and volume erosion. Accordingly, competition from generic equivalents would adversely, materially, and permanently

impact our revenues, profitability, and cash flows from those products. In this eventuality, it would substantially limit our ability to obtain a return on the investments we have made in our products and product candidates.

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

The pharmaceutical industry is characterized by rapidly advancing technologies, intense product-driven competition, and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as to our products and product candidates. These include large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and private and public research institutions. The availability of new products or the approval of new indications for existing products may limit the demand for and the price we are able to charge for any of our products. We may be unable to differentiate our products from competitive offerings.

In addition to competition for our current commercial products, we anticipate that we will face intense competition when our pipeline product candidates are approved by regulatory authorities and begin their commercialization process. In particular, we are aware of several companies with various product candidates under development to treat ADHD. These may compete with our SPN-812 product candidate. These companies include Sunovion, Ironshore Pharmaceuticals & Development Inc. (a subsidiary of Highland Therapeutics), and Otsuka Pharmaceutical Company. In addition, Serina Therapeutics and AbbVie are developing product candidates that may compete with SPN-830.

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. Moreover, many competitors have substantially greater:

- Capital resources;
- Research and development resources and experience, including personnel and technology;
- Drug development, clinical trial and regulatory resources and experience, including personnel and technology;
- Sales and marketing resources and experience;
- Manufacturing and distribution resources and experience;
- Name recognition; and
- Resources, experience and expertise in prosecution and enforcement of intellectual property rights.

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

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

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

information. To date, the only consequence of our failure to meet our PREA commitment deadlines has been a notation on FDA websites, making the status of PREA publicly known.

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

We have post-marketing clinical and manufacturing studies and data commitments for MYOBLOC. We are required to conduct a post-marketing study of MYOBLOC for treatment of sialorrhea and spasticity.

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

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

- Issue warning letters or untitled letters;
- Impose civil or criminal penalties;
- Suspend regulatory approval;
- Suspend any ongoing bioequivalence and/or clinical trials;
- Refuse to approve pending applications or supplements to applications filed by us;
- Impose restrictions on operations, including costly new manufacturing requirements, or suspend production for a sustained period of time; or
- Seize or detain products or require us to initiate a product recall.

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

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

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

We have a license agreement with United Therapeutics Corporation to use one of our proprietary technologies in an oral formulation of treprostinil diethanolamine, or treprostinil, for the treatment of pulmonary arterial hypertension and for other indications. United Therapeutics Corporation launched Orenitram (treprostinil) in 2014, which triggered payment of a milestone payment to us of $2.0 million. In the third quarter of 2014, we received a cash payment of $30.0 million from HC Royalty for the purchase of certain of our rights under our license agreement with United Therapeutics Corporation related to the commercialization of Orenitram. Ownership of the royalty rights will return to us if/when a certain cumulative threshold payment to HC Royalty is reached.

We are entitled to receive milestones and royalties for the use of this formulation in indications other than arterial hypertension. If we materially breach any of our obligations under the license agreement, we could lose the right to receive any future royalty payments thereunder, which could be financially significant to us.

Under the Britannia Supply Agreement, we have been granted certain intellectual property and product rights in relation to APOKYN, including the right to use and market APOKYN in the United States. Additionally, the Britannia Supply Agreement grants Britannia certain intellectual property and product rights in relation to APOKYN, including the right to use and market APOKYN in the rest of the world, excluding the United States. Per the Agreement, Britannia has an obligation to supply us with APOKYN for our marketing and sale of the product.

Britannia may terminate its obligation to supply APOKYN for cause, or at any time, by giving at least twenty-four months' written notice. The Britannia Supply Agreement does not provide technology transfer assistance from Britannia to any new suppliers we might engage following termination. In addition, the Britannia Supply Agreement is silent in providing us with an explicit license grant to any intellectual property, or to access know-how necessary or useful for manufacturing APOKYN. If we materially breach the Britannia Supply Agreement, or Britannia chooses to terminate the Britannia Supply Agreement for convenience, we could lose the right and resources necessary for the manufacture of APOKYN or could incur significant costs implementing technology transfer assistance.

Refer to Part I, Item 1, Business, *Collaborations and Licensing Agreements*, for discussion on the different collaborations and licensing arrangements.

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

Our future collaboration agreements may limit the areas of research and development that we may pursue, either alone or in collaboration with third parties. Much of the potential revenues from these future collaborations may consist of contingent payments, such as payments for achieving certain development milestones and royalties payable on product sales. The milestones and royalty revenues that we may receive under these collaborations will depend upon our collaborators' ability to successfully develop, introduce, market and sell new products. Future collaboration partners may fail to develop or effectively commercialize products, product candidates, or technologies because they, among other things, may:

- Change the focus of their development and commercialization efforts, or may have insufficient resources to effectively develop our product candidates;
- Pharmaceutical and biotechnology companies historically have re-evaluated their development and commercialization priorities following mergers and consolidations, which have been common in recent years. The ability of some of our product candidates to reach their potential could be limited if our future collaborators fail to apply sufficient development or commercialization efforts related to those product candidates;
- Decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources, or in the belief that other internal drug development programs may have a higher likelihood of obtaining marketing approval, or may potentially generate a greater return on investment;

- Develop and commercialize, either alone or with others, drugs that are similar to or competitive with the product candidates that are the subject of their collaboration with us;
- Not have necessary and sufficient resources to develop the product candidate through clinical development, marketing approval, and commercialization;
- Fail to comply with applicable regulatory requirements;
- Are unable to obtain the necessary marketing approvals; or
- Breach or terminate their arrangement with us.

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

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

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

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

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

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

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

As part of our growth strategy, we intend to develop and market additional product candidates. We may spend substantial resources and several years completing the development of a particular current or future internal product candidate, during which process we can experience failure at any stage, and for many reasons. The product candidates to which we allocate our resources, even if approved, may not be commercially successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists, and other researchers to sell or license

products or technologies to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and approved products, and to manage our spending as expenses related to undertaking clinical trials can be substantial.

In November 2019, we submitted the NDA for SPN-812 to the FDA. We received a Complete Response Letter (CRL) issued by the FDA regarding the NDA for SPN-812 in November 2020. The FDA issued the CRL to indicate that the review cycle for the application was complete and that the application was not ready for approval in its present form. The FDA cited that the primary issue relates to our in-house laboratory that conducts analytical testing, which recently moved to a new location. In January 2021, we met with the FDA in a Type A meeting to discuss the CRL and the requirements for the NDA resubmission. In February 2021, we resubmitted the SPN-812 NDA and removed the reference to our in-house laboratory, and addressed other contents of the CRL. The FDA notified us that the NDA resubmission is a Class I resubmission with a PDUFA target action date in early April 2021.

In September 2020, we submitted the NDA for SPN-830 to the FDA. We received a Refusal to File (RTF) letter from the FDA regarding the NDA in which the FDA determined that the NDA was not sufficiently complete to permit a substantive review. In the letter, the FDA requested certain documents and reports to be submitted in support of the NDA. We are seeking guidance from the FDA, including a Type A meeting, to discuss the contents of the RTF letter and clarify the steps required for the resubmission of the NDA for SPN-830.

We may be unable to acquire product candidates or products.

The process of proposing, negotiating, and implementing a license, or acquiring a product candidate or an approved product, is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license, the product candidate, or approved product. We have limited resources, including financial resources, to identify and execute the acquisition or in-licensing of third-party products, businesses, and technologies and integrate them into our current infrastructure. Moreover, we may devote significant 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;
- Incur substantial debt, or dilutive issuances of securities, or depletion of cash to pay for acquisitions;
- Incur higher than expected acquisition, integration, and operating costs;
- Experience difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- Impair relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- Unable to retain and/or motivate key employees of any acquired businesses.

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

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

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

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

We do not own or operate manufacturing facilities for the production of any of our products or product candidates beyond Phase II clinical trials, nor do we have plans in the foreseeable future to develop our own manufacturing operations to support Phase III clinical trials or support commercial production. We currently depend on third-party CMOs for all of our required raw materials and drug substances for our preclinical research and clinical trials. For our commercial products, including Oxtellar XR, Trokendi XR, and APOKYN, we currently rely on single source suppliers for raw materials, including API, and rely on third-party manufacturers for the production and packaging of final commercial products. In addition, we rely on a single source supplier of API for SPN-812 and API and infusion delivery pump system for SPN-830. If any of these vendors are unable to perform their obligations to us, including due to violations of the FDA's requirements, our ability to meet regulatory requirements, projected timelines, and necessary quality standards for the development or commercialization of products would be adversely affected. Further, if we were required to change vendors, it could result in substantial delays in our regulatory approval efforts, significantly increase our costs, and delay generation of revenues. Accordingly, the loss of any of our current or future third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition, and business prospects.

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

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

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

In addition, the results from the trials that we have completed for our product candidates may not be replicated in future trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced development, even after promising results in earlier trials. If our product candidates are not shown to be safe and effective, these clinical development programs might be terminated.

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

Delays or failures in the completion of clinical trials for our product candidates could significantly raise our product development costs. For example, in November 2020, we received a RFT letter from the FDA concerning the NDA for SPN-830. We do not know whether current or planned trials will be completed on schedule, if at all. The commencement and completion of clinical development can be delayed or halted for a number of reasons, including:

- Difficulties in obtaining regulatory approval to commence a clinical trial or in complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- Difficulties obtaining IRB or ethics committee approval to conduct a trial at a prospective site;
- Delays in reaching or failure to reach agreement on acceptable terms with prospective trial sites and investigators, the contractual terms of which can be subject to extensive negotiation and may vary significantly from site to site;

- Insufficient or inadequate supply of or quantity of a product candidate for use in trials;
- Challenges recruiting and enrolling patients to participate in clinical trials, for any and all reasons, including competition from other programs for the treatment of similar conditions;
- Severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- Difficulty retaining patients who have enrolled in a clinical trial but who may be prone to withdraw due to side effects from the therapy, lack of efficacy, or personal issues;
- Temporary cessation of clinical trials (clinical holds); or
- Delays due to ambiguous or negative interim results in clinical trials.

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

- Failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols;
- Observations during an inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities which ultimately result in the imposition of a delay or clinical hold;
- Unforeseen safety issues; or
- Lack of adequate funding to continue the trial.

Failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols may result in the inability to use the trial data to support product approval. Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may adversely impact the cost, timing, and/or successful completion of a clinical trial.

In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If we experience delays in completion, or if we terminate any of our clinical trials, our ability to obtain regulatory approval of our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues diminished.

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

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

Immediate release oxcarbazepine and topiramate products, which use the same APIs as Oxtellar XR and Trokendi XR, are known to cause various side effects, including but not limited to: dizziness; paresthesia; headaches, and cognitive deficiencies such as memory loss and speech impediment; digestive problems; somnolence; double vision; gingival enlargement; nausea; weight gain; oral malformation birth defects; visual field defects; infants small for gestational age; and fatigue. The use of Oxtellar XR and Trokendi XR may cause similar side effects as compared to their reference products or may cause additional or different side effects.

Apomorphine hydrochloride products, which use the same API as APOKYN, are known to cause various side effects, including but not limited to: yawning; sleepiness; dyskinesias; dizziness; runny nose; nausea and/or vomiting; hallucinations/confusion; and swelling of hands, arms, legs, and feet, somnolence. The use of APOKYN may cause similar side effects compared to these reference products, or may cause additional or different side effects.

Safinamide products, which use the same API as XADAGO, are known to cause various side effects, including but not limited to: dyskinesia, nausea, falls, insomnia. The use of XADAGO may cause similar side effects compared to these reference products or may cause additional or different side effects.

Botulinum toxin products, which use the same API as MYOBLOC, are known to cause various side effects due to the spread of botulinum toxins from the area of injections. These may include: asthenia; generalized muscle weakness; diplopia; blurred vision; ptosis; dysphagia; dysphonia; dysarthria; urinary incontinence; and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening. There have been reports of death. The use of MYOBLOC may cause similar side effects compared to its reference products or may cause additional or different side effects.

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

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

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

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

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

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

Although we have been granted FDA orphan drug designation for SPN-817 for the treatment of Dravet Syndrome and Lennox-Gaustaut Syndrome, and we intend to expand our designation for alternative uses where applicable, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or it may result from a competing product reaching the market with an orphan designation for the same disease indication. Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the U.S. for seven years. Even if we obtain exclusivity, the FDA could subsequently approve an alternative drug for the same condition if the FDA concludes that the second

to reach the market is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. In addition, a competitor may receive approval of different products for the same indication for which our orphan product has exclusivity or may obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

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

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

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

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

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

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

- An annual, nondeductible fee payable to the U.S. federal government by any entity that manufactures or imports specified branded prescription drugs or biologic agents. This fee is based on each company’s market share of prior year total sales of branded products to certain federal healthcare programs;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- Rebates owed by manufacturers under the Medicaid Drug Rebate Program for drugs that are inhaled, infused, instilled, implanted, or injected. In addition, on December 21, 2020, the Centers for Medicare & Medicaid Services issued a Final Rule that makes significant modifications to the Medicaid Drug Rebate Program regulations in several areas, including with respect to the treatment of value-based purchasing arrangements, the definition of key terms, and the price reporting treatment of manufacturer-sponsored patient benefit programs;
- A Medicare Part D coverage gap discount program, in which manufacturers must agree to offer a substantial point-of-sale discount off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- Extension of manufacturers’ Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- Expansion of the eligibility criteria for Medicaid programs in certain states;

- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- A requirement to annually report the number of drug samples that manufacturers and distributors provide to physicians; and
- A Patient-Centered Outcomes Research Institute to oversee, identify priorities for, and conduct comparative clinical effectiveness research, along with funding for such research.

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

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

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

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. Since January 2017, then President Trump signed two Executive Orders as well as other directives designed to delay, circumvent or loosen the implementation of certain provisions mandated by the Affordable Care Act that would otherwise impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals. Concurrently, Congress has considered legislation that would repeal or replace all or part of the Affordable Care Act. While Congress has not passed repeal legislation, on December 22, 2017, then President Trump signed the Tax Cuts and Jobs Act (Tax Act), which included a provision that repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year. This is commonly referred to as the "individual mandate." Additionally, in January 2018, then President Trump signed a continuing resolution on appropriations for the fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including: the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans; the annual fee imposed on certain health insurance providers based on market share; and the medical device excise tax on non-exempt medical devices. In addition, in December 2018, a Texas Federal District Court struck down the entire Affordable Care Act as unconstitutional, holding that following the elimination of the tax penalty under the Affordable Care Act, the remaining individual mandate portion of the Affordable Care Act could not be justified as proper and legitimate use of Congress' taxing power. Because the Court deemed the individual mandate as inseverable from the rest of the Affordable Care Act, the entire Affordable Care Act was rendered unconstitutional. Further, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari and held oral arguments on November 10, 2020. Therefore, we continue to evaluate the potential impact of the Affordable Care Act and its possible repeal or replacement on our business.

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

Healthcare cost containment legislation and the failure of third-party payors to provide appropriate levels of coverage and reimbursement for the use of products and treatments facilitated by our products could harm our business and prospects.

Our products are dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. These policies affect which products customers purchase and the prices customers are willing to pay. Reimbursement varies by country and can significantly impact the acceptance of new products and technologies. Even if we develop a promising new product, we may find limited demand for the product unless appropriate

reimbursement approval is obtained from private and governmental third-party payors. Further legislative or administrative reforms to the reimbursement systems in the U.S. and other countries in a manner that significantly reduces reimbursement for our products, including price regulation, competitive bidding and tendering, coverage and payment policies, comparative effectiveness of therapies, technology assessments, and managed-care arrangements, could have a material adverse effect on our business, financial condition or results of operations.

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

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

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

The Drug Quality and Security Act (DQSA) became law in 2013. DQSA creates the requirement for companies to trace, verify and identify all products through the entire supply chain, from manufacturer to dispenser. Title I of the DQSA increased regulation of compounding drugs. Title II of the DQSA Drug Supply Chain Security established requirements to facilitate improved tracking of prescription drug products through the supply chain with increased product identification requirements. DQSA requires such tracking to be done farther down the distribution chain, including (i) wholesalers' verification and tracking in November 2019, (ii) pharmacy verification and tracking in the Fall of 2020, and (iii) at the unit level throughout the entire supply chain near the end of 2023.

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

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

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

In addition, the former Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has solicited feedback on some of these measures and has implemented others. On July 24, 2020, and September 13, 2020, then President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule on September 24, 2020, providing guidance for states to build and submit plans to import drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The likelihood of implementation of any of the other Trump administration reform initiatives is uncertain, particularly in light of the recent U.S. presidential election.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms could result in reduced demand for our product candidates or additional pricing pressures and may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

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

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

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

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

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

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

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

As a supplier of pharmaceuticals, certain U.S. federal and state healthcare laws and regulations pertaining to patients' rights to privacy, fraud and abuse protection, and others, are and will be applicable to our business. We could be subject to allegations of healthcare fraud and abuse, patient privacy violations, as well as other violations of healthcare regulations by both the federal government and the states in which we conduct our business. Regulations include, but are not limited to, the:

- Federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge or specific intent to violate the statute in order to have committed a violation. Further, the government may assert that a claim, including items and services resulting from a violation of the federal Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below. On December 2, 2020, additional Anti-Kickback regulations were finalized, creating new and change existing safe harbors, which take effect in January 2021. Safe harbors protect certain arrangements from prosecution if each of the elements of the safe harbor is satisfied;

- Federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things: individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; knowingly making a false statement material to an obligation to pay or transmit money to the federal government; or knowingly concealing or improperly avoiding or decreasing an obligation to pay money to the federal government. This may apply to entities like us, which provide coding and billing advice to customers;

- Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which prohibits 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. On December 10, 2020, the U.S. Department of Health and Human Services released proposed modifications to the HIPAA Privacy Rule, which, if adopted, would change rules related to patient access to HIPAA protected records, among others;

- 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, commonly referred to as the Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments, and to report other transfers of value, physician ownership, and investment interests;

- Federal price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our commercial products;

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

- State law equivalents of each of the above federal laws, such as state anti-kickback laws, physician payment, and drug pricing transparency laws, and false claims laws which may apply to our business practices, including, but not limited to: research, distribution, sales and marketing arrangements; claims for items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and the applicable compliance guidance promulgated by the federal government; otherwise restrict payments that may be made to healthcare providers; and state laws governing the privacy and security of health information in certain circumstances. Many of these state laws differ from one another in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

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

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

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

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

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

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

For example, we received a Paragraph IV Notice Letter from generic drug makers Apotex Inc. and Apotex Corp. (collectively “Apotex”) in May 2020, directed to nine of its Oxtellar XR Orange Book patents, which generally cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. The FDA Orange Book lists all nine of our Oxtellar XR patents as expiring on April 13, 2027. In June 2020, we filed a lawsuit against Apotex alleging infringement of all nine patents. In September 2020, Apotex answered the Complaint and denied the substantive allegations of the Complaint. Apotex also asserted Counterclaims seeking declaratory judgments of non-infringement for the nine Oxtellar XR Orange Book patents. Our responses to Apotex’s counterclaims were filed in October 2020.

We also received a Paragraph IV Notice Letter from generic drug maker Ajanta Pharma Limited on February 11, 2021, directed to ten of its Trokendi XR Orange Book patents, which generally cover once-a-day topiramate formulations and methods of treating seizures using those formulations. The FDA Orange Book lists one patent with an expiration date of April 4, 2028 and nine patents with an expiration date of November 16, 2027. The Company is currently reviewing Ajanta’s Notice Letter and intends to vigorously enforce its intellectual property rights relating to Trokendi XR.

For more information, refer to Part I, Item 3—*Legal Proceedings* contained in this Annual Report on Form 10-K.

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

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

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

In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings 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 product sales, it could have a substantial adverse effect on the price of our common stock.

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

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

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

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

We also rely upon unpatented trade secrets, unpatented know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees, with our collaborators, and with our consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us.

It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies. We could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or could be independently discovered by our competitors. Any failure to adequately prevent disclosure of our trade secrets and other proprietary information could have a material, adverse impact on our business.

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

If we are sued for infringing the intellectual property rights of third parties, it could be costly and time consuming to defend such a suit. An unfavorable outcome in such litigation could have a material adverse effect on our business.

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

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

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

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

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

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

The use of our product candidates in clinical trials and the commercial sale of any of our products expose us to the risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, product liability claims may result in:

- Decreased demand for a commercial product;
- Impairment of our business reputation and exposure to adverse publicity;
- Withdrawal of bioequivalence and/or clinical trial participants;
- Initiation of investigations by regulators;
- Costs related to litigation;
- Distraction of management's attention from our primary business;
- Substantial monetary awards to patients or other claimants;
- Loss of revenues; and
- Our inability to commercialize products for which we are obtaining marketing approval.

Our product liability insurance coverage for our clinical trials is limited to $30 million per claim and $30 million in the aggregate. Insurance covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions, and exclusions. On occasion, large judgments have been awarded in class action lawsuits for drugs that had unanticipated side effects. In the future, the potential inability to obtain sufficient product liability insurance at an acceptable cost, or at all, to protect against potential product liability claims could prevent or inhibit the development and commercialization of the pharmaceutical products we develop.

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, to a significant degree, on our ability to effectively manage our recent and any future growth. In 2020, we increased employee headcount from 464 employees to 563 employees. Revenues in 2020 were $520.4 million, compared to $392.8 million in 2019. Our need to effectively execute our growth strategy requires that we:

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

This growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or to recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure; give rise to operational mistakes; loss of business opportunities; loss of employees; and reduced productivity.

We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. In addition, our growth will cause us to comply with an increasing number of regulations and statutory requirements. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected; our ability to generate or increase our revenues could be impaired; and we may not be able to implement our business strategy.

Cybersecurity incidents may adversely impact our financial condition, results of operations, and reputation.

Our operations involve the use of multiple systems that process, store and transmit sensitive information about our customers, suppliers, employees, financial position, operating results, and strategies. Cyberattacks or security breaches could compromise confidential client information, cause a disruption in our operations, harm our reputation, and expose us to liability, which in turn could negatively impact our business and the value of our common shares. We have and continue to implement measures to safeguard our systems and information and mitigate potential risks, including employee training around phishing, malware, and other cyber risks, but there is no assurance that such actions will be sufficient to prevent cyberattacks or security breaches that manipulate or improperly use our systems, compromise sensitive information, destroy or corrupt data, or otherwise disrupt our operations. The occurrence of such events, including breaches of our security measures or those of our third-party service providers, could negatively impact our reputation and our competitive position and could result in litigation with third parties, regulatory action, loss of business due to disruption of operations, and/or reputational damage, potential liability and increased remediation and protection costs, any of which could have a material adverse effect on our financial condition and results of operations. However, such coverage may be insufficient to cover the full impact of a cyberattack. Additionally, as cybersecurity risks become more sophisticated, we may need to increase our investments in security measures, which could have a material adverse effect on our financial condition and results of operations.

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

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

competitive. In addition, our ability to hire qualified personnel also depends on our flexibility to reward superior performance and to pay competitive compensation.

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

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

We are highly dependent on the development, regulatory, commercial, and financial expertise of our management, particularly Jack A. Khattar, our President and Chief Executive Officer. Mr. Khattar has an employment agreement. Other members of the senior management team have executive retention agreements, but these agreements do not guarantee the services of these executives will continue to be available to us. If we lose key members of our management team, we may not be able to find suitable replacements in a timely fashion, if at all. We cannot be certain that future management transitions will not disrupt our operations or will not generate concern among employees and those with whom we do business.

In addition to competition for personnel, our corporate offices are located in the greater Washington D.C. metropolitan area, an area that is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our Company and may be required to expend significant financial resources in our employee recruitment efforts. As a result, despite significant efforts on our part, we may be unable to attract and retain qualified individuals in sufficient numbers, which could have an adverse effect on our business, financial condition, and results of operations.

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

Our activities and the activities conducted by our third-party manufacturers and suppliers involve the controlled storage, use, and disposal of hazardous materials. We and our manufacturers and suppliers are subject to federal, state, city, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. Although we believe that the safety procedures we use for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, local, city, state, or federal authorities may curtail the use of these materials and may interrupt our business operations, including our commercialization, research and development efforts. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by applicable laws and regulations, we have no direct control over our third-party manufacturers, and therefore cannot guarantee that this is the case. We can eliminate the risk of accidental contamination or that such safety procedures will prevent injury from these materials. In such an event, we may be held liable for any resulting damages. Such liability could exceed our resources.

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

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

In 2005, we purchased substantially all of the assets of Shire Laboratories Inc., the predecessor of Supernus Pharmaceuticals. Under the purchase agreement, we agreed to refrain perpetually from engaging in any research, formulation development, analytical testing, manufacture, technology assessment, or oral bioavailability screening that relate to five specific drug compounds (i.e., amphetamine, carbamazepine, guanfacine, lanthanum, and mesalamine), and any derivative thereof.

Although these various restrictions and covenants on us do not currently impact our products, product candidates, or business, they could in the future limit or delay our ability to take advantage of business opportunities that may relate to such compounds.

The Company's financial condition and results of operations for fiscal year 2021 and beyond may be materially and adversely affected by the ongoing COVID-19 outbreak.

The Company is currently following the recommendations of local and federal health authorities to minimize exposure risk for its various stakeholders, including employees. The full extent of the impact of COVID-19 on our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions required to contain COVID-19 or treat its impact, among others.

Although the Company currently continues to have an uninterrupted wholesale and retail distribution of its products, and the Company does not anticipate a shortage of its commercial products due to COVID-19 at this time, disruptions may occur for the Company's customers or suppliers that may materially affect the Company's ability to obtain supplies or components for its products, manufacture an additional product, or deliver inventory in a timely manner. This would result in lost sales, additional costs, penalties, or damage to the Company's reputation.

Workforce limitations and travel restrictions resulting from related government actions taken to contain the spread of the disease may impact many aspects of our business. If a significant percentage of our workforce is unable to work, including because of illness or travel or government restrictions in connection with the COVID-19 outbreak, our operations may be negatively impacted. As a result of government restrictions and social distancing guidelines in the United States, there is an increased reliance on working from home for our employees. For example, the Company's sales force is currently functioning largely utilizing digital engagement tools, tactics, and virtual detailing, which may be less effective than the Company's ordinary course sales and marketing programs. In addition, patients may not be able to get their prescriptions or visit their physicians, which in turn could adversely impact the prescription volumes of our commercial products. Similarly, investigative sites, subjects in clinical trials, and vendors that include our contract research organizations may be subject to the same workforce limitations and travel restrictions. As a result, we may experience delays or disruptions in our preclinical studies, clinical studies, and non-clinical experiments due to unforeseen circumstances, including but not limited to, interruption of key clinical trial activities, such as clinical trial site data monitoring, and interruption of clinical trial subject visits and study procedures.

The Company may also experience other unknown impacts from COVID-19 that cannot be predicted. While there has been no specific notice of delay from the federal authorities, potential interruptions, delays, or changes to the operations of the U.S. Food and Drug Administration may impact the approval of SPN-812. We may also experience delays in receiving supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, stoppages, disruptions in delivery systems.

The Company may also require an increased level of working capital if it experiences extended billing and collection cycles as a result of displaced employees at the Company, payors, revenue cycle management contractors, or otherwise. In addition, the disease outbreak could result in a widespread health crisis that could adversely affect the U.S. economy and financial markets, resulting in an economic downturn that could affect customers' demand for our products and our ability to raise additional capital or obtain financing on favorable terms.

The Company may experience delays in receipt of financial information, which may preclude timely reporting of financial results to investors and to the U.S. Securities and Exchange Commission.

Accordingly, disruptions to the Company's business as a result of COVID-19 could result in a material adverse effect on the Company's business, results of operations, financial condition, and prospects in the near-term and beyond 2020.

While the Company has developed a comprehensive COVID-19 contingency plan designed to potentially address the challenges and risks presented by this pandemic, there can be no assurance that such plan will be effective in mitigating the effects of the COVID-19 pandemic on our business operations and consequently the potential material adverse impact on our anticipated revenue, earnings and liquidity.

Compliance with the terms and conditions of our Corporate Integrity Agreement requires significant resources and management time and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.

We are subject to a CIA requiring a number of extensive obligations relating to the establishment and ongoing maintenance of an effective compliance program. Maintaining the broad array of processes, policies and procedures necessary to

comply with the CIA will require a significant portion of management's attention and the application of significant resources. The costs associated with implementation of and compliance with the CIA could be substantial and may be greater than we currently anticipate. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal regulations and laws and all requirements of the CIA. In the event of a breach of the CIA, we could become liable for payment of certain stipulated monetary penalties or could be excluded from participation in federal health care programs. The costs associated with compliance with the CIA, or any liability or consequences associated with its breach, could have an adverse effect on our business, revenues, earnings and cash flows.

Risks Related to Our Finances and Capital Requirements

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

In recent years, we have focused primarily on developing our current products and product candidates, with the goal of commercializing these products and supporting regulatory approval for our product candidates. We have financed our operations through revenue generated from operations and various transactions, including the following:

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

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

As of December 31, 2020, we had retained earnings of approximately $326.5 million. However, prior to 2018, we reported accumulated deficit due to significant operating losses incurred since inception through 2014, substantially as a consequence of costs incurred in connection with our development programs, expenses associated with launching our products, and from selling, general and administrative costs associated with our operations. We expect our research and development costs to continue to be substantial and to increase as we advance our product candidates through preclinical studies, clinical trials, manufacturing scale-up, and other pre-approval activities. We expect our selling, general and administrative costs to continue to increase as we continue to support the ongoing commercialization of our products and to further increase in anticipation of launching our product candidates.

While we anticipate operating profitably in 2021 and beyond, we cannot be certain that we will do so. Any potential future losses, if and when they occur, could have an adverse impact on our stockholders' equity and working capital.

Our operating results may fluctuate significantly.

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

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

- The level of market acceptance for any approved product candidate, underlying demand for that product, and wholesalers' buying patterns;
- Variations in the level of expenses related to our development programs;

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

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

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

Our ability to utilize our U.S. federal and state net operating losses or U.S. federal tax credits is currently limited and may be limited further, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders change their aggregate ownership position by more than 50 percentage points over their lowest ownership percentage in a testing period, which is typically three years, or since the last ownership change. We are already subject to Section 382 limitations due to cumulative ownership changes that, as of November 15, 2013, totaled more than 50%. As of December 31, 2020, we had U.S. federal net operating loss carryforwards of approximately $57.9 million and research and development tax credit carryforwards of approximately $3.5 million. Future changes in stock ownership may also trigger an additional ownership change and, consequently, another Section 382 or Section 383 limitation.

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

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.

Maintaining effective internal controls over financial reporting is necessary for us to produce reliable financial statements. Effective internal control over financial reporting and adequate disclosure controls and procedures are designed to prevent fraud.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Moreover, we must maintain effective disclosure controls and procedures in order to provide reasonable assurance that the information required to be reported in our periodic reports filed with the SEC is recorded, processed, summarized, and reported within the time periods specified by the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

In addition, any testing conducted by us in connection with Section 404(a) of the Sarbanes-Oxley Act of 2002 (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. 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. If we are unable to maintain effective internal controls over financial reporting or disclosure controls and procedures or remediate any material weakness, it could result in a material misstatement of our consolidated financial statements that would require a restatement or other materially deficient disclosures, investor confidence in the accuracy and timeliness of our financial reports and other disclosures may be adversely impacted, and the market price of our common shares could be negatively impacted.

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.

In June 2020, we completed the USWM Acquisition. The integration of the acquired business may result in our systems and controls becoming increasingly complex and more difficult to manage. In addition, the integration of the two companies may result in material challenges, including managing a larger, more complex combined business, maintaining employee morale and retaining key management and other employees, unanticipated issues in integrating financial reporting, information technology infrastructure, harmonizing the companies' operating practices, internal controls, compliance programs and other policies, procedures, and processes. We may also encounter difficulties in addressing possible differences in business backgrounds, corporate cultures and management philosophies, and maintaining adequate staffing, which could potentially pose challenges in the implementation and operation of controls. We may also identify or fail to identify potential deficiencies in internal controls at the acquired or combined business.

We have excluded the acquisition of USWM Enterprises, LLC from our evaluation of internal control over financial reporting for the year ended December 31, 2020. This exclusion is in accordance with the U.S. Securities and Exchange Commission's guidance permitting a company to exclude an acquired business from management's assessment of the effectiveness of internal control over financial reporting for up to one year following the acquisition.

We devote significant resources and time to comply with the internal control over financial reporting requirements of the Sarbanes-Oxley Act of 2002. However, we cannot be certain that these measures will ensure that we design, implement, and maintain adequate control over our financial processes and reporting in the future, particularly in the context of acquisitions of other businesses, regardless of whether such acquired business was previously privately or publicly held. Any difficulties in the assimilation of acquired businesses into our internal control framework could harm our operating results or cause us to fail to meet our financial reporting obligations. These risks, among others, could be heightened if we complete a large acquisition or other business venture or multiple transactions within a relatively short period of time.

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

We have and may further expand our business through acquisitions of new product lines or businesses, which exposes us to various risks, including difficulties in integrating acquisitions. Our recent acquisition poses certain incremental risks to the Company.

Our acquisition strategy entails numerous risks. In June 2020, we completed the USWM Acquisition, which is the largest acquisition in our history.

Our continued ability to grow through acquisitions will depend, in part, on the availability of suitable candidates at acceptable prices, terms, and conditions, our ability to compete effectively for acquisition candidates, and the availability of capital and personnel resources to complete such acquisitions and run and integrate the acquired business effectively. We anticipate competition for attractive candidates from other parties, some of whom have substantially greater financial and other resources than we have. Any acquisition, alliance, joint venture, investment, or partnership could impair our business, financial condition, reputation, and operating results. For instance, the benefits of an acquisition, or new alliance, joint venture, investment, or partnership may take more time than expected to develop or integrate into our operations, and we cannot guarantee that previous or future acquisitions, alliances, joint ventures, investments, or partnerships will, in fact, produce any benefits. 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, including our recent USWM Acquisition, may involve a number of risks, the occurrence of which could adversely affect our business, reputation, financial condition, and operating results, including:

- Dilutive issuances of equity securities;
- Incurrence of additional debt and contingent liabilities;
- Increased amortization of expenses related to intangible assets;
- Difficulties in the integration of the operations, technologies, services, and products of the acquired companies
- Diversion of management's attention from our other business activities;
- Assumption of debt and liabilities of the target company or any ongoing lawsuits
- Failing to achieve anticipated revenues, profits, benefits, or cost savings;
- Difficulty in coordinating, establishing, or expanding sales, distribution and marketing functions, as necessary;
- Potential inability to realize the value of the acquired assets relative to the price paid;
- Inaccurate assessment of additional post-acquisition, undisclosed, contingent, or other liabilities or problems, unanticipated costs associated with an acquisition and despite the existence of representations, warranties, and indemnities in any definitive agreement and, in the case of the USWM Acquisition or as may be applicable to future acquisitions, a representation and warranty insurance policy, an inability to recover or manage such liabilities and costs;
- Possibility of incurring significant restructuring charges and amortization expense;
- Potential impairment to assets that we recorded as a part of an acquisition, including intangible assets and goodwill;
- Potential loss of key employees, customers or distribution partners;
- Difficulties implementing and maintaining sufficient controls, policies, and procedures over the systems, products, and processes of the acquired company and the potential for deficiencies in internal controls at the acquired or combined business; and
- Adverse tax consequences;
- Reallocation of amounts of capital from other operating initiatives and/or an increase in our leverage and debt service requirements to pay acquisition purchase prices or other business venture investment costs, which could, in turn, restrict our ability to access additional capital when needed, result in a decrease in our credit rating, or limit our ability to pursue other important elements of our business strategy;
- Failure by acquired businesses or other business ventures to comply with applicable international, federal, and state product safety or other regulatory standards;
- Impacts as a result of purchase accounting adjustments, incorrect estimates made in the accounting for acquisitions, the incurrence of non-recurring charges, or other potential financial accounting or reporting impacts.

As regards to the USWM Acquisition, the Company acquired the right to further develop and commercialize APOKYN, XADAGO, and the Apomorphine Infusion Pump (SPN-830) in the U.S. and MYOBLOC worldwide (the Products) for an upfront cash payment of $300 million and the potential for additional contingent consideration payments of up to $230 million.

The potential $230 million in contingent consideration payments includes up to $130 million for the achievement of certain SPN-830 regulatory and commercial activities and up to $100 million related to future sales performance of the acquired products. The regulatory and commercial milestone activities include milestones related to FDA acceptance and approval of NDA and milestones dependent on the timing of NDA approval and commercial launch of SPN-830. Sales-based milestones are dependent on achievement of future product sales targets. The fair value of these contingent consideration liabilities is determined as of the acquisition date using estimated or forecast inputs.

In addition, the assets acquired in the USWM acquisition, which included intangible assets, were recorded at their estimated fair value at date of acquisition. The fair value of intangible assets, including acquired in-process research and development (IPR&D), were determined using information available as of the acquisition date and were based on estimates and assumptions that were deemed reasonable by management. Changes in any of the inputs or assumptions to the fair value estimate may result in a significantly different fair value adjustment, which may impact the results of operations in the period in which the adjustment is made.

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. If we do not achieve the anticipated benefits of 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. Further, we expect to incur substantial expenses in connection with the integration activities, and actual integration may result in additional and unforeseen expenses.

Any impairment in the value of our intangible assets, including goodwill, would negatively affect our operating results and total capitalization.

In June 2020, we completed the USWM Acquisition. As part of the acquisition, we acquired substantial intangible assets, including goodwill. We may not realize all the economic benefits from the acquisition, which could cause an impairment of goodwill or intangibles. We review our amortizable intangible assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. We test goodwill for impairment at least annually. Factors that may cause a change in circumstances, indicating that the carrying value of our goodwill or amortizable intangible assets may not be recoverable, include a decline in our stock price and market capitalization, reduced future cash flow estimates if significant and prolonged negative industry or economic trends exist and slower growth rates in industry segments in which we participate. We may be required to record a significant charge in our consolidated financial statements during the period in which any impairment of our goodwill or intangible assets is determined, negatively affecting our results of operations and equity book value, the effect of which could be material.

Risks Related to Securities Markets and Investment in Our Stock

The issuance of additional shares of our common stock, or instruments convertible into or rights to acquire shares or our common stock, or market sales of our common stock, could affect the market 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, fund acquisitions, or for other purposes. 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.

In addition, as of December 31, 2020, we had outstanding 52,868,482 shares of common stock, of which approximately 2,166,199 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, 2020, we had outstanding options to purchase 5,451,862 shares of common stock that, if exercised, would result in these additional shares becoming available for sale. Approximately 6.7% 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 3,922,631 and 954,570 shares of our common stock are reserved for future issuance under the 2012 Equity Incentive Plan and the 2012 Employee Stock Purchase Plan, respectively.

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

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

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

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 acquirer from conducting a solicitation of proxies to elect such acquirer'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.

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

As of December 31, 2020, we had issued options to purchase 5,451,862 shares of common stock outstanding, with exercise prices ranging from $5.40 to $58.15 per share and a weighted average exercise price of $23.26 per share. Upon the vesting of each of these options, the holder may exercise his or her options, which would result in dilution to investors.

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

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

- Increasing our vulnerability to adverse economic and industry conditions;

- Limiting our ability to obtain additional financing;

- Requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which would reduce the amount of cash available for other purposes;

- Limiting our flexibility to plan for, or react to, changes in our business;

- Diluting the economic interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2023 Notes, notwithstanding the convertible hedge and warrant transactions; and

- Placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

General Risk Factors

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. There are situations in which noncompliance can result

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

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

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

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

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

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

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

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

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

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

We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. In addition, we rely on various information technology, and systems, some of which are dependent on services provided by third parties, to manage our technology platform and operations. These systems provide critical data and services for internal and external users, including procurement, inventory management, transaction processing, financial, commercial, and operational data, human resources management, legal and tax compliance, financial reporting, and other information necessary to operate and manage our business. These systems are complex and are frequently updated as technology improves. This includes software and hardware that is licensed, leased, or purchased from third parties. If our information technology, equipment, or systems fail to function properly due to internal errors or defects, implementation or integration issues, catastrophic events, or power outages, we may experience a material disruption in our ability to manage our business operations. Failure or disruption of these systems could have an adverse effect on our operating results and financial condition. In addition, we may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Any failure to

manage, expand, or update our information technology infrastructure, or any failure in the operation of this infrastructure, could harm our business.

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

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

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

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

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

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

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

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

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

We face increased legal, accounting, administrative, and other costs and expenses as a public company. Compliance with Section 404 of SOX, the Dodd-Frank Act of 2010, as well as rules of the Securities and Exchange Commission and NASDAQ, for example, has resulted in significant initial cost to us as well as ongoing increases in our legal, audit and financial reporting costs. As of the beginning of 2017, we transitioned from "accelerated filer" to "large accelerated filer" status, which led to further increases in our legal, audit, NASDAQ listing fees, and financial compliance costs. The Securities Exchange Act of 1934, as amended (the Exchange Act), requires, among other things, that we file annual, quarterly, and current reports with respect to our business and financial condition. Our board of directors, management, and outside advisors need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and require us to incur substantial and increasing costs to maintain the same or similar coverage.

As a public company, we are subject to Section 404 of SOX relating to internal controls over financial reporting. We have and expect to continue to incur significant expense and to devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit group. We have hired additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We expect that we will have to compete in the marketplace 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 have never paid dividends on our capital stock. Because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock.

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

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 cover 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.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

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

ITEM 3. LEGAL PROCEEDINGS.

From time to time and in the ordinary course of business, we may be subject to various claims, charges, and litigation. We may be required to file infringement claims against third parties for the infringement of our patents.

Oxtellar XR

The Company received a Paragraph IV Notice Letter from generic drug makers Apotex Inc. and Apotex Corp. (collectively "Apotex") dated May 13, 2020, directed to nine of its Oxtellar XR Orange Book patents. Supernus's U.S. Patent Nos. 7,722,898, 7,910,131, 8,617,600, 8,821,930, 9,119,791, 9,351,975, 9,370,525, 9,855,278, and 10,220,042 generally cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. The FDA Orange Book lists all nine of the Company's Oxtellar XR patents expiring on April 13, 2027. On June 26, 2020, the Company filed a lawsuit against Apotex alleging infringement of the Company's nine patents. The Complaint-filed in the U.S. District Court for the District of New Jersey-alleges, inter alia, that Apotex infringed the Company's Oxtellar XR patents by submitting to the FDA an Abbreviated New Drug Application (ANDA) seeking to market a generic version of Oxtellar XR prior to the expiration of the Company's patents. Filing its June 26, 2020 Complaint within 45 days of receiving Apotex's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Apotex's ANDA for 30 months from the date of our receipt of the Paragraph IV Notice Letter. On September 4, 2020, Apotex answered the Complaint and denied the substantive allegations of the Complaint. Apotex also asserted Counterclaims seeking declaratory judgments of non-infringement for the nine Oxtellar XR Orange Book patents. On October 30, 2020, the Company filed its Reply, denying the substantive allegations of Apotex's Counterclaims. Following the initial Rule 16 Scheduling Conference, the Court issued a case schedule that provides for a trial in June or July 2022. Pretrial discovery is ongoing as of the date of this filing.

Trokendi XR

The Company received a Paragraph IV Notice Letter from generic drug maker Ajanta Pharma Limited on February 11, 2021, directed to the following Trokendi XR patents: U.S. Patent Nos. 8,298,576; 8,298,580; 8,663,683; 8,877,248; 8,889,191; 8,992,989; 9,549,940; 9,555,004; 9,622,983; and 10,314,790. The FDA Orange Book lists an expiration date of April 4, 2028 for U.S. Patent No. 8,298,576 and an expiration date of November 16, 2027 for U.S. Patent Nos. 8,298,580; 8,663,683; 8,877,248; 8,889,191; 8,992,989; 9,549,940; 9,555,004; 9,622,983; and 10,314,790. These patents generally cover once-a-day topiramate formulations and methods of treating seizures using those formulations. The Company is currently reviewing Ajanta’s Notice Letter and intends to vigorously enforce its intellectual property rights relating to Trokendi XR.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market and Shareholder Information

Our common stock has been listed on the NASDAQ Global Market under the symbol "SUPN" since May 1, 2012.

On December 31, 2020, the closing price of our common stock on the NASDAQ Global Market was $25.16 per share. As of December 31, 2020, we had 19 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

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

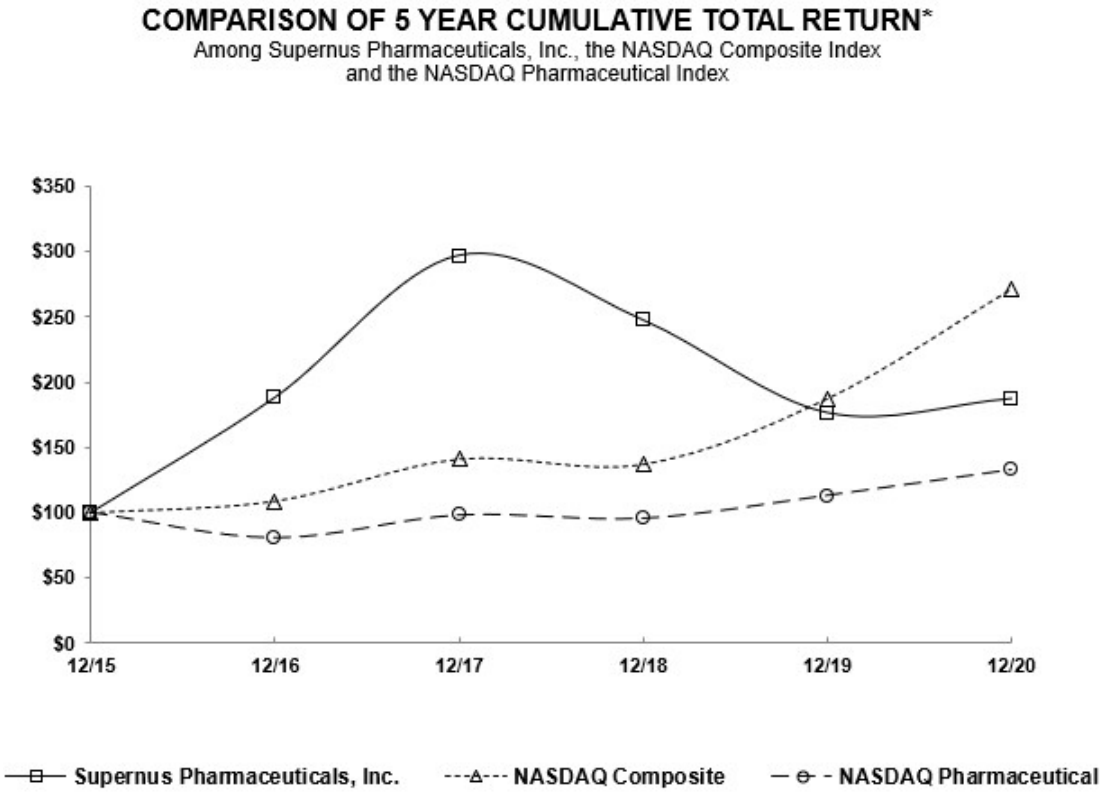
Option Grants

During the three-month period ended December 31, 2020, the Company granted options to employees to purchase an aggregate of 160,200 shares of common stock at a weighted average exercise price of $21.21 per share. The options are exercisable for a period of ten years from the grant date. These issuances were exempt from registration in reliance on Section 4(a)(2) of the Securities Act as transactions not involving any public offering.

Performance Graph

The following graph sets forth the Company's total cumulative stockholder return as compared to the NASDAQ Stock Market Composite Index and the NASDAQ Biotechnology Index for the period beginning December 31, 2015, and ending December 31, 2020.

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.



* $100 invested on 12/31/2015 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, 2015	100.00	100.00	100.00
December 31, 2016	187.87	108.87	80.51
December 31, 2017	296.50	141.13	97.95
December 31, 2018	247.17	137.12	95.46
December 31, 2019	176.49	187.44	113.09
December 31, 2020	187.20	271.64	132.91

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, 2020, 2019, and 2018 and balance sheet data as of December 31, 2020, and 2019 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, 2017, and 2016 and the balance sheet data as of December 31, 2018, 2017, and 2016 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. Dollars are in thousands, except share and per share data.

	Years Ended December 31,				
	2020	2019	2018	2017	2016
Statements of Earnings Data:					
Revenues	$ 520,397	$ 392,755	$ 408,897	$ 302,238	$ 215,003
Net earnings	126,950	113,056	110,993	57,284	91,221
Earnings per share					
Basic	$ 2.41	$ 2.16	$ 2.13	$ 1.13	$ 1.84
Diluted	2.36	2.10	2.05	1.08	1.76
Weighted-average shares outstanding					
Basic	52,615,269	52,412,181	51,989,824	50,756,603	49,472,434
Diluted	53,689,743	53,816,754	54,098,872	53,301,150	51,708,983
Balance Sheet and Other Data:					
Cash and cash equivalents and marketable securities	$ 422,533	$ 347,073	$ 356,018	$ 140,040	$ 90,121
Long-term marketable securities	350,359	591,773	418,798	133,638	75,410
Working capital	385,309	312,057	332,134	105,451	70,662
Total assets	1,504,102	1,160,282	977,811	424,464	309,568
Convertible notes, net	361,751	345,170	329,462	—	4,165
Non-recourse liability related to sale of future royalties [(1)]	18,731	22,492	24,758	26,541	30,390
Retained earnings (accumulated deficit)	326,498	199,548	86,492	(26,823)	(84,288)
Total stockholders' equity	744,858	595,428	453,023	267,480	191,755

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

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

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

Overview

We are a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. Our diverse neuroscience portfolio includes approved treatments for epilepsy, migraine, hypomobility in Parkinson’s Disease (PD), cervical dystonia, and chronic sialorrhea. We are developing a broad range of novel CNS product candidates including new potential treatments for attention-deficit hyperactivity disorder (ADHD), hypomobility in Parkinson’s disease, epilepsy, depression, and rare CNS disorders.

On April 21, 2020, the Company entered into a Development and Option Agreement (Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor). Under the terms of the Development Agreement, the Company and Navitor will jointly conduct a Phase II clinical program for NV-5138 (mTORC1 activator) (SPN-820) in treatment-resistant depression (TRD). Initiation of Phase II clinical program is targeted in the fourth quarter of 2021.

On April 28, 2020, the Company entered into a Sale and Purchase Agreement with US WorldMeds Partners, LLC to acquire the CNS portfolio of USWM Enterprises, LLC (USWM Enterprises) (USWM Acquisition). With the acquisition,

completed on June 9, 2020, the Company added three established commercial products and a product candidate in late-stage development to its portfolio.

We have a portfolio of commercial products and product candidates.

Commercial Products

- Trokendi XR (topiramate) is the first once-daily extended release topiramate product indicated for the treatment of epilepsy in the United States (U.S.) market. It is also indicated for the prophylaxis of migraine headache.
- Oxtellar XR (oxcarbazepine) is indicated as therapy of partial onset seizures in adults and children 6 years to 17 years of age and is the first once-daily extended release oxcarbazepine product indicated for the treatment of epilepsy in the U.S.
- APOKYN (apomorphine hydrochloride injection) is a product indicated for the acute, intermittent treatment of hypomobility or “off” episodes (“end-of-dose wearing off” and unpredictable “on-off” episodes) in patients with advanced PD.
- XADAGO (safinamide) is a once-daily product indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing “off” episodes.
- MYOBLOC (rimabotulinumtoxinB) is a product indicated for the treatment of cervical dystonia and sialorrhea in adults, and it is the only Type B toxin available on the market.

Product Candidates

- SPN-812 (viloxazine hydrochloride), a novel non-stimulant product candidate for the treatment of ADHD.
- SPN-830 (Apomorphine Infusion Pump) is a late-stage drug/device combination product candidate for the continuous prevention of “off” episodes in PD.
- SPN-817, a novel product candidate for the treatment of severe epilepsy.
- SPN-820 is a first-in-class, orally active small molecule that directly activates brain mTORC1 and is a novel product candidate for treatment resistant depression.

Operational Highlights

SPN-812 - Novel non-stimulant for the treatment of ADHD in children and adults

- In February 2021, we received notice from the FDA that the NDA resubmission for SPN-812 for the treatment of ADHD in pediatric patients is considered a Class I resubmission, thereby assigning a timeline of two months for review by the FDA and establishing a new Prescription Drug User Fee Act (PDUFA) target action date in early April 2021. We are preparing for the commercial launch of SPN-812 for the treatment of ADHD in pediatric patients in the second quarter of 2021, if approved by the FDA.
- In December 2020, we announced positive results from a Phase III trial in adult patients with ADHD. Assuming approval for pediatric patients, we plan to submit a supplemental NDA (sNDA) to the FDA for SPN-812 in adults in the second half of 2021.

SPN-830 (Apomorphine infusion pump) - Continuous treatment of motor fluctuations (“on-off” episodes) in PD

- We are scheduled to meet with the FDA in March 2021 in a Type A meeting to discuss the contents of the Refusal to File (RTF) letter it received in November 2020 regarding its NDA for SPN-830. In the letter, the FDA requested certain documents and reports to be submitted in support of the application. We believe additional testing of the device will be necessary to support the SPN-830 NDA resubmission. We plan to resubmit the SPN-830 NDA after completing discussions with the FDA and the required activities for filing.

SPN-820 - Novel first-in-class activator of mTORC1

- Development activities are ongoing, including a multiple-ascending dose study in healthy volunteers, with the goal of initiating a Phase II clinical program in treatment-resistant depression by the end of 2021.

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

Intellectual property portfolio

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

COVID-19 Impact

In March 2020, we began to observe the impact of the COVID-19 pandemic in the U.S and globally and the impact it may have on our business operations and our financial results. The macroeconomic impacts of COVID-19 are significant and continue to evolve, as exhibited by, among other things, a rise in unemployment, changes in consumer behavior, and market volatility.

The full impact of the COVID-19 pandemic on our business remains uncertain and subject to change. We are closely monitoring the impact of the COVID-19 pandemic on all aspects of our business operations and have assessed the impact of the COVID-19 pandemic on our consolidated financial statements. Although the COVID-19 pandemic has not significantly impacted our consolidated financial statements as of and for the year ended December 31, 2020, it may have a future impact, especially if the severity worsens, the duration lengthens, or the nature of the effects changes.

The effects of the pandemic may vary significantly across different aspects of our business operations. We do not and cannot yet know the full extent of the potential impact on our execution of clinical trials, new product launches, including SPN-812, our manufacturing and supply chain, or related impacts on our business or financial condition. These effects could include the adverse impact on research and development activities as a result of a disruption in clinical projects; adverse impact on selling and marketing efforts as a result of temporarily halting in-person interactions by our sales force with healthcare providers; adverse impact on net product sales as a result of decreased new prescriptions due to fewer patient visits to physicians to begin treatment; potential changes in payor segment mix; increased use of co-pay programs due to rising unemployment; and potential future disruption to our supply chain and manufacturing operations.

These effects could have a material impact on the Company's liquidity, cash flows, capital resources, and business operations. Financial effects could include impairment of intangible and long-lived assets, increased sales deductions that could adversely impact our net product sales, and cash collections and adjustments for market volatility for items subject to fair value measurement, such as marketable securities. See "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K for additional information on risk factors that could impact our business and our results.

For the year ended December 31, 2020, except for the effects already cited, there has been no material impact on our operations, liquidity, and financial position due to the COVID-19 pandemic. We expect to continue to generate positive cash flows and to meet our short-term liquidity needs.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis of presentation for our consolidated financial statements are described in Part II, Item 8—*Financial Statements and Supplementary Data*, Note 2, *Summary of Significant Accounting Policies*, in the Notes to the Consolidated Financial Statements. Our consolidated financial statements are prepared in accordance with the U.S. generally accepted accounting principles (U.S. GAAP), requiring us to make estimates, judgments, and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses, and other related disclosures. Some judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

We believe the judgments, estimates, and assumptions associated with the following critical accounting policies have the greatest potential impact on our consolidated financial statements:

- Revenue recognition;
- Business combination accounting and valuation of acquired assets, including goodwill and intangible assets;
- Valuation of contingent consideration;
- Inventories produced in preparation of product launches; and

- Income taxes.

Revenue Recognition

Our principal source of revenue is product sales. Revenue from product sales is recognized when physical control of our products is transferred to our customers, who are primarily pharmaceutical wholesalers, specialty pharmacies, and distributors. Product sales are recorded net of various forms of variable consideration, including: estimated rebates; sales discounts; and an estimated liability for future product returns (collectively, "sales deductions").

The variability in the net transaction price for our products arises primarily from the aforementioned sales deductions. Significant judgment is required in estimating certain sales deductions. In making these estimates, we consider: historical experience; product price increases; current contractual arrangements under applicable payor programs; unbilled claims; processing time lags for claims; inventory levels in the wholesale, specialty pharmacy, and retail distribution channel; and product life cycle. 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. Variable consideration on product sales is only recognized when it is probable that a significant reversal will not occur. If actual results in the future vary from our estimates, we adjust our estimates in the period identified. These adjustments could materially affect net product sales and earnings in the period in which the adjustment(s) is recorded. Refer to Part II, Item 8—*Financial Statements and Supplementary Data*, Note 2, *Summary of Significant Accounting Policies*, in the Notes to the Consolidated Financial Statements, for discussion on each of the different sales deductions.

Business Combination Accounting and Valuation of Acquired Assets, Including Goodwill and Intangible Assets

The Company completed the USWM Acquisition on June 9, 2020, and accounted for the transaction as a business combination. To determine whether the acquisition should be accounted for as a business combination or as an asset acquisition, the Company made certain judgments regarding whether the acquired set of activities and assets met the definition of a business. Significant judgment is required in assessing whether the acquired processes or activities, along with their inputs, would be substantive to constitute a business, as defined by U.S. GAAP.

As of December 31, 2020, the total estimated purchase price was $380.3 million and the preliminary estimate of fair value of the acquired intangible assets at the acquisition date was $355 million, of which $123 million was estimated fair value of the IPR&D asset and the remaining $232 million is fair value of the acquired definite-lived intangible assets. We also have recorded a preliminary estimate of $77.9 million goodwill at the acquisition date related to the business combination. When identifiable intangible assets, including in-process research and development (IPR&D) asset, are acquired, we determine the fair values of the assets as of the acquisition date. An income approach, which generally relies upon projected cash flow models, was used in estimating the fair value of the acquired intangible assets. Some of the more significant inputs and assumptions used in the intangible asset valuation include: the timing and probability of success of clinical events or regulatory approvals for the IPR&D asset; the estimated future cash flows from product sales resulting from approved products and IPR&D asset; the timing and projection of costs and expenses, including costs to complete the IPR&D asset; tax rates; and discount rates.

During the measurement period, if we obtain new information regarding facts and circumstances that existed as of the Closing Date that, if known, would have resulted in revised estimates of fair values of acquired assets, assumed liabilities or contingent consideration, the Company will accordingly revise its estimates of fair values and purchase price allocation.

Intangible assets with indefinite lives are not amortized but are tested for impairment at least annually or when indicators of impairment are identified. Our annual evaluation is generally based on an assessment of qualitative factors to determine whether it is more likely than not the fair value of the asset is less than its carrying amount. Significant judgment is required in assessing the qualitative factors. If the Company is unable to conclude that the indefinite intangible asset is not impaired during its qualitative assessment, the Company will perform a quantitative assessment by estimating the fair value of the indefinite-lived intangible asset and comparing the fair value to the carrying amount. Estimating fair value of the indefinite-lived intangible assets require the use of significant estimates and assumptions. We rely upon cash flow projections attributable to the indefinite-lived intangible asset in estimating the fair value. Some of the more significant inputs and assumptions in estimating fair value are the same inputs and assumptions described above for estimating fair value of the acquired intangible assets.

Intangible assets with definite useful lives are amortized over their estimated useful lives and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When performing our impairment assessment for definite-lived intangible assets, we rely upon cash flow projections attributable to the asset group to determine if the carrying value of the asset group is recoverable, on an undiscounted cash flow basis. If the carrying value of a definite lived intangible asset is not recoverable, we will recognize impairment in the amount by which the carrying value of the asset exceeds its fair value. Some of the more significant inputs and assumptions in estimating fair value are the same inputs and assumptions described above for estimating fair value of the acquired intangible assets.

Changes to assumptions used in the cash flow projections could result in an impairment. Impairments will be recorded within the impairment of intangible assets in our consolidated statements of earnings.

Goodwill represents the excess of the purchase price over the fair value of net assets acquired in a business combination and is not amortized. Goodwill is subject to impairment testing at least annually or more often if and when events or circumstances indicate goodwill may be impaired. We are organized and operate as a single reporting unit, and therefore the goodwill impairment test is performed using our overall market value compared to our book value of net assets at the reporting unit level.

Valuation of Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. As of December 31, 2020, we recorded $76.7 million of contingent consideration liability. Some of the more significant inputs and assumptions used in determining the fair value of the contingent consideration include: probability and timing of milestone achievements, such as the probability and timing of obtaining regulatory approval; estimated amount and timing of projected revenues from the Products; and discount rates.

A contingent consideration liability arose in connection with the USWM Acquisition, which was accounted for as a business combination. During the measurement period, if we obtain new information regarding facts and circumstances that existed as of the Closing Date that, if known, would have resulted in revised estimates of fair values of acquired assets, assumed liabilities or contingent consideration, the Company will accordingly revise its estimates of fair values and purchase price allocation. In addition, on a quarterly basis, we revalue the contingent consideration liability and record increases or decreases in their fair value as an adjustment to operating earnings.

Changes to the contingent consideration liability can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the timing of achievement the milestones which includes both regulatory and developmental and commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval. The assumptions related to determining the fair value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded and, therefore, our results of operations in any given period.

Inventories Produced in Preparation of Product Launches

We capitalize inventories produced in preparation for product launches when future commercialization of a product is probable and when a future economic benefit is expected to be realized. The determination to capitalize is based on the particular facts and circumstances relating to the product. Capitalization of such inventory begins when we determine that (i) positive clinical trial results have been obtained in order to support regulatory approval; (ii) uncertainties regarding regulatory approval have been significantly reduced; and (iii) it is probable that these capitalized costs will provide future economic benefit, in excess of capitalized costs.

As of December 31, 2020, we capitalized $19.1 million of pre-launch inventory for SPN-812. In assessing and making the determination to capitalize inventory prior to product launch, we are required to use significant judgments and assumptions to evaluate and consider a number of factors, including: the product candidate’s current status in the regulatory approval process; results from the related pivotal clinical trial; results from meetings with relevant regulatory agencies prior to the filing of regulatory applications; historical experience; as well as potential impediments to approval; such as product safety or efficacy; commercialization potential; and market trends.

We estimate a range of likely commercial prices based on our comparable commercial products. We consider the product candidate’s stability data for all pre-approval production to date to determine whether there is an adequate expected shelf life for the capitalized pre-launch production costs. We also consider the likely selling price to determine if there is a sufficient profit margin to fully recover the cost of the inventory.

We periodically analyze our pre-launch inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value and write-down such inventories as appropriate. In addition, our products are subject to strict quality control and monitoring, which we perform throughout the manufacturing process. If certain batches or units of a product no longer meet quality specifications or become obsolete due to expiration, we record a charge to write down such unmarketable inventory to its estimated realizable value.

Income taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and deferred tax liabilities are determined based on the difference between the financial reporting and tax reporting bases. These differences are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. If our estimate of the tax effect of reversing temporary differences is not reflective of actual outcomes, is modified to reflect new developments or interpretations of the tax law, revised to incorporate new accounting principles or changes in the expected timing or manner of the reversal, our results of operations could be materially impacted.

A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets will not be realized. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized based on all available evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, results of recent operations, and our historical earnings experience by taxing jurisdiction. Significant judgment is required in making this assessment and, to the extent future expectations change, we would assess the recoverability of our deferred tax assets at that time. If we determine that the deferred tax assets are not realizable in a future period, we will record adjustments to income tax expense in that period, and such adjustments may be material.

Uncertain tax positions, for which management's assessment is more than a 50% probability that the position will be sustained upon examination by a taxing authority based upon its technical merits, are subjected to certain recognition and measurement criteria. Significant judgment is required in making this assessment, and, therefore, we re-evaluate uncertain tax positions and consider various factors, including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain positions. Our estimates for unrecognized tax benefits may be subject to material adjustments until matters are resolved with taxing authorities or statutes expire. If our estimates are not representative of actual outcomes, our results of operations could be materially impacted.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2020, compared to the year ended December 31, 2019. Our Annual Report on Form 10-K for the year ended December 31, 2019, includes a discussion and analysis of our financial condition and results of operations for the year ended December 31, 2018, in Part II,
Item 7—*Management's Discussion and Analysis of Financial Condition and Results of Operations*.

Revenues

Our primary source of revenue is from the sale of our commercial products. The table below lists our net product sales by product and royalty revenues from our collaborative licensing arrangements (dollars in thousands):

	Years Ended December 31,		Change	
	2020	2019	Amount	Percent
Net product sales				
Trokendi XR	$ 319,640	$ 295,214	$ 24,426	8%
Oxtellar XR	98,725	88,186	10,539	12%
APOKYN	74,296	—	74,296	**
XADAGO	6,943	—	6,943	**
MYOBLOC	9,746	—	9,746	**
Total net product sales	$ 509,350	$ 383,400	$ 125,950	33%
Royalty revenues	11,047	9,355	1,692	18%
Total revenues	$ 520,397	$ 392,755	$ 127,642	32%

Net Product Sales

The $126.0 million and 33% increase in net product sales for the year ended December 31, 2020, as compared to the prior year, was primarily due to the inclusion of $91.0 million in net product sales, consequent to the completion of the USWM acquisition on June 9, 2020. The combined annual growth of Trokendi XR and Oxtellar XR was $35.0 million or 9% as compared to 2019.

Trokendi XR net product sales increased by 8% in 2020 as compared to 2019. This increase was attributable to the favorable impact of the price increase taken in January 2020, coupled with favorable improvements in sales deductions that offset a decline in unit demand. Oxtellar XR net product sales increased by 12% in 2020 as compared to 2019. This increase was primarily attributable to the favorable impact of both unit demand and a price increase in January 2020.

Sales deductions and related accruals

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

The following table provides a summary of activities with respect to accrued product returns and rebates for the years ended December 31, 2020 and 2019 (dollars in thousands):

	Accrued Product Returns and Rebates			
	Product Rebates	Product Returns	Allowance for Sales Discounts	Total
Balance at December 31, 2018	$ 85,003	$ 22,060	$ 11,548	$ 118,611
Provision				
Provision for sales in current year	307,430	10,199	61,123	378,752
Adjustments relating to prior year sales	(888)	549	(43)	(382)
Total provision	306,542	10,748	61,080	378,370
Less: Actual payments/credits	(302,734)	(13,990)	(61,615)	(378,339)
Balance at December 31, 2019	$ 88,811	$ 18,818	$ 11,013	$ 118,642
Balance at December 31, 2019	$ 88,811	$ 18,818	$ 11,013	$ 118,642
USWM Acquisition liabilities assumed	5,112	3,072	293	8,477
Provision				
Provision for sales in current year	347,139	13,144	67,775	428,058
Adjustments relating to prior year sales	2,913	10,738	134	13,785
Total provision	350,052	23,882	67,909	441,843
Less: Actual payments/credits	(347,386)	(16,169)	(67,811)	(431,366)
Balance at December 31, 2020	$ 96,589	$ 29,603	$ 11,404	$ 137,596

The total provision for sales deductions on gross product sales increased by $63.5 million, or approximately 16.8%, from $378.4 million in 2019 to $441.8 million in 2020. This increase was primarily attributable to the year over year increase in the provision for product rebates, from $306.5 million in 2019 to $350.1 million in 2020.

The year over year increase in the provision for product rebates of $43.5 million was primarily attributable to greater utilization of our patient co-pay programs and higher per patient payments under both Medicaid and commercial managed care programs.

The provision for product returns of $23.9 million in 2020 increased from $10.7 million in 2019. The increase is primarily due to unfavorable actual returns experienced in the first quarter of 2020 for discontinued Trokendi XR commercial blister pack configurations, for which all production and distribution ceased in 2017.

The provision for sales discounts increased by $6.8 million, from $61.1 million in 2019 to $67.9 million in 2020. The increase is due to impact of price increase.

Adjustments related to prior year sales were $13.8 million, which included the $10.7 million aforementioned adjustment for discontinued Trokendi XR configuration, against $509.4 million of net product sales in 2020 and $0.4 million against $383.4 million of net product sales in 2019.

Royalty Revenue

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

	2020	2019	Change Amount	Change Percent
Mydayis [1]	$ 2,504	$ 2,428	$ 76	3%
Orenitram [2]	8,543	6,927	1,616	23%
Total	$ 11,047	$ 9,355	$ 1,692	18%

[1] Royalty from net product sales of Mydayis, a product of Takeda Pharmaceuticals Company Ltd.

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

Royalty revenue increased by approximately $1.7 million, or 18%, in 2020 compared to 2019, primarily due to increased product sales of Orenitram.

Cost of Goods Sold

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

	2020	2019	Change Amount	Change Percent
Cost of goods sold	$ 52,459	$ 16,660	$ 35,799	215%

Cost of goods sold includes the cost of royalties; cost of materials, including active pharmaceutical ingredients (API); and cost to manufacture, including tableting, packaging, personnel, overhead, stability testing, and distribution. Cost of good sold increased by $35.8 million to $52.5 million in 2020 as compared to 2019. The increase was primarily attributable to the inclusion of the cost of goods sold of the acquired products from the USWM Acquisition. Royalty payments associated with APOKYN and XADAGO made up the majority of this cost increase. Inventory and cost of goods sold associated with the acquired inventory balances for USWM Acquisition products were subject to a purchase accounting step-up in fair market value. Refer to Part II, Item 8—*Financial Statements and Supplementary Data*, Note 3, *USWM Acquisition*, in the Notes to the Consolidated Financial Statements for further discussion of the USWM Acquisition.

Research and Development Expenses

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

	2020	2019	Change Amount	Change Percent
Direct Project Costs [1]				
SPN-812	$ 22,192	$ 31,375	$ (9,183)	(29)%
SPN-830	1,168	—	1,168	**
SPN-820 [3]	7,812	—	7,812	**
SPN-810 [2]	3,030	10,237	(7,207)	(70)%
Others	7,537	4,664	2,873	62%
	41,739	46,276	(4,537)	(10)%
Upfront License Payments [3]	10,000	—	10,000	**
Indirect Project Costs [1]				
Stock-based compensation	2,431	2,599	(168)	(6)%
Other indirect overhead	21,791	20,224	1,567	8%
	24,222	22,823	1,399	6%
Research and development expense	$ 75,961	$ 69,099	$ 6,862	10%

[1] Direct costs, which include personnel costs and related benefits, are recorded on a project-by-project basis. Many of our R&D costs are not attributable to any individual project because we share resources across several development projects. Indirect costs that support a number of our R&D activities are recorded in the aggregate, including stock-based compensation.

[2] R&D program terminated in 2020.

[3] On April 21, 2020, we entered into a Development and Option Agreement (Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor). Under the terms of the Development Agreement, the Company and Navitor will jointly conduct a Phase II clinical program for NV-5138 (SPN-820) in treatment-resistant depression (TRD).

R&D expenses increased by $6.9 million in 2020 as compared to 2019. This increase consists of a $10 million option fee paid in conjunction with the Navitor collaboration for SPN-820, a reduction of direct project costs of $4.5 million, and an increase in indirect project costs of $1.4 million.

Selling, General, and Administrative Expense

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

	2020	2019	Change Amount	Change Percent
Selling and marketing expense	$ 134,753	$ 109,982	$ 24,771	23%
General and administrative expense	65,924	43,264	22,660	52%
Total	$ 200,677	$ 153,246	$ 47,431	31%

Selling and Marketing Expense

Selling and marketing expenses increased by $24.8 million in 2020 compared to the same period in 2019. The increase was primarily attributable to increased marketing expenses and professional consulting spend related to the commercial products, including the acquired commercial products from the USWM Acquisition and preparations for the launch of SPN-812.

General and Administrative Expense

General and administrative expenses increased by $22.7 million in 2020, compared to the same period in 2019. The change was primarily due to an increase in business development expenses, including $12.5 million of acquisition-related transaction cost and post-acquisition integration costs.

Amortization of Intangible Assets

The following table provides information regarding the amortization expense for intangible assets during the periods indicated (dollars in thousands):

			Change	
	2020	2019	Amount	Percent
Amortization of intangible assets	$ 15,702	$ 5,179	$ 10,523	203%

Amortization of intangible assets increased for the year ended December 31, 2020, primarily due to the amortization of the definite-lived intangible assets acquired in the USWM Acquisition.

Contingent Consideration Expense

The following table provides information regarding the contingent consideration expense during the periods indicated (dollars in thousands):

			Change	
	2020	2019	Amount	Percent
Contingent consideration expense	$ 1,900	$ —	$ 1,900	**

Contingent consideration expense recorded for the year ended December 31, 2020 of $1.9 million reflects the periodic fair value remeasurement of the contingent milestones payable to USWM in connection with the closing of the USWM Acquisition in June 2020. The expense recognized in 2020 is from the increase in the fair value of the contingent consideration liabilities, which was primarily due to the changes made in the assumptions on the expected timing of the achievement of milestones and changes to the estimate of projected revenues that did not qualify as measurement period adjustments.

During 2020, the Company recorded a measurement period adjustment of $40.9 million, which was recorded against goodwill and therefore did not have an impact on the results of operations in 2020. These measurement period adjustments were based on new information obtained by the Company regarding the facts and circumstances that existed as of the Closing Date of June 9, 2020. Refer to Note 3, *USWM Acquisition* in Item 8—*Financial Statements and Supplementary Data* in this report.

Other (Expense) Income

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

			Change	
	2020	2019	Amount	Percent
Interest and other income, net	$ 18,704	$ 21,623	$ (2,919)	(13)%
Interest expense	(19,435)	(18,207)	(1,228)	7%
Interest expense on nonrecourse liability related to sale of future royalties	(4,319)	(4,500)	181	(4)%
Total	$ (5,050)	$ (1,084)	$ (3,966)	366%

Interest income includes primarily interest earned from cash, cash equivalents, and marketable securities holdings of $16.0 million and $21.3 million for the years ended December 31, 2020, and 2019, respectively. The year over year decrease in interest income, $2.9 million, was primarily due to decreased marketable securities holdings, mainly resulting from cash outlays for transaction related costs pertaining to the USWM Acquisition purchase price consideration plus the investment in Navitor and option fee paid to Navitor related to the NV-5138 (SPN-820) program license agreement.

Both the interest expense related to the 2023 Notes issued in March 2018 and noncash interest expense related to our nonrecourse royalty liability generally remained unchanged from 2019 to 2020.

Income Tax Expense

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

			2020 vs 2019 Change	
	2020	2019	Dollar	Percent
Income tax expense	$ 41,698	$ 34,431	$ 7,267	21%
Effective tax rate	24.7 %	23.3 %		

The increase in our income tax expense was primarily due to year over year increase in earnings. The increase in the effective tax rate is primarily due to the favorable impact to the 2019 effective tax rate of a decrease in our uncertain tax position reserve because of the expiring statute of limitations.

Net Earnings

The following table provides information regarding our net earnings during the periods indicated (dollars in thousands):

			Change	
	2020	2019	Amount	Percent
Net earnings	$ 126,950	$ 113,056	$ 13,894	12%

The increase in net earnings was primarily due to increased net product sales generated from our commercial products, offset by period over period increased operating expenses, including transaction costs related to the USWM Acquisition.

Liquidity and Capital Resources

We have financed our operations primarily with cash generated from product sales, supplemented by revenues from royalty and licensing arrangements, as well as proceeds from the sale of equity and debt securities. Continued cash generation is highly dependent on the success of our commercial products, Trokendi XR, Oxtellar XR, APOKYN, MYOBLOC, and XADAGO, as well as the success of our product candidates if approved by the U.S. Food and Drug Administration (FDA).

While we expect continued profitability in future years, we anticipate there may be significant variability from year to year in the level of our profits, particularly as we move forward with the anticipated commercial launch of SPN-812, assuming FDA approval, and the likely unfavorable impact of the upcoming loss of patent exclusivity for Trokendi XR in January 2023.

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

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

Financial Condition

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

			2020 vs 2019 Change	
	2020	2019	Dollar	Percent
Cash and cash equivalents	$ 288,640	$ 181,381	$ 107,259	59%
Marketable securities	133,893	165,692	(31,799)	(19)%
Long term marketable securities	350,359	591,773	(241,414)	(41)%
Total	$ 772,892	$ 938,846	$ (165,954)	(18)%
Working capital	$ 385,309	$ 312,057	$ 73,252	23%
Convertible notes, net (2023 Notes)	$ 361,751	$ 345,170	$ 16,581	5%
Total stockholder's equity	$ 744,858	$ 595,428	$ 149,430	25%

Total cash and cash equivalents, marketable securities, and long term marketable securities decreased in 2020 by $166.0 million to $772.9 million in 2020 compared to 2019. Transaction related uses of capital equaled $331.9 million, consisting of $298.5 million USWM Acquisition purchase price consideration, $8.4 million acquisition-related transaction costs, $15 million investment in Navitor and $10 million option fee paid to Navitor related to the NV-5138 (SPN-820) program license agreement. Net cash generated from operations of $138.4 million and net proceeds from the sale and maturity of marketable securities sales offset the transaction related outlays in 2020.

Working capital increased in 2020 as compared to 2019 by $73.3 million, primarily driven by increased operating earnings, reduced by incremental cash absorbed by operations in 2020.

As of December 31, 2020, the outstanding principal on the 0.625% Convertible Senior Notes due 2023 (2023 Notes) was $402.5 million. No 2023 Notes were converted as of December 31, 2020. Contemporaneous with the issuance of the 2023 Notes, the Company also entered into separate convertible note hedge transactions (collectively, the Convertible Note Hedge Transactions), issuing 402,500 convertible note hedge options. The Convertible Note Hedge Transactions are expected to reduce the potential dilution of the Company's common stock upon conversion of the 2023 Notes. Concurrently with entering into the Convertible Note Hedge Transactions, the Company also entered into separate warrant transactions, issuing a total of 6,783,939 warrants (the Warrant Transactions). See Note 9, *Convertible Senior Notes Due 2023* in the Notes to the Consolidated Financial Statements for further discussion of the 2023 Notes and our other indebtedness.

Stockholders' equity increased in 2020 as compared to 2019 by $149.4 million, primarily due to net earnings of $127.0 million, issuance of common stock of $4.4 million, and share-based compensation of $16.6 million.

Summary of Cash Flows

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

	December 31,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ 138,399	$ 143,129
Investing activities	(34,699)	(157,924)
Financing activities	3,559	3,928
Net change in cash and cash equivalents	$ 107,259	$ (10,867)

Operating Activities

Net cash provided by operating activities is comprised of two components: cash provided by operating earnings; and cash provided by (used in) changes in working capital. The net cash provided by operating activities, $138.4 million, was primarily driven by increased operating earnings, reduced by incremental cash absorbed by increased working capital.

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

The changes in cashflows related to operating assets and liabilities are as follows (dollars in thousands):

	Years Ended December 31,		
	2020	2019	Explanation of Change
(Increase) Decrease in:			
Accounts receivable	$ (34,607)	$ 15,751	Receivables increased in 2020 due to increased prescription unit volume and pricing and the timing of receivable collections. Receivables decreased in 2019 due to a sequential decline in prescription volume, amplified by channel inventory reduction in the first quarter of 2019.
Inventories	(10,124)	(969)	Inventory increase in 2020 due to capitalization of pre-launch inventory, offset by the timing of manufacturing campaigns. Inventory increase in 2019 due to timing of manufacturing campaigns.
Prepaid expenses and other assets	(10,442)	(2,864)	The increase in 2020 was primarily due to the timing of income tax payments. The increase in 2019 was due to timing differences related to deposits for equipment purchases and prepaid clinical trial costs.
Increase (Decrease) in:			
Accounts payable and other liabilities	8,272	(11,683)	The change in both periods was due to the timing of receipt of vendor invoices, vendor payments and timing of income tax payments.
Accrued product returns and rebates	10,386	566	The increase in both periods was due to: greater utilization of the patient co-pay programs, as well as higher per patient payments under both Medicaid and commercial managed care programs; and higher provision for returns.
Total	$ (36,515)	$ 801	

Investing Activities

Net cash used in investing activities decreased by $123.2 million, for the year ended December 31, 2020, from $157.9 million in 2019 to $34.7 million in 2020. The change in 2020 primarily reflects the sale of marketable securities of $378.4 million in 2020, offset by outlays for the USWM Acquisition of $298.5 million, the equity investment in Navitor of $15.0 million and the purchase of marketable securities of $95.9 million. Purchases of marketable securities of $409.7 million in 2019 resulted from investment of excess cash in long-term marketable securities.

Financing Activities

Net cash provided by financing activities decreased to $3.6 million for the year ended December 31, 2020 from $3.9 million provided in the same period in 2019. This year over year change is primarily attributable to cash outflows from finance lease activity partially offset by the increase in proceeds from the issuance of common stock

Contractual Obligations and Commitments

The following table summarizes our non-cancellable long-term contractual obligations and commitments as of December 31, 2020, except as noted below (dollars in thousands):

Contractual Obligations	FY2021	FY2022	FY2023	FY2024	FY2025	Thereafter	Total
2023 Convertible Notes	$ —	$ —	$ 402,500	$ —	$ —	$ —	$ 402,500
Interest on 2023 Convertible Notes (1)	2,516	2,516	629	—	—	—	5,661
Operating Leases (2)	5,066	4,474	2,701	2,587	2,638	24,145	41,611
Finance Lease (3)	3,946	3,665	3,665	3,665	3,665	7,329	25,935
XADAGO Annual Promotional Spend (3)	1,673	2,000	—	—	—	—	3,673
Total (4)	$ 13,201	$ 12,655	$ 409,495	$ 6,252	$ 6,303	$ 31,474	$ 479,380

(1) Relates to the 2023 Notes (see Note 6, *Convertible Senior Notes due 2023*, 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 fleet vehicles and the lease of the current headquarters office and laboratory space, as of December 31, 2020.

(3) As part of the USWM Acquisition, the Company assumed the remaining commitments of USWM Enterprises and its subsidiaries. Under the contract manufacturing agreement with Merz for the manufacture and supply of MYOBLOC, NeuroBloc and NerBloc (finished products), the Company has an annual minimum purchase quantity requirement of finished products amounting to an estimated €3.0 million. In addition, the existing license and distribution agreement for XADAGO requires an annual minimum promotional spend to support the marketing of XADAGO for the first five years of the agreement. As of December 31, 2020, the remaining contractual obligation is $3.7 million for the period from June 2021 to July 2022. (See Note 3, *USWM Acquisition*, for further discussion on the USWM Acquisition and Note 10, *Leases*, for further discussion on the finance lease related to the Merz Agreement, in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report).

(4) This table does not include the following:

- contingent consideration milestones payable related to the USWM Acquisition. (See Note 3, *USWM Acquisition*, in the Notes to Consolidated Financial Statements in Part II, Item 8 of this report for further discussion on the USWM Acquisition).
- any milestone payments which may become payable to third parties under license agreements or contractual agreements regarding our clinical trials, or those which may become payable upon achieving sales and developmental milestones per contractual agreements, as the timing, and likelihood of such payments are not known.
- any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known.
- contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

- agreements related to product sales deduction liabilities for our commercial products.
- obligations from the Development Agreement with Navitor. In April 2020, the Company entered into the Development Agreement with Navitor. The Company can terminate the Development Agreement upon 30 days' notice. Under the terms of the Development Agreement, the Company and Navitor will jointly conduct a Phase II clinical program for NV-5138 (SPN-820) for treatment-resistant depression. The Company will bear all of Phase I and Phase II development costs incurred by either party, up to a maximum of $50 million. In addition, the Company will incur certain other research and development support costs.
- 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.
- nonrecourse liability as of December 31, 2020. 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 $18.7 million as of December 31, 2020, related to this obligation, it is a non-recourse liability for which we have no obligation to make any cash payments to HC Royalty under any circumstances. Accordingly, this obligation has no impact on our liquidity at any time, hence the non-recourse liability has not been included in the table above.

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

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

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

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

The primary objective of our investment activities is to preserve our capital to fund operations and to facilitate business development activities. We also seek to maximize income from our investments without assuming significant interest rate risk, liquidity risk, or risk of default by investing in investment grade securities with maturities of four years or less. Our exposure to market risk is confined to investments in cash, cash equivalents, marketable securities, and long term marketable securities. As of December 31, 2020, we had unrestricted cash, cash equivalents, marketable securities, and long term marketable securities of $772.9 million.

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

Our cash and cash equivalents consist primarily of cash held at banks and investments in highly liquid financial instruments with an original maturity of three months or less. Our marketable securities, which are reported at fair value, consist of investments in U.S. Treasury bills and notes; bank certificates of deposit; various U.S. governmental agency debt securities; corporate and municipal debt securities; and other fixed income securities. We place all investments with governmental, industrial, or financial institutions whose debt is rated as investment grade. We generally hold these securities to maturities of one to four years. Because of the relatively short period that we hold our investments and because we generally hold these securities to maturity, we do not believe that an increase in interest rates would have any significant impact on the realizable value of our investments. We do not have any currency or other derivative financial instruments other than outstanding warrants to purchase common stock and the convertible note hedges.

We may contract with clinical research organizations (CROs) and investigational sites globally. Currently, we have only one ongoing trial, for SPN-817, outside the U.S. We do not hedge our foreign currency exchange rate risk. Transactions denominated in currencies other than the U.S. dollar are recorded based on exchange rates at the time such transactions arise. As of December 31, 2020, and December 31, 2019, substantially all of our liabilities were denominated in the U.S. dollar.

Inflation generally affects us by increasing our cost of labor and the cost of services provided by our vendors. We do not believe that inflation and changing prices over the years ended December 31, 2020, and 2019 had a significant impact on our consolidated results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Supernus Pharmaceuticals, Inc.
Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Supernus Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020, 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 8, 2021 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matters

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

Accrued sales deductions related to product returns

As disclosed in Notes 2 and 17 to the consolidated financial statements, the Company recorded accrued product returns of $29,603 (dollars in thousands) as of December 31, 2020. The related provision for product returns is reflected as a reduction of gross product sales, and is recorded at the time of sale when the customer takes title to the product. Sale of the Company's products are not subject to a general right of return; however, the Company will accept return of expired product six months prior to and up to 12 months subsequent to the product's expiry date. The Company's products have a shelf life of up to 48 months from date of manufacture.

We identified the evaluation of accrued sales deductions related to Trokendi XR and Oxtellar XR product returns, and specifically the assessment of the expected long-term return rates, as a critical audit matter. The assessment of the expected long-term return rates included a comparison to actual returns experience and involved a high degree of auditor judgment due to the significant passage of time between product sale and the time at which the Company issues credit for expired product.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the accrued sales deductions process. This included a control over the expected long-term return rate assumptions used in estimating the accrued product returns. We assessed the Company's long-term return rate assumptions by evaluating the consistency of those assumptions with the trend of actual historical return rates. We compared prior period expected long-term return rate assumptions against actual return rates experience.

Fair value of IPR&D asset

As discussed in Note 3 to the consolidated financial statements, the Company recorded $123,000 (dollars in thousands) for an acquired in process research and development intangible (IPR&D) asset as a result of the acquisition of US WorldMeds Partners, LLC on June 9, 2020. The acquired IPR&D asset is related to the infusion pump product candidate used in the treatment of Parkinson's patients, for which the Company determined the estimated fair value using an income approach. The fair value of the IPR&D asset is based on the projected cash flows from the infusion pump, which include estimates of revenues, expenses, and operating profit, and risks related to the viability of and commercial potential for alternative treatments. The projected cash flows were discounted at a rate commensurate with their associated level of risk.

We identified the evaluation of the fair value of the IPR&D asset as a critical audit matter. Specifically, a high degree of auditor judgment was required to evaluate the timing and amount of projected revenues associated with the infusion pump.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls over the Company's IPR&D asset valuation process, including controls related to the assessment of the timing and amount of projected revenue associated with the infusion pump. We evaluated the Company's assumptions for the timing and amount of projected revenue from commercialization of the pump by comparing to relevant industry data and studies. We performed sensitivity analysis around the timing and amount of the projected revenue compared to industry data and studies.

/s/ KPMG LLP

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

Baltimore, Maryland
March 8, 2021

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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes (collectively, the consolidated financial statements), and our report dated March 8, 2021 expressed an unqualified opinion on those consolidated financial statements.

The Company acquired USWM Enterprises during 2020, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2020, USWM Enterprises' internal control over financial reporting associated with total assets of 8.8% (excluding the goodwill and other intangible assets, which are included within the scope of the assessment) and total revenues of 17.5% included in the consolidated financial statements of the Company as of and for the year ended December 31, 2020. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of USWM Enterprises.

Basis for Opinion

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ KPMG LLP

Baltimore, Maryland
March 8, 2021

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 288,640	$ 181,381
Marketable securities	133,893	165,692
Accounts receivable, net	140,877	87,332
Inventories, net	48,325	26,628
Prepaid expenses and other current assets	18,682	11,611
Total current assets	630,417	472,644
Long term marketable securities	350,359	591,773
Property and equipment, net	37,824	17,068
Intangible assets, net	364,342	24,840
Goodwill	77,911	—
Deferred income taxes	—	32,063
Other assets	43,249	21,894
Total assets	$ 1,504,102	$ 1,160,282
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 78,934	$ 49,714
Accrued product returns and rebates	126,192	107,629
Contingent consideration, current portion	30,900	—
Other current liabilities	9,082	3,244
Total current liabilities	245,108	160,587
Convertible notes, net	361,751	345,170
Contingent consideration, long term	45,800	—
Operating lease liabilities, long term	28,579	30,440
Deferred income tax liabilities	35,215	—
Other liabilities	42,791	28,657
Total liabilities	759,244	564,854
Stockholders' equity		
Common stock, $0.001 par value; 130,000,000 shares authorized; 52,868,482 and 52,533,348 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	53	53
Additional paid-in capital	409,332	388,410
Accumulated other comprehensive earnings, net of tax	8,975	7,417
Retained earnings	326,498	199,548
Total stockholders' equity	744,858	595,428
Total liabilities and stockholders' equity	$ 1,504,102	$ 1,160,282

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Earnings

(in thousands, except share and per share data)

	Years Ended December 31,		
	2020	2019	2018
Revenue			
Net product sales	$ 509,350	$ 383,400	$ 399,871
Royalty revenue	11,047	9,355	8,276
Licensing revenue	—	—	750
Total revenues	520,397	392,755	408,897
Costs and expenses			
Cost of goods sold [a]	52,459	16,660	15,356
Research and development	75,961	69,099	89,209
Selling, general and administrative	200,677	153,246	154,698
Amortization of intangible assets	15,702	5,179	5,190
Contingent consideration expense	1,900	—	—
Total costs and expenses	346,699	244,184	264,453
Operating earnings	173,698	148,571	144,444
Other (expense) income			
Interest expense	(23,754)	(22,707)	(18,111)
Interest and other income, net	18,704	21,623	13,843
Total other expense	(5,050)	(1,084)	(4,268)
Earnings before income taxes	168,648	147,487	140,176
Income tax expense	41,698	34,431	29,183
Net earnings	$ 126,950	$ 113,056	$ 110,993
Earnings per share			
Basic	$ 2.41	$ 2.16	$ 2.13
Diluted	$ 2.36	$ 2.10	$ 2.05
Weighted-average shares outstanding			
Basic	52,615,269	52,412,181	51,989,824
Diluted	53,689,743	53,816,754	54,098,872

[a] Excludes amortization of acquired intangible assets.

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Earnings

(in thousands)

	Years Ended December 31,		
	2020	2019	2018
Net earnings	$ 126,950	$ 113,056	$ 110,993
Other comprehensive earnings (loss):			
Unrealized gain (loss) on marketable securities, net of tax	1,558	10,575	(2,411)
Other comprehensive earnings (loss), net of tax	1,558	10,575	(2,411)
Comprehensive earnings	$ 128,508	$ 123,631	$ 108,582

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity

Years Ended December 31, 2018, 2019 and 2020

(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, 2017	51,314,850	$ 51	$ 294,999	$ (747)	$ (26,823)	$ 267,480
Cumulative effect of adoption of ASC 606	—	—	—	—	2,322	2,322
Balance, January 1, 2018	51,314,850	51	294,999	(747)	(24,501)	269,802
Share-based compensation	—	—	11,291	—	—	11,291
Issuance of common stock in connection with the Company's equity award plans	1,001,733	1	11,581	—	—	11,582
Equity issued on conversion of convertible notes	—	—	56,215	—	—	56,215
Purchase of convertible note hedges, net of tax	—	—	(70,137)	—	—	(70,137)
Issuance of warrants	—	—	65,688	—	—	65,688
Net earnings	—	—	—	—	110,993	110,993
Unrealized loss on marketable securities, net of tax	—	—	—	(2,411)	—	(2,411)
Balance, December 31, 2018	52,316,583	52	369,637	(3,158)	86,492	453,023
Share-based compensation	—	—	14,846	—	—	14,846
Issuance of common stock in connection with the Company's equity award plans	216,765	1	3,927	—	—	3,928
Net earnings	—	—	—	—	113,056	113,056
Unrealized gain on marketable securities, net of tax	—	—	—	10,575	—	10,575
Balance, December 31, 2019	52,533,348	53	388,410	7,417	199,548	595,428
Share-based compensation	—	—	16,561	—	—	16,561
Issuance of common stock in connection with the Company's equity award plans	335,134	—	4,361	—	—	4,361
Net earnings	—	—	—	—	126,950	126,950
Unrealized gain on marketable securities, net of tax	—	—	—	1,558	—	1,558
Balance, December 31, 2020	52,868,482	$ 53	$ 409,332	$ 8,975	$ 326,498	$ 744,858

See accompanying notes.

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities			
Net earnings	$ 126,950	$ 113,056	$ 110,993
Adjustments to reconcile net earnings to net cash provided by operating activities:			
Depreciation and amortization	18,141	6,659	7,063
Amortization of deferred financing costs and debt discount	16,581	15,708	11,848
Share-based compensation expense	16,561	14,846	11,291
Realized gains from sales of marketable securities	(4,352)	(301)	—
Amortization of premium/discount on marketable securities	(2,889)	(4,034)	(1,665)
Changes in fair value of contingent consideration	1,900	—	—
Other noncash adjustments, net	1,454	2,226	(1,643)
Deferred income tax (benefit) provision	568	(5,832)	(4,167)
Changes in operating assets and liabilities:			
Accounts receivable	(34,607)	15,751	(35,856)
Inventories	(10,124)	(969)	(9,355)
Prepaid expenses and other assets	(10,442)	(2,864)	(2,367)
Accrued product returns and rebates	10,386	566	38,720
Accounts payable and other liabilities	8,272	(11,683)	4,124
Net cash provided by operating activities	138,399	143,129	128,986
Cash flows from investing activities			
Sales and maturities of marketable securities	378,422	253,170	79,827
Acquisition of USWM, net of cash acquired	(298,541)	—	—
Purchases of marketable securities	(95,890)	(409,707)	(491,654)
Investment in Navitor Pharmaceuticals, Inc.	(15,000)	—	—
Purchases of property and equipment	(3,449)	(2,736)	(844)
Deferred legal fees	(241)	1,349	(809)
Net cash used in investing activities	(34,699)	(157,924)	(413,480)
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
Proceeds from issuance of common stock	4,361	3,928	11,582
Payments on finance lease liability	(802)	—	(92,897)
Net cash provided by financing activities	3,559	3,928	376,438
Net change in cash and cash equivalents	107,259	(10,867)	91,944
Cash and cash equivalents at beginning of year	181,381	192,248	100,304
Cash and cash equivalents at end of period	$ 288,640	$ 181,381	$ 192,248
Supplemental cash flow information:			
Cash paid for interest on convertible notes	$ 2,516	$ 2,516	$ 1,342
Cash paid for Biscayne acquisition	$ —	$ —	$ 15,000
Income taxes paid	$ 45,428	$ 51,540	$ 34,772
Noncash investing and financing activity:			
Contingent consideration liability related to USWM acquisition	$ 76,700	$ —	$ —
Deferred legal fees and fixed assets included in accounts payable and accrued expenses	$ 213	$ 1,832	$ 250
Property and equipment additions from utilization of tenant improvement allowance	$ —	$ 10,151	$ —

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

1. Organization and Business

Supernus Pharmaceuticals, Inc. (the Company) was incorporated in Delaware and commenced operations in 2005. The Company is a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company's diverse neuroscience portfolio includes approved treatments for epilepsy, migraine, hypomobility in Parkinson's Disease, cervical dystonia, and chronic sialorrhea. The Company is developing a broad range of novel CNS product candidates including new potential treatments for attention-deficit hyperactivity disorder (ADHD), hypomobility in Parkinson's disease, epilepsy, depression, and rare CNS disorders.

The Company has five commercial products: Trokendi XR, Oxtellar XR, APOKYN, XADAGO, and MYOBLOC. In addition, the Company has two late-stage development products included in its product candidates portfolio.

2020 USWM Acquisition and Navitor Development Agreements

On April 21, 2020, the Company entered into a Development and Option Agreement (Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor). Under the terms of the Development Agreement, the Company and Navitor will jointly conduct a Phase II clinical program for NV-5138 (SPN-820) in treatment-resistant depression (TRD). Refer to Note 12, *Investments in Unconsolidated VIEs*, for further discussion on the Navitor Development Agreement.

On April 28, 2020, the Company entered into a Sale and Purchase Agreement with US WorldMeds Partners, LLC to acquire the CNS portfolio of USWM Enterprises, LLC (USWM Enterprises) (USWM Acquisition). With the acquisition, completed on June 9, 2020, the Company added three established commercial products, APOKYN, XADAGO, and MYOBLOC, and a product candidate in late-stage development, SPN-830 (apomorphine infusion pump), to its portfolio. Refer to Note 3, *USWM Acquisition*, for further discussion on the USWM Acquisition.

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

Reclassifications

Certain prior year amounts in the consolidated balance sheets, statements of cashflows, and statements of earnings have been reclassified to conform to the current year presentation, including a reclassification made to present amortization of intangible assets separately. This was previously included in *Selling, general and administrative expenses* and now is recorded as a component of *Amortization of intangible assets* on the consolidated statements of earnings. These reclassifications did not affect operating earnings or other consolidated financial statements for the years ended December 31, 2020, 2019, and 2018.

Consolidation

The Company's consolidated financial statements include the accounts of: Supernus Pharmaceuticals, Inc.; Supernus Europe Ltd.; Biscayne Neurotherapeutics, Inc. and its wholly owned subsidiary; MDD US Enterprises, LLC (formerly USWM Enterprises, LLC) and its wholly owned subsidiaries. These are collectively referred to herein as "Supernus" or "the Company." All significant intercompany transactions and balances have been eliminated in consolidation.

2. Summary of Significant Accounting Policies (Continued)

The consolidated financial statements reflect the consolidation of entities in which the Company has a controlling financial interest. In determining whether there is a controlling financial interest, the Company considers if it has a majority of the voting interests of the entity, or if the entity is a variable interest entity (VIE) and if the Company is the primary beneficiary. In determining the primary beneficiary of a VIE, the Company evaluates whether it has both: the power to direct the activities of the VIE that most significantly impact the VIE's economic performance; and the obligation to absorb losses of, or the right to receive benefits from the VIE that could potentially be significant to that VIE. The Company's judgment with respect to its level of influence or control of an entity involves the consideration of various factors, including the form of an ownership interest; representation in the entity's governance; the size of the investment; estimates of future cash flows; the ability to participate in policymaking decisions; and the rights of the other investors to participate in the decision making process, including the right to liquidate the entity, if applicable. If the Company is not the primary beneficiary of the VIE, and an ownership interest is maintained in the entity, the interest is accounted for under the equity or cost methods of accounting, as appropriate.

The Company continuously assesses whether it is the primary beneficiary of a VIE as changes to existing relationships or future transactions may affect its conclusions.

Use of Estimates

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

The extent to which the COVID-19 pandemic may directly or indirectly impact our business, financial condition and results of operations is highly uncertain and subject to change. As a result, certain of our estimates and assumptions, including the provision for sales deductions, the creditworthiness of customers entering into revenue arrangements, the valuation of the assets and liabilities acquired in the USWM Acquisition, and the fair values of our financial instruments, require increased judgment and carry a higher degree of variability and volatility that could result in material changes to our estimates in future periods.

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; bank certificates of deposit; various U.S. government agency debt securities; corporate and municipal debt securities; and other fixed income securities. The Company places all investments with governmental, industrial, or financial institutions whose debt is rated as investment grade.

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

Any unrealized holding gains or losses on debt securities, including their tax effect, are reported as components of *Other comprehensive earnings (loss)* in the consolidated statement of comprehensive earnings. Realized gains and losses, included in *Interest and other income, net* in the consolidated statement of earnings, are determined using the specific identification method for determining the cost of securities sold.

The Company adopted Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)* on January 1, 2020, using the allowance approach. Declines in fair value below amortized cost related to credit losses (i.e., impairment due to credit losses) are included in the consolidated statement of earnings, with a corresponding allowance established. If the estimate of expected credit losses decreases in subsequent periods, the Company will reverse the credit losses through current period earnings and adjust the allowance accordingly. Refer to Recently Issued Accounting Pronouncements in this Note 2.

2. Summary of Significant Accounting Policies (Continued)

Business Combinations and Contingent Considerations

In determining whether an acquisition should be accounted for as a business combination or as an asset acquisition, the Company makes certain judgments regarding whether the acquired set of activities and assets meets the definition of a business. Significant judgment is required in assessing whether the acquired processes or activities, along with their inputs, would be substantive to constitute a business, as defined by U.S. GAAP.

If the acquired set of activities and assets does not meet the definition of a business, the transaction is accounted for as an asset acquisition. In an asset acquisition, any acquired research and development that does not have an alternative future use is charged to expense as of the acquisition date, and no goodwill is recorded.

If the acquired set of activities and assets meets the definition of a business, the Company applies the acquisition method of accounting and accounts for the transaction as a business combination. In a business combination, assets acquired and liabilities assumed are recorded at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets, if applicable, is recorded as goodwill. The Company accounted for the USWM Acquisition as a business combination.

In a business combination, the operating results of the acquired business are included in the Company’s consolidated statement of earnings, beginning on the effective acquisition date. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

Significant judgment is involved in the determination of the fair value assigned to assets acquired and liabilities assumed in a business combination, as well as the estimated useful lives of assets. These estimates can materially affect our consolidated results of operations and financial position. The fair value of intangible assets, including acquired in-process research and development (IPR&D), are determined using information available as of the acquisition date and are based on estimates and assumptions that are deemed reasonable by management. Significant estimates and assumptions include but are not limited to: the probability of regulatory approval, revenue growth, and appropriate discount rate. Depending on the facts and circumstances, the Company may deem it necessary to engage an independent valuation expert to assist in valuing significant assets and liabilities.

While the Company uses its best estimates and assumptions to accurately value assets acquired and liabilities assumed as of the acquisition date, estimates are inherently uncertain and subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, the Company may record adjustments to the assets acquired and liabilities assumed with the corresponding offset to goodwill.

Uncertain tax positions and tax-related valuation allowances are initially recorded in connection with a business combination as of the acquisition date. The Company continues to collect information related to facts and circumstances existing as of the acquisition date and evaluate these estimates and assumptions. The Company records any adjustments to the Company’s preliminary estimates to goodwill based on the facts and circumstances existing as of the acquisition date (measurement period adjustments).

Upon the conclusion of the measurement period, any subsequent adjustments are recorded to our consolidated statements of earnings in the period that these adjustments are identified.

Contingent Considerations

The USWM Acquisition involved potential future payments contingent upon the achievement of certain milestones primarily related to the development and commercial sale of the acquired IPR&D, SPN-830 (apomorphine infusion pump), including product development milestones and sales-based milestone payments on future product sales. The fair value of the contingent consideration liability is determined as of the acquisition date using estimated or forecast inputs. These inputs include the estimated amount and timing of projected revenues, probability and timing of milestone achievement, probability of IPR&D achieving regulatory approval, revenue volatility, and the estimated discount rates and risk-free rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period prior to the resolution of the contingency, the contingent consideration liability is remeasured at current fair value, with changes recorded in earnings in the period of remeasurement.

2. Summary of Significant Accounting Policies (Continued)

The determination of the initial and subsequent fair value of the contingent consideration liability requires significant judgment by management. Changes in any of the inputs not related to facts and circumstances existing as of the acquisition date may result in a significant fair value adjustment, which can impact the results of operations in the period in which the adjustment is made. Changes that are not measurement period adjustments are reported on the consolidated statement of earnings in *Contingent consideration expense*.

Additional information regarding the USWM Acquisition is included in Note 3, *USWM Acquisition*.

Accounts Receivable, Net

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

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

Concentration of Credit Risk

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

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

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

	Percentage of Net Product Sales			Percentage of Accounts Receivable, net	
	2020	2019	2018	2020	2019
Customer A	29 %	32 %	33 %	31 %	45 %
Customer B	31 %	32 %	33 %	32 %	21 %
Customer C	29 %	34 %	32 %	22 %	30 %
	89 %	98 %	98 %	85 %	96 %

Refer to Note 4, *Disaggregated Revenues*, for the concentration of net product sales.

Inventories

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

2. Summary of Significant Accounting Policies (Continued)

Inventories Produced in Preparation of Product Launches

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

In evaluating whether these conditions are met, the Company considers the following factors: the product candidate's current status in the regulatory approval process; results from the related pivotal and supportive clinical trials; results from meetings with relevant regulatory agencies prior to the filing of regulatory applications; completion of the regulatory applications; consequent acceptance by the regulatory agency; potential impediments to the approval process such as product safety or efficacy concerns, potential labeling restrictions, and other impediments: historical experience with manufacturing and commercializing similar products as well as the manufacture of the relevant product candidate; and the Company's manufacturing environment, and supply chain in determining logistical constraints that could hamper approval or commercialization.

In assessing the economic benefit that the Company is likely to realize, the Company considers the shelf life of the product in relation to the expected timeline for approval; patent related or contractual issues that may prevent or delay commercialization and product stability data of all pre-approval production to assess the adequacy of expected shelf life; viability of commercialization taking into account competitive dynamics in the marketplace and market acceptance; and anticipated future sales and anticipated reimbursement strategies that may prevail with respect to the product, to determine product profit margin.

In applying the lower of cost or net realizable value to pre-launch inventory, the Company estimates a range of likely commercial prices based on the pricing of competitive commercial products and pre-launch discussions with managed care providers.

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

Intangible Assets

Intangible assets consist of definite-lived intangible assets: acquired developed technology and product rights, and patent defense costs, and an indefinite-lived intangible asset: acquired IPR&D.

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

Definite-lived intangible assets are carried at cost less accumulated amortization, with amortization calculated on a straight line basis over the estimated useful lives of the assets. The Company evaluates the estimated remaining useful life of its intangible assets annually, or when events or changes in circumstances warrant a revision to the remaining periods of amortization.

Acquired IPR&D in a business combination is considered an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon successful completion of the project, the Company will determine as to the then-useful life of the intangible asset. This is generally determined as the period over which the substantial majority of the cash flows are expected to be generated. The capitalized amount is then amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. During the period prior to completion or abandonment, the IPR&D asset is not amortized but tested for impairment on an annual basis or when potential indicators of impairment are identified.

2. Summary of Significant Accounting Policies (Continued)

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment, operating and finance lease assets, and definite-lived intangible assets. The Company assesses the recoverability of its long-lived assets with definite lives 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 would be compared to the carrying value of the asset to determine whether the asset's value is recoverable. If impairment is determined, the Company writes down the asset to its estimated fair value and records an impairment loss equal to the excess of the carrying value of the long-lived asset over its estimated fair value in the period at which such a determination is made.

Impairment of Indefinite-Lived Intangible Assets

For indefinite-lived intangible assets, such as the acquired IPR&D asset, the Company evaluates impairment annually in the fourth quarter or more frequently if impairment indicators exist. The annual evaluation is generally based on an assessment of qualitative factors to determine whether it is more likely than not that the fair value of the asset is less than its carrying amount. The Company considers various factors including but is not limited to significant or adverse changes in the legal and regulatory environment, adverse clinical trial results, significant trial delays, inability to obtain governmental approval, inability to commercialize a product candidate the introduction or advancement of competitive products, and product candidates, or other events that indicate it is more likely than not that fair value is less than its carrying value. If the Company is unable to conclude whether the indefinite-lived intangible asset is not impaired after considering the totality of events and circumstances during its qualitative assessment, the Company performs a quantitative assessment by estimating the fair value of the indefinite-lived intangible asset and comparing the fair value to the carrying amount. If the carrying amount of the indefinite-lived intangible asset exceeds its fair value, the Company writes down the indefinite-lived intangible asset to its estimated fair value, and an impairment loss equal to the difference between the assets fair value and carrying value is recognized in the consolidated statement of earnings in the period at which such determination is made.

Evaluating for goodwill impairment requires judgment, including evaluating current economic and competitive circumstances, estimating future cash flows, future growth rates, future profitability, and the expected life over which projected cash flows would occur.

Goodwill and Goodwill Impairment Assessment

Goodwill is calculated as the excess of the consideration paid consequent to completing an acquisition compared to the net assets recognized in a business combination. Goodwill represents the future economic benefits from the other acquired assets that could not be individually identified and separately quantified.

The Company evaluates goodwill for possible impairment at least annually (during the fourth quarter of each fiscal year), or more often, if and when events and circumstances indicate that goodwill may be impaired. The annual evaluation is generally based on an assessment of qualitative factors to determine whether it is more likely than not that the fair value of the asset is less than its carrying amount. This includes but is not limited to significant adverse changes in the business climate, market conditions, or other events that indicate that it is more likely than not that the fair value of the reporting unit is less than its carrying value. If the Company is unable to conclude whether the goodwill is not impaired after considering the totality of events and circumstances during its qualitative assessment, the Company performs a quantitative assessment by estimating the fair value of the reporting unit and comparing the fair value to the carrying amount. If the carrying amount of the reporting unit exceeds its fair value, the Company writes down the goodwill to the estimated fair value, and an impairment loss equal to the difference is recognized in the consolidated statement of earnings in the period at which such determination is made.

Evaluating for impairment requires judgment, including identifying reporting units and estimating future cash flows. The Company estimates the fair values of its reporting unit using discounted cash flow models or other valuation models, such as comparative transactions or market multiples.

2. Summary of Significant Accounting Policies (Continued)

Interest Expense

Interest expense includes stated interest and the amortization of deferred financing costs and debt discount incurred by the Company in connection with the issuance of $402.5 million of 0.625% Convertible Senior Notes due 2023, (see Note 6). The Company amortizes the deferred financing costs and debt discount over the term of the debt, using the effective interest method.

Revenue Recognition

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

No contract assets or liabilities were recorded as of December 31, 2020, or 2019.

Revenue from Product Sales

The Company’s customers are primarily pharmaceutical wholesalers, specialty pharmacies, and pharmaceutical distributors. Customers purchase product to fulfill orders from retail pharmacy chains and independent pharmacies of varying size and purchasing power. The Company recognizes gross revenue when its products are shipped from a third party fulfillment center and physically received by its customers. The Company's customers take control of its products, including title and ownership, upon the physical receipt of its products at their facilities. Customer orders are generally fulfilled within a few days of order receipt, resulting in minimal order backlog. There are no minimum product purchase requirements with our customers.

The Company recognizes revenue from product sales in an amount that reflects the consideration the Company expects to ultimately receive in exchange for those goods. Product sales are recorded net of various forms of variable consideration, including: provision for estimated rebates; provision for estimated future product returns; and an estimated provision for discounts. These are collectively considered "sales deductions."

As described below, variability in the net transaction price for the Company’s products arises primarily from the aforementioned sales deductions. Significant judgment is required in estimating certain sales deductions. In making these estimates, the Company considers: historical experience; product price increases; current contractual arrangements under applicable payor programs; unbilled claims; processing time lags for claims; inventory levels in the wholesale, specialty pharmacy, and retail distribution channel; and product life cycle. The Company adjusts its estimates of revenue either when the most likely amount of consideration it expects to receive changes, or when the consideration becomes fixed.

Variable consideration on product sales is only recognized when it is probable that a significant reversal will not occur.

If actual results in the future vary from our estimates, the Company adjusts its estimates in the period identified. These adjustments could materially affect net product sales and earnings in the period in which the adjustment(s) is recorded.

Sales Deductions

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

Rebates:

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

Public sector rebate programs encompass: various Medicaid drug rebate programs; Medicare gap coverage programs; programs covering public health service institutions; and programs covering government entities. All federal employees and agencies purchase drugs under the Federal Supply Schedule.

2. Summary of Significant Accounting Policies (Continued)

Private sector rebate programs include: contractual agreements with managed care providers, under which the Company pays fees to gain access to that provider's patient drug formulary; and Company-sponsored programs, under which the Company defrays or eliminates patient co-payment charges that the patient would otherwise be obligated to pay to their managed care provider in order to fill their prescription.

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

The Company's estimates of expected rebate claims vary by program and by type of customer because the period between the date at which the prescription is filled and the date the Company receives and pays the invoice varies substantially. For each of its products, the Company bases its estimates of expected rebate claims on multiple factors, including: historical levels of deductions; contractual terms with managed care providers; actual and anticipated changes in product price; prospective changes in managed care fee for service contracts; prospective changes in co-payment assistance programs; and anticipated changes in program utilization rates; i.e., patient participation rates under each specific program.

The Company records an estimated liability for rebates at the time the customer takes title to the product (i.e., at the time of sale to wholesalers/distributors). This liability is recorded as a reduction to gross product sales, and an increase in *Accrued product returns and rebates.* The liability is recorded as a component of current liabilities on the consolidated balance sheets.

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

Returns:

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

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

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

Because the Company's products have a shelf life up to 48 months from the date of manufacture, and because the Company accepts return of product up to 12 months post its expiry date, there is a time lag of several years between the time when the product is sold and the time when the Company issues credit on the expired product.

The Company's returns policy generally permits product returns to be processed at the current wholesaler price rather than at historical acquisition price; hence, the Company's estimated liability for product returns is affected by price increases taken subsequent to the date of sale and prior to its return.

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

2. Summary of Significant Accounting Policies (Continued)

Sales discounts:

Distributors and wholesalers of the Company's pharmaceutical products are generally offered various forms of consideration, including allowances, service fees and prompt payment discounts, for distributing our products. Distributor and wholesaler allowances and service fees arise from contractual agreements and are estimated as a percentage of the price at which the Company sells product to them. In addition, distributors and wholesalers are offered a prompt pay discount for payment within a specified period. Prompt pay discounts are estimated as a percentage of the price at which the Company sells product.

The Company accounts for these discounts at the time of sale as a reduction to gross product sales.

License Revenue

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

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

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

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

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

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

Royalty Revenue

The Company recognizes noncash royalty revenue for amounts earned pursuant to its royalty agreement with United Therapeutics Corporation (United Therapeutics), based on estimated product sales of Orenitram by United Therapeutics (see Note 4). This agreement includes the right to use the Company’s intellectual property as a functional license.

In 2014, the Company sold certain of these royalty rights to Healthcare Royalty Partners III, L.P. (HC Royalty) (see Note 21). Consequent to this agreement, the Company recorded a nonrecourse liability related to this transaction and amortizes this liability as noncash royalty revenue. Sales of Orenitram by United Therapeutics result in payments from United Therapeutics to HC Royalty, in accordance with this agreement.

The Company also recognizes noncash interest expense related to the nonrecourse liability and accrues interest expense at an estimated effective interest rate (see Note 19). This interest rate is determined based on projections of HC Royalty’s rate of return.

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

2. Summary of Significant Accounting Policies (Continued)

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

Cost of Goods Sold

The cost of goods sold consists primarily of materials; third-party manufacturing costs; freight and distribution costs; direct labor; cost of royalties; cost to write down inventory to net realizable value and manufacturing overhead costs, including quality control and assurance.

Research and Development Expenses

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

The Company estimates preclinical and clinical trial expenses based on services performed pursuant to contracts with research institutions, clinical investigators, clinical research organizations (CROs), and other service providers that perform services on the Company's behalf. In recording service fees, the Company estimates the cost of those services performed on behalf of the Company during the current period and compares those costs with the cumulative expenses recorded and payments made for such services. As appropriate, the Company accrues additional expense for services that have been delivered or defers nonrefundable advance payments until the related services are performed.

If the actual timing of the performance of services or the level of effort varies from our estimate, the Company adjusts its accrued expenses, or its deferred advance payments, accordingly. If the Company subsequently determines that it no longer expects the services associated with a nonrefundable advance payment to be rendered, the remaining portion of that advance payment is charged to expense in the period in which such determination is made.

Share-Based Compensation

Stock Options

The Company recognizes share-based compensation expense over the service period, using the straight-line method. Employee share-based compensation for stock options is determined using the Black-Scholes option-pricing model to compute the fair value of option grants as of their grant date. Forfeitures are accounted for as incurred. The Company uses the following assumptions for estimating the fair value of option grants:

- *Fair Value of Common Stock*—The fair value of the common stock underlying the option grants is determined based on observable market prices of the Company's common stock.
- *Expected Volatility*—Volatility is a measure of the amount by which the Company's share price has historically fluctuated or is expected to fluctuate on a daily basis and is expected to fluctuate (i.e., expected volatility) in the future.
- *Dividend Yield*—The Company has never declared or paid dividends and has no plans to do so in the foreseeable future. Dividend yield is therefore zero.
- *Expected Term*—This is the period of time during which options are expected to remain unexercised. For the years ended December 31, 2020, and 2019, we determined the expected term based on the historical exercise behavior of the stock option plan participants. Options have a maximum contractual term of ten years.
- *Risk-Free Interest Rate*—This is the observed U.S. Treasury Note rate as of the week each option grant is issued, with a term that most closely resembles the expected term of the option.

2. Summary of Significant Accounting Policies (Continued)

Restricted Stock Units (RSUs)

Share-based compensation expense is recorded based on amortizing the fair market value of the RSU as of the date of the grant over the implied service period. RSUs generally vest one year from the date of the grant and are subject to continued service requirements. Forfeitures are accounted for as incurred.

Performance Stock Units (PSUs)

Performance-Based Awards

Share-based compensation expense for performance-based awards is recognized based on amortizing the fair market value of the award as of the grant date over the periods during which the achievement of the performance target is probable. Performance-based awards require certain performance targets to be achieved in order for the award to vest. Vesting occurs on the date of achievement of the performance target. Forfeitures are accounted for as incurred.

Market-Based Awards

Share-based compensation expense for market-based awards is recognized on a straight-line basis over the requisite service period, regardless of whether the market condition has been satisfied. Market-based PSU awards vest upon the achievement of the performance target. Forfeitures are accounted for as incurred.

The Company estimates the fair value of these awards as of the grant date using a Monte Carlo simulation that incorporates option-pricing inputs. This simulation covers the period from the grant date through the end of the derived requisite service period. Volatility as of the grant date is estimated based on historical daily volatility of the Company's common stock over a period of time, which is equivalent to the expected term of the award. The risk-free interest rate is based on the U.S. Treasury Note rate, as of the week, the award is issued, with a duration that most closely resembles the expected term of the award.

Leases

On January 1, 2019, the Company adopted Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842) (New Lease Standard) using the modified retrospective transition approach. We applied the new standard to all leases existing at the date of initial application. Refer to the discussion under *Recently Issued Accounting Pronouncements* in Note 2.

The Company determines if an arrangement is a lease considering whether there is an identified asset and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Right-of-use (ROU) assets and lease liabilities are recognized at the commencement date based on the present value of remaining lease payments over the lease term. For this purpose, the Company considers only payments that are fixed and determinable at the time of commencement. The Company calculates the present value of future payments by using an estimated incremental borrowing rate, which approximates the rate at which the Company would borrow, on a secured basis and over a similar term. This rate is estimated based on information available at the commencement date of the lease and may differ for individual leases or portfolios of leased assets. Additionally, for certain equipment leases, the Company applies a portfolio approach to effectively account for the operating lease ROU assets and lease liabilities.

Lease expense for operating leases is recognized on a straight-line basis over the expected lease term and recognized as an operating cost. The finance lease asset related to a manufacturing facility is amortized on a straight-line basis over the lease term. Interest expense on finance lease liability is also recognized over the lease term.

Some of the Company’s leases include options to terminate prior to the end of the lease term or to extend the lease for one or more years. These options are included in the lease term when it is reasonably certain that the option will be exercised.

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

2. Summary of Significant Accounting Policies (Continued)

Advertising Expense

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

The Company incurred approximately $54.5 million, $40.8 million, and $43.3 million in advertising expense for the years ended December 31, 2020, 2019, and 2018, respectively. These expenses are recorded as a component of *Selling, general and administrative expenses* in the consolidated statements of earnings.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and deferred tax liabilities are determined based on differences between their financial reporting and tax reporting bases. These differences 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 are initially and subsequently estimated as the largest amount of the tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authorities. These estimates are based on 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

ASU 2016-02, *Leases (Topic 842)* and subsequently issued related amendments codified in ASC 842, *Leases*, (the New Lease Standard), effective January 1, 2019, requires lessees to recognize lease assets and lease liabilities for those leases classified as operating leases under the previous GAAP, ASC 840, on the balance sheet and provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements.

The Company adopted the New Lease Standard using the modified retrospective transition approach on January 1, 2019, by applying the New Lease Standard to all leases existing at the date of the initial adoption and not restating comparative periods. The adoption of the New Lease Standard resulted in recognition of lease assets and lease liabilities as of January 1, 2019, of approximately $4.0 million. The Company elected the package of practical expedients permitted under the transition guidance, which, among other things, allowed the Company to carryforward the historical lease classification, the assessment on whether a contract was or contains a lease, and the initial direct costs for any leases that existed prior to January 1, 2019. Refer to Note 10, *Leases*.

2. Summary of Significant Accounting Policies (Continued)

ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)* - The new standard, issued in July 2016, requires credit losses on financial assets to be measured as the net amount expected to be collected, rather than based on actual incurred losses. For available-for-sale debt securities, the new standard did not revise the definition of impairment. The new standard also eliminated the concept of "other than temporary" from the impairment model for available-for-sale debt securities. Changes to the impairment model include recognition of credit losses on available-for-sale debt securities using the allowance method and limiting the allowance to the amount by which fair value is below amortized cost. The Company adopted the new standard effective January 1, 2020, using the modified retrospective approach. The adoption of the standard did not have a material impact on its consolidated financial statements.

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

ASU 2018-15, Intangibles - Goodwill and Other - *Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* - The new standard, issued in August 2018, aligns the requirements for capitalizing implementation costs incurred under a service contract for a hosting arrangement with the requirements for capitalizing implementation costs incurred to develop or to obtain internal-use software. This includes hosting arrangements that include an internal-use software license. This ASU also requires that the implementation costs of a hosting arrangement under a service contract be expensed over the term of the hosting arrangement, including reasonably certain renewals. The Company adopted the new standard effective January 1, 2020, using the prospective transition approach. The adoption of the standard did not have a material impact on its consolidated financial statements.

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

New Accounting Pronouncements Not Yet Adopted

ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* - The new standard, issued in December 2019, simplifies the accounting for income taxes. This guidance will be effective on January 1, 2021, on a prospective basis, with early adoption permitted. ASU 2019-12 amends the requirements related to the accounting for “hybrid” tax regimes. Such regimes are tax jurisdictions that impose the greater of two taxes — one based on income or one based on items other than income. Under ASU 2019-02, an entity should include the amount of tax based on income in the tax provision and should record any incremental amount recorded as a tax not based on income. The Company will adopt the standard effective January 1, 2021. It is not expected to have a material effect on our consolidated financial statements.

ASU 2020-01, *Investments — Equity Securities (Topic 321), Investments — Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815), Clarifying the Interactions between Topic 321, Topic 323, and Topic 815* - The new standard, issued in January 2020, clarifies the interaction of the equity securities under Topic 321 and investments accounted for under the equity method of accounting in Topic 323 and the accounting for certain contracts and purchased options accounted under Topic 815. The amendment clarifies that an entity can elect to adopt the measurement alternative, which is if an entity identifies observable price changes in orderly transactions for the identical or a similar investment of the same issuer, it should measure the equity security at fair value as of the date that the observable transaction occurred before applying or upon discontinuing the equity method. ASU 2020-01 will be effective on January 1, 2021. The Company will adopt the standard effective January 1, 2021. It is not expected to have a material effect on our consolidated financial statements.

ASU 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* - The new standard, issued in August 2020, simplifies the accounting and disclosures for convertible instruments and contracts. Under ASU 2020-06, entities must apply the if-converted method to all convertible instruments; the treasury stock method is no longer available. This guidance will be effective on January 1, 2022, on a prospective basis, with early adoption

2. Summary of Significant Accounting Policies (Continued)

permitted but not earlier than January 1, 2021. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements.

3. USWM Acquisition

On June 9, 2020 (the Closing Date), the Company completed its acquisition of all of the outstanding equity of USWM Enterprises, LLC (USWM Enterprises), a privately-held biopharmaceutical company, pursuant to the Sale and Purchase Agreement with US WorldMeds Partners, LLC (Seller), dated April 28, 2020 (the Agreement). Under the terms of the Agreement, the Company acquired the right to further develop and commercialize APOKYN, XADAGO, and the Apomorphine Infusion Pump (SPN-830) in the U.S., and MYOBLOC worldwide (the Products) for an upfront cash payment of $297.2 million, subject to working capital adjustments, and the potential for additional contingent consideration payments of up to $230 million.

The potential $230 million in contingent consideration payments includes up to $130 million for the achievement of certain SPN-830 regulatory and commercial activities (regulatory and developmental contingent consideration payments) and up to $100 million related to future sales performance of the Products (sales-based contingent consideration payments). The regulatory and developmental contingent consideration payments include a $25 million milestone due upon the U.S. Food and Drug Administration's (FDA) acceptance of the SPN-830 New Drug Application (NDA) for review. The remaining $105 million of the $130 million contingent consideration payments include payments upon the FDA's regulatory approval and commercial launch of SPN-830. One of the regulatory milestones has a time-based mechanism for full or partial achievement. The $100 million sales-based contingent consideration payments include a $35 million milestone due upon achievement of certain U.S. net product sales of APOKYN during 2021. The remaining $65 million of the $100 million sales-based contingent consideration payments relate to the achievement of certain net product sales of the Products in 2022 and 2023.

The acquisition is being accounted for as a business combination under the acquisition method of accounting, in accordance with ASC 805, *Business Combinations*. The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill. The estimated fair values of the assets acquired and liabilities assumed, including goodwill, have been included in the Company's consolidated financial statements since the acquisition's Closing Date.

The Company's accounting for this acquisition is preliminary and fair value estimates for the assets acquired and liabilities assumed and the Company's estimates and assumptions are subject to change as the Company obtains additional information for its estimates during the measurement period. During the measurement period, if the Company obtains new information regarding facts and circumstances that existed as of the Closing Date that, if known, would have resulted in revised estimated values of those assets or liabilities, the Company will accordingly revise its estimates of fair values and purchase price allocation. The effect of measurement period adjustments on the estimated fair value elements will be reflected as if the adjustments had been made as of the Closing Date. The impact of all changes that do not qualify as measurement period adjustments will be included in current period earnings.

The Company expects to finalize its purchase price allocation within one year of the Closing Date. The Company continues to analyze and assess relevant information necessary to determine, recognize and record at fair value the assets acquired and liabilities assumed. Examples of areas that rely on preliminary estimates subject to measurement period adjustments include intangibles, lease asset and liability and deferred income tax assets and liabilities. The Company is in the process of obtaining additional market research that may inform the fair value of the acquired intangible assets and additional analysis that may be informative in the determination of the fair value of lease asset and other information. Accordingly, the preliminary recognition and measurement of assets acquired and liabilities assumed as of Closing Date are subject to change.

3. USWM Acquisition (Continued)

Purchase Price Consideration

	As Initially Reported	Measurement Period Adjustments	As Adjusted
Cash consideration	$ 304,194	$ 1,341	$ 305,535
Estimated fair value of contingent consideration	115,700	(40,900)	74,800
Estimated total purchase consideration	$ 419,894	$ (39,559)	$ 380,335
Cash consideration to Seller - net of cash acquired [1]	$ 297,200	$ 1,341	$ 298,541

[1] Represents total purchase price, less cash and cash equivalents acquired, and contingent consideration liabilities. Measurement period adjustment reflects additional payments made to Seller following the Closing date for working capital adjustments on the purchase price consistent with the Agreement

The Company paid the Seller $297.2 million in cash at the Closing Date. As of December 31, 2020, the Company paid the Seller an additional $1.3 million for working capital adjustment on the purchase price consistent with the Agreement resulting in an increase to the original cash consideration paid to the Seller.

Contingent Consideration

In addition to the cash paid to the Seller, contingent payments of up to $230 million are also due to the Seller upon the achievement of certain milestones related to the development of SPN-830, the IPR&D asset, and sale of the Products. The possible outcomes for the contingent consideration range from $0, if no milestone is achieved, to $230.0 million, if all milestones are achieved on an undiscounted basis.

The estimated fair value of the $130 million regulatory and developmental contingent consideration payments was estimated using the probability weighted cash flow income approach. Under this method, fair value is estimated by applying a probability assumption to each milestone payment, and then consolidating the probability payments to be discounted under a discounted cash flow method as of the date each payment is expected to be made. In addition to the discount rate, the more significant inputs and assumptions considered include estimated probability and timing of milestone achievement, such as the probability and timing of obtaining regulatory approval. The resulting probability weighted cash flows were discounted at a rate commensurate with the level of risk associated with the projected cash flows.

The estimated fair value of the $100 million sales-based contingent consideration payments was estimated using a Monte Carlo simulation. In addition to the discount rate and the estimated revenue volatility, the more significant inputs and assumptions considered include the estimated amount and timing of projected revenues from the Products. The projected revenues were discounted at a rate commensurate with the level of risk associated with the projected cash flows.

The Company initially recorded a contingent consideration liability of $115.7 million as of the Closing Date to reflect the estimated fair value of the contingent consideration based on information available at that time. Subsequent to the Closing Date, the Company adjusted the contingent consideration fair value based on new information related to the facts and circumstances that existed as of the acquisition date related to the timing of meeting the conditions of the milestone payments that are contingent upon regulatory approval and commercial launch of the acquired IPR&D asset as well as the estimated timing of projected revenues from the Products. This resulted in a measurement period adjustment of $40.9 million, and decreased the estimated fair value of the contingent consideration liability as of Closing Date to $74.8 million.

The fair value measurement of the contingent consideration liability was determined based on significant unobservable inputs and thus represents a Level 3 fair value measurement. These significant unobservable inputs include: the discount rates; the estimated probability and timing of milestone achievement including regulatory milestones related to the IPR&D asset; the estimated amount and timing of projected revenues from the Products; and the estimated revenue volatilities. Significant judgment is employed in determining the appropriateness of these inputs. Changes to the inputs described above could have a material impact on the Company's financial position and results of operations in any given period. The Company believes the assumptions are representative of those a market participant would use in estimating the fair value of the contingent considerations.

3. USWM Acquisition (Continued)

Fair Value of Net Assets Acquired

The following table presents the Company's preliminary estimates of the fair value of the assets acquired and liabilities assumed as of the Closing Date and subsequent measurement period adjustments recorded during the year ended December 31, 2020 (dollars in thousands):

	As Initially Reported	Measurement Period Adjustments	As Adjusted
Cash and cash equivalents	$ 6,994	$ —	$ 6,994
Accounts receivable	18,474	—	18,474
Inventories [1]	10,400	(700)	9,700
Prepaid expenses and other current assets	3,564	—	3,564
Property and equipment	454	—	454
Finance lease asset [2]	22,747	—	22,747
Intangible assets [1]	387,000	(32,000)	355,000
Other assets	340	—	340
Total of assets acquired	449,973	(32,700)	417,273
Accounts payable	(2,573)	—	(2,573)
Accrued expenses and other current liabilities	(23,339)	—	(23,339)
Finance lease liability [2]	(22,747)	—	(22,747)
Deferred income tax liabilities, net [3]	(69,515)	3,325	(66,190)
Total liabilities assumed	(118,174)	3,325	(114,849)
Total identifiable net assets	$ 331,799	$ (29,375)	$ 302,424
Goodwill	88,095	(10,184)	77,911
Total purchase price [4]	$ 419,894	$ (39,559)	$ 380,335

[1] Measurement period adjustments to intangible assets and inventory are primarily due to update in inputs and assumptions based on information related to the facts and circumstances that existed as of the acquisition date.
[2] Refer to Note 10 for further discussion of the acquired finance lease asset and assumed lease liability.
[3] Includes tax attributes that are subject to tax limitations. Measurement period adjustment is primarily due to the tax impact of the changes in the initial estimate of the fair value of intangible assets and inventories.
[4] Measurement period adjustments include an adjustment to the fair value of the contingent consideration net of the additional cash payment made to the Seller.

Acquired Inventory

The estimated fair value of the inventory was determined using the comparative sales method, which estimated the expected sales price of the product, reduced by all costs expected to be incurred to complete or to dispose of the inventory, as well as a profit on the sale. The Company recorded a measurement period adjustment of $0.7 million. The Company made refinements to the inputs and assumptions pertaining to the estimate of acquired inventories' obsolescence based on review of product dating information.

Acquired Intangible Assets

The acquired intangible assets include the acquired IPR&D asset related to the apomorphine infusion pump product candidate and the acquired developed technology, and product rights. The Company determined the estimated fair value of the acquired intangible assets as of the Closing Date using the income approach. This is a valuation technique based on the market participant's expectations of the cash flows that the intangible assets are forecasted to generate. The cash flows were discounted at

3. USWM Acquisition (Continued)

a rate commensurate with the level of risk associated with the projected cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value.

The fair value measurements of the acquired intangible assets were determined based on significant unobservable inputs and thus represents a Level 3 fair value measurement. Some of the more significant inputs and assumptions used in the intangible assets valuation includes: the timing and probability of success of clinical and regulatory approvals for the IPR&D asset, the estimated future cash flows from product sales, the timing and projection of costs and expenses, discount rates and tax rates.

The Company initially recorded a fair value of intangible assets of $387 million, which consisted of $150 million related to the acquired IPR&D and $237 million related to acquired developed technology and product rights. The initial estimate of the fair value of intangible assets recorded as of the Closing Date is based on information available at that time. During the year ended December 31, 2020, the Company recorded measurement period adjustments of $32 million, which adjusted the initial estimated fair value of the intangible assets to $355 million as of the Closing Date. The Company updated assumptions with respect to the timing of regulatory approval and the commercialization of the acquired IPR&D asset. In addition, the Company also made refinements on the estimates of projected cash flows based on review of terms of the contractual arrangements associated with the Products acquired. The revisions were based on updated assumptions and information related to the facts and circumstances that existed as of the acquisition date.

The following table summarizes the preliminary purchase price allocation and the preliminary average remaining useful lives for identifiable intangible assets (dollars in thousands):

	Estimated Fair Value	Estimated Useful Lives as of Closing Date (in years)
Acquired In-process Research & Development	$ 123,000	n/a
Acquired Developed Technology and Product Rights	232,000	10.5 - 12.5
Total intangible assets	$ 355,000	

Acquired intangible assets, excluding the acquired IPR&D, will be amortized over their estimated useful lives on a straight-line basis. IPR&D assets are considered indefinite-lived, until the successful completion or abandonment of the associated research and development efforts.

Goodwill

Goodwill was calculated as the excess of the consideration paid consequent to completing the acquisition, compared to the net assets recognized. Goodwill represents the future economic benefits arising from the acquired assets, and which could not be individually identified and separately valued. Goodwill is primarily attributable to the additional acquired growth platforms and an expanded revenue base. Goodwill is not expected to be deductible for tax purposes.

Acquisition-related Transaction Costs

Acquisition-related transaction costs, which primarily consisted of regulatory, financial advisory, and legal fees, totaled $8.4 million and $1.7 million for the year ended December 31, 2020, and December 31, 2019, respectively, were included in *Selling, general and administrative expense*, in the consolidated statements of earnings.

Revenues and Net Earnings of MDD Enterprises, LLC

The operations of MDD US Enterprises, LLC (formerly USWM Enterprises, LLC) and its subsidiaries have been included in the Company's consolidated statements of earnings for the period after the Closing Date through December 31, 2020. Total revenues of $91.0 million and net earnings of $9.9 million were recorded for the year ended December 31, 2020.

3. USWM Acquisition (Continued)

Pro forma Information

The following table presents the unaudited pro forma combined financial information for each of the periods presented as if the USWM Acquisition had occurred on January 1, 2019 (dollars in thousands):

	December 31,	
	2020	2019
	(unaudited)	
Pro forma total revenues	$ 583,657	$ 542,807
Pro forma net earnings	133,423	110,842

The unaudited pro forma combined financial information is based on historical financial information and the Company's preliminary allocation of the purchase price; therefore, it is subject to subsequent adjustment upon finalizing the purchase price allocation. In order to reflect the occurrence of the acquisition as if it occurred on January 1, 2019, the unaudited pro forma combined financial information reflects the adoption of ASC 842, *Leases;* the recognition of additional amortization expense on intangible assets, the removal of historical amortization charges and the elimination of non-recurring acquisition-related cumulative transaction costs of $10.1 million.

The unaudited pro forma combined financial information should not be considered indicative of the results that would have occurred if the acquisition had been consummated on the assumed completion date, nor are they indicative of future results.

4. Disaggregated Revenues

The following table summarizes the disaggregation of revenues by product or source (dollars in thousands):

	Years Ended December 31,		
	2020	2019	2018
Net product sales			
Trokendi XR	$ 319,640	$ 295,214	$ 315,295
Oxtellar XR	98,725	88,186	84,576
APOKYN	74,296	—	—
XADAGO	6,943	—	—
MYOBLOC	9,746	—	—
Total net product sales	509,350	383,400	399,871
Royalty revenues	11,047	9,355	8,276
Licensing revenues	—	—	750
Total revenues	$ 520,397	$ 392,755	$ 408,897

Trokendi XR accounted for more than 60% of the Company’s total net product sales in 2020 and more than 70% in 2019 and 2018.

The Company recognized noncash royalty revenue of $8.5 million, $6.9 million, and $5.9 million for the years ended December 31, 2020, 2019, and 2018, respectively, consequent to the Company's agreement with HC Royalty (see Note 2).

During 2020, the Company recorded a $10.7 million adjustment to its estimated provision for product returns related to prior year sales. The adjustment, which accounts for the majority of the total adjustments related to prior year net product sales of $13.8 million in 2020, was due to unfavorable actual returns experienced in the first quarter of 2020 for discontinued Trokendi XR commercial blister pack configurations, for which all production and distribution ceased in 2017. As a result, the Company changed its estimated provision for product returns, based on the most recent experience.

Adjustments related to prior year net product sales were $13.8 million, which included the $10.7 million aforementioned adjustment for discontinued Trokendi XR configuration, against $509.4 million of net product sales in 2020 and $0.4 million against $383.4 million of net product sales in 2019.

For the year ended December 31, 2020, revenues recognized from performance obligations related to prior periods (for example, due to changes in transaction price) on royalty revenues were not material in the aggregate.

5. 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 unrelated market participants.

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

- Level 1—Inputs are unadjusted quoted prices in active markets for identical assets. The Company has the ability to access these prices as of the measurement date. Level 1 assets include: cash held at banks; certificates of deposit; money market funds; investment grade corporate debt securities; and U.S. government agency and municipal debt securities.

- Level 2—Level 2 securities are valued using third-party pricing sources that apply relevant inputs and data in their models to estimate fair value. Inputs are quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; inputs other than quoted prices, but that are observable for the asset or liability (e.g., interest rates; yield curves); and inputs that are derived principally from or corroborated by observable market data by correlation or by other means (i.e., market corroborated inputs). Level 2 assets include: investment grade corporate debt securities; U.S. government agency and municipal debt securities; other fixed income securities; and SERP (Supplemental Executive Retirement Plan) assets. The fair value of the restricted marketable securities is recorded in *Other assets* on the consolidated balance sheets.

- Level 3—Unobservable inputs that reflect the Company’s own assumptions. These are based on the best information available, including the Company’s own data.

  There were no level 3 assets as of December 31, 2020, or December 31, 2019.

Supernus Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (Continued)

5. Fair Value of Financial Instruments (Continued)

Financial Assets Recorded at Fair Value

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

		Fair Value Measurements as of December 31, 2020	
	Total Fair value at December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash and cash equivalents			
Cash	$ 218,550	$ 218,550	$ —
Money market funds	70,090	70,090	—
Marketable securities			
Corporate debt securities	133,893	—	133,893
Long term marketable securities			
Corporate debt securities	350,359	256	350,103
Other noncurrent assets			
Marketable securities - restricted (SERP)	547	3	544
Total assets at fair value	$ 773,439	$ 288,899	$ 484,540

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

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

5. Fair Value of Financial Instruments (Continued)

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

	December 31, 2020	December 31, 2019
Corporate and U.S. government agency and municipal debt securities		
Amortized cost	$ 472,306	$ 747,598
Gross unrealized gains	11,987	10,031
Gross unrealized losses	(41)	(164)
Total fair value	$ 484,252	$ 757,465

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

	December 31, 2020
Less than 1 year	$ 133,893
1 year to 2 years	132,480
2 years to 3 years	129,743
3 years to 4 years	88,136
Greater than 4 years	—
Total	$ 484,252

There was no impairment on any available-for-sale marketable securities as of December 31, 2020, and December 31, 2019.

Financial Liabilities Recorded at Fair Value

Contingent Consideration

During the measurement period, changes in fair value due to measurement period adjustments are recorded against goodwill. In each reporting period after the acquisition, the Company remeasures the fair value of the contingent consideration liabilities from the USWM Acquisition and records in its consolidated statements of earnings the increases or decreases in the fair value of the liabilities. The contingent consideration liabilities are measured at fair value on a recurring basis, using the same methodology as of the acquisition date. The Company classifies the contingent consideration liabilities under Level 3 because the inputs and assumptions used in estimating fair value may not be observable in the market. These reflect the assumptions the Company believes would be made by a market participant. Refer to Note 3, *USWM Acquisition*, for further discussion of significant inputs and assumptions used for the valuation of the contingent consideration as of the acquisition date. Changes in any of those inputs together or in isolation may result in significantly lower or higher fair value measurement.

The following table provides the reconciliation of contingent consideration liabilities balance as of December 31, 2020 (dollars in thousands):

Balance at December 31, 2019	$ —
Initial estimate of contingent consideration at Closing Date	115,700
Measurement period adjustment	(40,900)
Change in fair value recognized in earnings	1,900
Balance at December 31, 2020	$ 76,700

Refer to Note 3 for further discussion on measurement period adjustments on the fair value at the Closing Date of the contingent consideration liability related to the USWM Acquisition.

During the year ended December 31, 2020, the Company recorded an increase to the contingent consideration liabilities of $1.9 million. Correspondingly, the change in fair value is reported in *Contingent consideration expense* in the consolidated

5. Fair Value of Financial Instruments (Continued)

statement of earnings for the year ended December 31, 2020. The increase in the fair value remeasurement of contingent consideration liabilities was primarily due to the changes made in the assumptions on the expected timing of the achievement of milestones and changes to the estimate of projected revenues that did not qualify as measurement period adjustments.

Financial Liabilities Recorded at Carrying Value

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

	December 31, 2020		December 31, 2019	
	Carrying Value	Fair Value (Level 2)	Carrying Value	Fair Value (Level 2)
Convertible notes, net	$ 361,751	$ 383,381	$ 345,170	$ 366,023

The fair value has been estimated based on actual trading information, and quoted prices, both provided by bond traders.

6. Convertible Senior Notes Due 2023

The 0.625% Convertible Senior Notes Due 2023 (2023 Notes), issued in March 2018, bear interest at an annual rate of 0.625%, payable semi-annually in arrears on April 1 and October 1 of each year. The 2023 Notes will mature on April 1, 2023, unless earlier converted or repurchased by the Company. The Notes are being amortized to interest expense at an effective interest rate of 5.41% over the contractual term of the 2023 Notes. The Company may not redeem the 2023 Notes at its option before maturity. The total principal amount of 2023 Notes is $402.5 million.

The 2023 Notes were issued pursuant to an 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 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.

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.

At its election, 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, 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. In the event of conversion, if converted in cash, the holders would forgo all future interest payments, any unpaid accrued interest, and the possibility of further stock price appreciation.

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.

Contemporaneous with the issuance of the 2023 Notes, the Company also entered into separate privately negotiated convertible note hedge transactions (collectively, the Convertible Note Hedge Transactions) with each of the call spread

6. Convertible Senior Notes Due 2023 (Continued)

counterparties. The Company issued 402,500 convertible note hedge options. In the event that shares or cash are deliverable to holders of the 2023 Notes upon conversion at limits defined in the Indenture, counterparties to the convertible note hedges will be required to deliver up to approximately 6.8 million shares of the Company's common stock or to pay cash to the Company in a similar amount as the value that the Company delivers to the holders of the 2023 Notes, based on a conversion price of $59.33 per share.

Concurrently with entering into the Convertible Note Hedge Transactions, the Company also entered into separate privately negotiated warrant transactions (collectively, the Warrant Transactions) with each of the call spread counterparties. The Company issued a total of 6,783,939 warrants. The warrants entitle the holder to one share per warrant. The strike price of the Warrant Transactions will initially be $80.9063 per share of the Company's common stock and is subject to adjustment.

The Convertible Note Hedge Transactions are expected to reduce the potential dilution of the Company's common stock upon conversion of the 2023 Notes, and/or offset any potential cash payments the Company is required to make in excess of the principal amount of converted 2023 Notes, as the case may be.

The Warrant Transactions were 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.

The liability component of the 2023 Notes consists of the following (dollars in thousands):

	December 31, 2020	December 31, 2019
2023 Notes	$ 402,500	$ 402,500
Unamortized debt discount and deferred financing costs	(40,749)	(57,330)
Total carrying value	$ 361,751	$ 345,170

No 2023 Notes were converted as of December 31, 2020, or December 31, 2019.

7. Stockholders' Equity

Common Stock

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

Stock Option Plan

The Company has adopted the Supernus Pharmaceuticals, Inc. 2012 Equity Incentive Plan, as amended (the 2012 Plan), which is stockholder approved. This plan provides for the grant of stock options and certain other equity awards, including: stock appreciation rights (SARs); restricted and unrestricted stock; stock units; performance awards; cash awards; and other awards that are convertible into or otherwise based on the Company's common stock, to the Company's key employees, directors, consultants, and advisors. The 2012 Plan is administered by the Company's Board of Directors and the Company's Compensation Committee of the Board and provides for the issuance of up to 11 million shares of the Company's common stock. Option awards are granted with an exercise price equal to the closing price of the Company's common stock as of the grant date. Option awards granted to employees, consultants and advisors generally vest in four equivalent annual installments, starting on the first anniversary of the grant's date. Awards have 10 year contractual terms. Option awards granted to the directors generally vest over a one year term and have a 10 year contractual term.

7. Stockholders' Equity (Continued)

Employee Stock Purchase Plan

The Company has adopted the Supernus Pharmaceuticals, Inc. 2012 Employee Stock Purchase Plan, as amended (the ESPP). The ESPP allows eligible employees the opportunity to acquire shares of the Company's common stock at periodic intervals through accumulated payroll deductions. These deductions are applied at the semi-annual purchase dates of June 30 and December 31 to purchase shares of common stock at a discount. Eligible employees may purchase shares at the lower of 85% of the fair market value at either the first day of the purchase period or the fair market value at the end of the purchase period. The ESPP provides for the issuance of up to 1.7 million shares of the Company's common stock. The Company records compensation expense related to its ESPP.

Share-based Compensation

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

	Years Ended December 31,		
	2020	2019	2018
Research and development	$ 2,431	$ 2,599	$ 1,943
Selling, general and administrative	14,130	12,247	9,348
Total	$ 16,561	$ 14,846	$ 11,291

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

	Years Ended December 31,		
	2020	2019	2018
Fair value of common stock	$21.13 - $23.99	$22.99 - $37.78	$37.20 - $58.15
Expected volatility	61.56% - 62.27%	61.36% - 63.28%	57.95% - 60.56%
Dividend yield	0%	0%	0%
Expected term	5.72 years - 6.54 years	5.53 years - 6.18 years	6.25 years
Risk-free interest rate	0.27% - 1.34%	1.69% - 2.55%	2.69% - 2.85%

As of December 31, 2020, the total unrecognized compensation expense was approximately $25.5 million. The Company expects to prospectively recognize these expenses over a weighted-average period of 2.52 years.

7. Stockholders' Equity (Continued)

Stock Option and Stock Appreciation Rights

The following table summarizes stock option and stock appreciation rights (SAR) activities:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding , December 31, 2018	3,916,963	$ 19.98	7.10	$ 57,220
Granted	880,235	$ 36.43		
Exercised	(114,753)	$ 12.90		
Forfeited	(75,886)	$ 34.80		
Outstanding, December 31, 2019	4,606,559	$ 23.06	6.66	$ 27,716
Granted	1,370,225	$ 23.55		
Exercised	(204,373)	$ 11.47		
Forfeited	(320,549)	$ 29.09		
Outstanding, December 31, 2020	5,451,862	$ 23.26	6.28	$ 29,877
As of December 31, 2020				
Vested and expected to vest	5,451,862	$ 23.26	6.28	$ 29,877
Exercisable	3,218,771	$ 19.36	4.77	$ 27,832

The weighted-average grant date fair value of options granted for the years ended December 31, 2020, 2019, and 2018 was $13.44, $21.50, and $23.43 per share, respectively.

The aggregate intrinsic value of shares exercised for the years ended December 31, 2020, 2019, and 2018 was $2.3 million, $2.4 million, and $36.3 million, respectively. Proceeds from the option exercise for the years ended December 31, 2020, 2019, and 2018 was $2.3 million, $1.5 million, $9.4 million, respectively.

The total fair value of the underlying common stock related to shares that vested during the years ended December 31, 2020, 2019, and 2018 was approximately $14.1 million, $10.8 million, and $8.3 million, respectively.

Restricted Stock Units

During the year ended December 31, 2020, the Company granted 26,055 RSUs, with a weighted average grant date fair value per share of $23.99. These RSUs generally vest one year from the date of grant. All RSUs are unvested as of December 31, 2020. The total unrecognized compensation expense was $0.2 million as of December 31, 2020. The Company expects to prospectively recognize these expenses over a weighted-average period of 0.4 years.

Performance Stock Units

Performance-Based Awards

During the year ended December 31, 2020, the Company granted 31,250 performance-based awards, with a weighted average grant date fair value per share of $21.35. These awards require certain performance targets to be achieved in order to vest. Vesting is also subject to continued service requirements through the date that the achievement of the performance target is certified. As of December 31, 2020, all of the performance-based awards were vested and issued as shares outstanding. There was no unrecognized compensation expense as of December 31, 2020. The total fair value of vested PSU during the year ended December 31, 2020, was $0.7 million.

Market-Based Awards

During the year ended December 31, 2020, the Company granted 15,625 market-based awards, with a weighted average grant date fair value per share of $23.41. These awards are subject to achievement of market-based performance targets in order to

7. Stockholders' Equity (Continued)

vest. All of the 15,625 market-based awards were unvested as of December 31, 2020. There was no unrecognized compensation expense as of December 31, 2020. The Company used a Monte-Carlo Simulation to determine the fair value and expected term of the award. The expected term of the award was 0.85 years.

8. Earnings per Share

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

Effect of Convertible Notes and Related Convertible Note Hedges and Warrants

In connection with the issuance of the 2023 Notes, the Company entered into Convertible Note Hedge and Warrant Transactions as described further in Note 6, *Convertible Senior Notes Due 2023*. The expected collective impact of the Convertible Note Hedge and Warrant Transactions is to reduce the potential dilution that would occur if the price of the Company's common stock was between the conversion price of $59.33 per share and the strike price of the warrants of $80.9063 per share.

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

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

	Years Ended December 31,		
	2020	2019	2018
Stock options, RSUs, PSUs	2,888,785	1,145,446	199,982

The following table sets forth the computation of basic and diluted net earnings per share for the years ended December 31, 2020, 2019, and 2018 (dollars in thousands, except share and per share amounts):

	Years Ended December 31,		
	2020	2019	2018
Numerator, dollars in thousands:			
Net earnings	$ 126,950	$ 113,056	$ 110,993
Denominator:			
Weighted average shares outstanding, basic	52,615,269	52,412,181	51,989,824
Effect of dilutive securities:			
Stock options, RSUs and SARs	1,074,474	1,404,573	2,109,048
Weighted average shares outstanding, diluted	53,689,743	53,816,754	54,098,872
Earnings per share, basic	$ 2.41	$ 2.16	2.13
Earnings per share, diluted	$ 2.36	$ 2.10	2.05

9. Income Taxes Expense

The summary of the income tax expense (benefit) for the years ended December 31, 2020, 2019, and 2018 is as follows (dollars in thousands):

	Years Ended December 31,		
	2020	2019	2018
Current			
Federal	$ 29,893	$ 29,333	$ 26,772
State	11,234	10,930	5,621
Deferred			
Federal	2,200	(4,551)	(2,450)
State	(1,629)	(1,281)	(760)
Total income tax expense	$ 41,698	$ 34,431	$ 29,183

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

	Years Ended December 31,		
	2020	2019	2018
Income tax expense computed at U.S. federal statutory income tax rate	$ 35,417	$ 30,972	$ 29,437
State income taxes	7,281	7,543	3,674
Permanent items	2,654	1,332	(2,196)
Research and development credits	(3,602)	(2,071)	(3,199)
Uncertain income tax position	348	(2,992)	716
Other	(400)	(353)	751
Income tax expense	$ 41,698	$ 34,431	$ 29,183

9. Income Taxes (Continued)

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

	As of December 31,	
	2020	2019
Deferred tax assets:		
Convertible bond hedge	$ 12,420	$ 17,197
Accrued product returns and rebates	17,529	15,123
Accrued compensation and stock based compensation	13,547	10,349
Non-recourse liability related to sale of future royalties	3,777	5,320
Research and development credit carryforwards	3,151	3,817
Amortization of intangibles	—	4,617
Net operating loss carryforwards	13,164	2,245
Operating lease liability	14,542	8,187
Other	5,303	2,510
Total deferred tax assets	83,433	69,365
Less: valuation allowance	(582)	(11)
Total deferred tax asset, net of valuation allowance	82,851	69,354
Deferred tax liabilities:		
Amortization of intangibles	(79,545)	—
Debt discount on 2023 Notes	(10,190)	(14,109)
Patent infringement legal costs	(10,897)	(10,613)
Operating lease assets	(10,674)	(5,237)
Depreciation	(3,458)	(2,778)
IRC Section 481(a) liability	(315)	(2,126)
Unrealized gain on marketable securities	(2,987)	(2,428)
Total deferred tax liabilities	(118,066)	(37,291)
Net deferred tax (liabilities) assets	$ (35,215)	$ 32,063

In assessing the realizability of deferred income tax assets, the Company 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. The Company 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, the Company had determined it is more-likely-than-not to realize such net deferred tax assets.

Associated with the acquisition of MDD US Enterprises, LLC (formerly USWM Enterprises, LLC), the Company recorded a valuation allowance of $0.6 million and $0.6 million as of the acquisition date and December 31, 2020, respectively, related to the foreign net operating losses and certain state charitable contribution carryforwards that are not expected to be realizable in the future.

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

9. Income Taxes (Continued)

As of December 31, 2020, the U.S. federal and state NOL carryforwards amounted to approximately $57.9 million and $21.9 million, respectively, and will expire in various years beginning in 2023. For the year ended December 31, 2020, the Company utilized federal NOLs of approximately $6.4 million and state NOLs of approximately $13.6 million. The Company expects the remaining federal and state NOL carryforwards to become available in the future years.

As of December 31, 2020, the Company has available research and development credit carryforwards of $3.5 million, which will become available in 2021 and will expire, if unused, starting in 2027.

The Company is no longer subject to U.S. Federal income tax examinations for years prior to 2017. Operating loss or tax credit carryforwards generated prior to 2017 may be subject to tax audit adjustment.

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

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

	Years Ended December 31,		
	2020	2019	2018
Balance as of January 1	$ 5,978	$ 8,848	$ 8,859
Gross increases related to current year tax positions	1,027	208	1,108
Gross increases related to prior year tax positions	221	—	—
Gross decreases related to prior year tax positions	—	(49)	(484)
Lapse of statute of limitations	(1,345)	(3,029)	(635)
Balance as of December 31	$ 5,881	$ 5,978	$ 8,848

The Company recorded $0.6 million, $3.0 million, and $0.6 million of net tax benefit in 2020, 2019 and 2018, respectively, as a result of the expiration of statutes of limitation. The Company also recorded $0.3 million, $0.2 million, and $0.3 million for uncertain tax positions related to research and development tax credits in 2020, 2019, and 2018, respectively, and an additional expense of $0.2 million related to a prior year position. The Company does not anticipate a material impact to the financial statements in the next 12 months as a result of uncertain tax positions and expiring statutes of limitation.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax incentives to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of the COVID-19 pandemic. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which are expected to impact the Company’s financial statements include the removal of certain limitations on the utilization of net operating losses, increasing the ability to deduct interest expense, and amending certain provisions of the previously enacted Tax Cuts and Jobs Act.

As of December 31, 2020, the Company expects that these provisions will not have a material impact, as the Company does not have net operating losses that would fall under the provisions of this legislation, nor does it expect interest expense to be limited. The ultimate impact of the CARES Act may differ from this estimate due to changes in interpretations and assumptions, additional guidance that may be issued, and actions the Company may take in response to the CARES Act. The Company will continue to assess the impact that various provisions may have on its business.

10. Leases

Operating Leases

The Company has operating leases for its former headquarters office and lab space at 1550 East Gude Drive in Rockville, MD, its new headquarters lease, and its fleet vehicles. The Company's leases for its former headquarters office and lab space ended in April 2020. With respect to the fleet vehicle leases, given the volume of individual leases involved in the overall arrangement, the Company applies a portfolio approach to effectively account for the operating lease assets and liabilities. The Company also elected to combine the lease and non-lease components for the fleet vehicle and headquarters leases.

Headquarters Lease

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

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

The lease also provides for a tenant improvement allowance of $10.2 million in aggregate. All tenant improvement allowances have been utilized as of December 31, 2019.

Finance Lease

Contemporaneous with the USWM Acquisition, USWM Enterprises adopted ASC 842, *Leases.* USWM Enterprises had an existing contract manufacturing agreement with Merz Pharma GmbH & Co. KGaA (Merz) for the manufacture and supply of MYOBLOC, NeuroBloc and NerBloc (finished products). Pursuant to the Merz Agreement, Merz agreed to provide a dedicated manufacturing facility that included a stand-alone building, dedicated cleanroom suites, dedicated manufacturing, and purification equipment, and filling and packaging production lines (collectively, the manufacturing facility) to manufacture finished products. The Merz Agreement will expire in July 2027 unless the Company and Merz mutually agree to extend the terms. The Merz Agreement may not be terminated for convenience.

Under the terms of the agreement, the Company is required to purchase a minimum quantity of finished products on an annual basis. This minimum purchase requirement represents the in-substance fixed contract consideration associated with the dedicated manufacturing facility. Refer to Note 21, *Commitments and Contingencies*.

As of the Closing Date, the finance ROU lease asset and corresponding ROU lease liability relating to the dedicated manufacturing facility was $22.7 million. The ROU lease asset and ROU lease liability represent the present value of estimated future payments; i.e., the minimum purchase obligations as of the Closing Date.

The embedded lease is preliminarily classified as a finance lease. The in-substance fixed contract consideration was allocated to the lease component since the Company has preliminarily elected not to separate lease and non-lease components. Refer to Note 3 for further discussion of the USWM Acquisition.

The Company recognized $1.9 million of fixed lease costs on the finance lease for the year ended December 31, 2020. Purchases of MYOBLOC in excess of the annual minimum purchase obligations will be recorded as variable lease cost. There were no purchases made during the year in excess of the annual minimum purchase obligations.

10. Leases (Continued)

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

	Balance Sheet Classification	December 31, 2020	December 31, 2019
Assets			
Operating lease assets	Other assets	$ 20,231	$ 21,279
Finance lease asset	Property and equipment, net	20,874	—
Total lease assets		$ 41,105	$ 21,279
Liabilities			
Lease liabilities, current			
Operating lease liabilities, current portion	Accounts payable and accrued liabilities	$ 3,760	$ 2,825
Finance lease liability, current portion	Other current liabilities	3,761	—
Lease liabilities, long term			
Operating lease liabilities, long term	Operating lease liabilities, long term	28,579	30,440
Finance lease liability, long term	Other liabilities	20,235	—
Total lease liabilities		$ 56,335	$ 33,265

The components of operating and finance lease costs are as follows (dollars in thousands):

	December 31, 2020	December 31, 2019
Operating lease cost:		
Fixed lease cost	$ 5,333	$ 4,990
Variable lease cost	2,145	1,887
Total	$ 7,478	$ 6,877
Finance lease cost:		
Amortization on finance lease asset	$ 1,873	$ —
Interest on lease liability	333	—
Total	$ 2,206	$ —

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

	December 31, 2020	December 31, 2019
Cash paid for operating leases	$ 6,949	$ 5,337
Cash paid for finance lease	802	—
Lease assets and tenant receivables obtained for new operating leases	2,478	35,594
Lease assets obtained for new finance lease	22,747	—

10. Leases (Continued)

Weighted average lease term, and weighted average discount rate for operating and finance leases as of December 31, 2020, are as follows:

Operating leases	
Weighted-average remaining lease term (years)	11.7
Weighted-average discount rate	4.33 %
Finance lease	
Weighted-average remaining lease term (years)	6.4
Weighted-average discount rate	2.47 %

Future minimum lease payments under noncancellable operating and finance leases as of December 31, 2020, are as follows (dollars in thousands):

	Operating Leases	Finance Lease
Year ending December 31:		
2021	$ 5,066	$ 3,946
2022	4,474	3,665
2023	2,701	3,665
2024	2,587	3,665
2025	2,638	3,665
Thereafter	24,145	7,329
Total future minimum lease payments	$ 41,611	$ 25,935
Less: Imputed interest [(1)]	(9,272)	(1,939)
Present value of lease liabilities	$ 32,339	$ 23,996

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

11. Goodwill and Intangible Assets, Net

Goodwill

Goodwill represents the excess of the USWM Acquisition purchase price over the fair value of the tangible and identifiable intangible net assets acquired. The following table sets forth the reconciliation of the goodwill balance as of December 31, 2020 (dollars in thousands):

	December 31, 2020
Balance at December 31, 2019	$ —
Initial estimate of Goodwill at Closing Date	88,095
Measurement period adjustment	(10,184)
Balance at December 31, 2020	$ 77,911

In 2020, the Company recorded cumulative measurement period adjustments to the fair value of intangibles, inventory, and contingent consideration liability that resulted in a corresponding adjustment of $10.2 million to the initial estimate of

goodwill recorded at Closing Date. Refer to Note 3 for further discussion of these measurement period adjustments related to the USWM Acquisition.

As of December 31, 2020, there were no identified indicators of impairment.

Intangible assets, net

Intangible assets include: patent defense costs, which are deferred legal fees incurred in conjunction with defending patents for Oxtellar XR and Trokendi XR; acquired developed technology and product rights, and an acquired IPR&D asset associated with the USWM acquisition. The Company amortizes intangible assets over their useful lives, except for the acquired IPR&D asset.

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

	Remaining Weighted-Average Life (Years)	December 31, 2020	December 31, 2019
Acquired In-process Research & Development		$ 123,000	$ —
Intangible assets subject to amortization			
Acquired Developed Technology and Product Rights	10 - 12	232,000	—
Capitalized patent defense costs	2.00 - 6.25	43,579	43,375
Less accumulated amortization		(34,237)	(18,535)
Total intangible assets, net		$ 364,342	$ 24,840

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

Amortization expense for intangible assets was approximately $15.7 million, $5.2 million, and $5.2 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Anticipated annual amortization expense for intangible assets in 2021 and 2022 is estimated at $24.2 million per year. Anticipated annual amortization expense for intangible assets from 2023 to 2025 is estimated at $21.4 million per year.

As of December 31, 2020, there were no identified indicators of impairment.

12. Investments in Unconsolidated VIEs

In April 2020, the Company entered into a Development and Option Agreement (Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor). The Company can terminate the Development Agreement upon 30 days' notice.

Under the terms of the Development Agreement, the Company and Navitor will jointly conduct a Phase II clinical program for NV-5138 (SPN-820) for treatment-resistant depression. The Company will bear all of Phase I and Phase II development costs incurred by either party, up to a maximum of $50 million. In addition, the Company will incur certain other research and development support costs.

There are certain additional payment amounts which the Company could incur. These costs are contingent upon Navitor achieving defined development milestones.

The Company has an option to acquire or license NV-5138 (SPN-820), for which additional payments would be required. The Company paid Navitor a one time, nonrefundable, and non-creditable fee of $10 million for the option to acquire or license NV-5138 (SPN-820). This expense is included in *Research and development expense* in the consolidated statement of earnings for the year ended December 31, 2020.

In addition to entering into the Development Agreement, the Company acquired Series D Preferred Shares of Navitor for $15 million, representing an approximately 13% ownership position in Navitor. The Company has determined that Navitor is a VIE. The Company has not consolidated this VIE because the Company lacks the power to direct the activities that most significantly impact Navitor's economic performance. This investment is accounted for under the practical expedient allowed for equity securities without readily determinable fair value, which is cost minus impairment plus any changes in observable price changes from an orderly transaction of similar investments of Navitor. The investment is recorded in *Other assets* in the consolidated balance sheets.

As of December 31, 2020, the carrying value of our investment in Navitor was approximately $15 million. The maximum exposure to losses related to Navitor is limited to: the $15 million carrying value of the investment; a maximum of approximately $50 million in expense for Phase I and Phase II development of NV-5138 (SPN-820); and the cost of other development and formulation activities provided by the Company.

We have provided no financing to Navitor other than the amounts committed under the Development Agreement.

13. Accounts Receivable

As of December 31, 2020, and December 31, 2019, the Company recorded allowances of approximately $11.4 million and $11.0 million, respectively, for prompt pay discounts and contractual service fees paid to the Company's customers. The Company's customers are primarily pharmaceutical wholesalers and distributors, and specialty pharmacies.

14. Inventories

Inventories consist of the following (dollars in thousands):

	December 31, 2020	December 31, 2019
Raw materials	$ 22,208	$ 4,582
Work in process	8,985	11,428
Finished goods	17,132	10,618
Total	$ 48,325	$ 26,628

As of December 31, 2020, the Company capitalized $19.1 million of pre-launch inventory costs for SPN-812. As of December 31, 2019, the Company had not capitalized any pre-launch inventory costs.

Inventories include the acquired inventories from the USWM Acquisition. Refer to Note 3 for further discussion of the USWM Acquisition.

15. Property and Equipment

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

	December 31, 2020	December 31, 2019
Lab equipment and furniture	$ 12,526	$ 11,053
Leasehold improvements	15,183	14,217
Software	2,295	2,225
Finance lease assets [1]	22,747	—
Computer equipment	2,113	1,839
Construction-in-progress	—	433
	54,864	29,767
Less accumulated depreciation and amortization	(17,040)	(12,699)
Total	$ 37,824	$ 17,068

[1] Refer to Note 10, *Leases*.

Depreciation and amortization expense on property and equipment was approximately $4.3 million, $1.5 million, and $1.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

As of December 31, 2020, there were no identified indicators of impairment.

16. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of the following (dollars in thousands):

	December 31, 2020	December 31, 2019
Accrued compensation	$ 16,008	$ 11,223
Accrued royalties [1]	13,890	—
Accrued clinical trial costs [2]	12,842	13,285
Inventory-related accruals	9,587	1,095
Accrued professional fees	7,730	3,936
Accounts payable	6,147	10,141
Operating lease liabilities portion [3]	3,760	2,825
Income taxes payable	—	2,443
Other accrued expenses	8,970	4,766
Total	$ 78,934	$ 49,714

[1] Refer to Note 21, *Commitments and Contingencies*.
[2] Includes preclinical and all clinical trial-related costs.
[3] Refer to Note 10, *Leases*.

17. Accrued Product Returns and Rebates

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

	December 31, 2020	December 31, 2019
Accrued product rebates	$ 96,589	$ 88,811
Accrued product returns	29,603	18,818
Total	$ 126,192	$ 107,629

18. Other Liabilities

Other liabilities consist of the following (dollars in thousands):

	December 31, 2020	December 31, 2019
Nonrecourse liability related to sale of future royalties, long term	$ 13,410	$ 19,248
Finance lease liability, long term [1]	20,235	—
Other liabilities	9,146	9,409
Total	$ 42,791	$ 28,657

[1] Refer to Note 10, *Leases*.

19. Other (Expense) Income

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

	Years Ended December 31,		
	2020	2019	2018
Interest and other income, net	$ 18,704	$ 21,623	$ 13,843
Interest expense	(19,435)	(18,207)	(13,840)
Interest expense on nonrecourse liability related to sale of future royalties	(4,319)	(4,500)	(4,271)
Total	$ (5,050)	$ (1,084)	$ (4,268)

Interest expense includes noncash interest expense related to amortization of deferred financing costs and amortization of the debt discount on the 2023 Notes, in the amount of $16.6 million, $15.7 million, and $11.8 million for the years ended December 31, 2020, 2019 and 2018, respectively (see Note 6).

Interest income includes interest earned from cash, cash equivalents, and marketable securities of $16.0 million, $21.3 million, and $13.8 million for the years ended December 31, 2020, 2019, and 2018, respectively.

20. 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 IRC. 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 $2.6 million, $2.3 million, and $2.1 million for the years ended December 31, 2020, 2019, and 2018, respectively.

21. Commitments and Contingencies

Product Licenses

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

Through the USWM Acquisition, the Company acquired licensing agreements with other pharmaceutical companies for APOKYN, XADAGO, and MYOBLOC. The Company is obligated to pay royalties to third parties, computed as a percentage of net product sales, for each of the products under the respective license agreements. The royalty expense incurred for these acquired products is recognized as *Cost of goods sold* in the consolidated statement of earnings.

Royalty Agreement

In the third quarter of 2014, the Company received a $30.0 million pursuant to a Royalty Interest Acquisition Agreement related to the purchase by HC Royalty of certain of the Company's rights under the Company's agreement with United Therapeutics related to the commercialization of Orenitram (treprostinil) Extended-Release Tablets. Full ownership of the royalty rights will revert to the Company if and when a certain cumulative payment threshold is reached (see Note 2, Note 4, and Note 18).

USWM Enterprise Commitments Assumed

As part of the USWM Acquisition, the Company assumed the remaining commitments of USWM Enterprises and its subsidiaries, which are discussed below.

In addition to the annual minimum purchase requirement of MYOBLOC, amounting to an estimated €3.0 million annually, under the contract manufacturing agreement with Merz for manufacture and supply, USWM Enterprises had an existing license and distribution agreement for XADAGO. This included an annual minimum promotional spend to support the marketing of XADAGO for the first five years of the agreement. As of December 31, 2020, the total remaining contractual commitment through 2020 is $3.7 million. (See Note 3, *USWM Acquisition* for further discussion on the USWM Acquisition and Note 10, *Leases* for further discussion on the finance lease related to the Merz Agreement).

In March 2019, MDD US Operations, LLC (formerly US WorldMeds, LLC) and its subsidiary, Solstice Neurosciences, LLC (US) (collectively, the MDD Subsidiaries) entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. Under the CIA, the MDD Subsidiaries agreed to and paid $17.5 million to resolve U.S. Department of Justice allegations that it violated the False Claims Act and committed to the establishment and ongoing maintenance of an effective compliance program. The fine was paid by the MDD Subsidiaries prior to closing of the USWM Acquisition. As part of the USWM Acquisition, we assumed the obligations of the CIA and could become liable for payment of certain stipulated monetary penalties in the event of any CIA violations. In addition, we will continue to incur significant costs through March 2024 to maintain a broad array of processes, policies and procedures necessary to comply with the CIA.

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 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 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, 2020, 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, 2020.

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.

As discussed in Note 3 in the Notes to the Consolidated Financial Statements in Part II, Item 8, of this report, the Company completed its acquisition of USWM Enterprises, LLC, a privately-held biopharmaceutical company (USWM Acquisition) on June 9, 2020. Management has excluded the acquisition of USWM Enterprises, LLC from its assessment of the effectiveness of internal control over financial reporting as of December 31, 2020. The acquired business represented approximately 8.8% of the total assets (excluding the goodwill and other intangible assets, which are included within the scope of the assessment) and 17.5% of total revenues as of and for the year ended December 31, 2020.

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, 2020, 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 the criteria set forth above, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2020.

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, 2020. Their responsibility is to evaluate whether internal controls over financial reporting were designed and operating effectively. Their report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2020 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 year ended December 31, 2020.

In 2020, we began the process to integrate the financial reporting systems and processes of the business acquired through the USWM Acquisition into ours. As the phased implementation of the integration continues, we are experiencing certain changes to our processes and procedures, which, in turn, result in changes to our internal control over financial reporting. While management has extended its oversight and monitoring processes that support our internal control over financial reporting, we continue to integrate the acquired operations of USWM Enterprises, LLC, which may result to additions and changes in our internal controls over financial reporting.

There were no other 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, 2020 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 2021 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2020.

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 2021 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2020.

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 2021 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2020.

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, 2020:

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	5,451,862	$ 23.26	3,922,631
Equity compensation plans not approved by security holders	—	—	—
Total	5,451,862	$ 23.26	3,922,631

(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 2021 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2020.

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 2021 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2020.

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, 2020 and 2019 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).
2.2	††#*	Sale and Purchase Agreement Relating to USWM Enterprises, LLC, dated April 28, 2020, by and between US WorldMeds Partners, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Form 10-Q filed on August 17, 2020, 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.
10.10	††**	Guanfacine License Agreement, dated as of December 22, 2005, by and among the Registrant, Shire LLC and Shire plc, as amended.
10.11	††**	Exclusive License Agreement, dated as of June 6, 2006, by and between the Registrant and United Therapeutics Corporation.
10.12	††**	Purchase and Sale Agreement, dated as of June 9, 2006, by and between the Registrant and Rune HealthCare Limited.
10.13	*	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.
10.14	*+	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).
10.15	*+	Amended and Restated Employment Agreement, dated February 29, 2012, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.16	*+	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).
10.17	*+	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).
10.18	*+	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).
10.19	†*	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).

Exhibit Number		Description
10.20	*	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).
10.21	†*	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).
10.22	*+	Compensatory Arrangements of Certain Executive Officers for 2021 (incorporated by reference to Item 5.02 of the Form 8-K filed on February 24, 2021, File No. 001-35518).
10.23	*	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).
10.24	*	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).
10.25	*+	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).
10.26	*+	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).
10.27	*	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).
10.28	*	First Amendment to Lease Agreement, dated October 20, 2014, by and between ARE-1500 East Gude, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on October 24, 2014, File No. 001-35518).
10.29	*+	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).
10.30	†*	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).
10.31	*+	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).

Exhibit Number		Description
10.32	*+	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).
10.33	†*	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).
10.34	†*	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).
10.35	†*	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).
10.36	*	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).
10.37	*	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).
10.38	*	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).
10.39	*	Base Issuer Warrant Transaction, dated March 14, 2018, between Deutsche Bank AG, London Branch and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 to the Form 8-K filed on March 20, 2018, File No. 001-35518).
10.40	*	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).
10.41	*	Base Issuer Warrant 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).
10.42	*	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).
10.43	*	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).

Exhibit Number		Description
10.44	*	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).
10.45	*	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).
10.46	*	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).
10.47	*	Additional Issuer Warrant 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).
10.48	*+	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).
10.49	*+	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).
10.50	*	Lease Agreement, dated January 31, 2019, between Advent Key West, LLC and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 5, 2019, File No. 001-35518).
10.51	*	Form of Restricted Stock Unit Award Agreement for Non-Management Directors, issued under the Supernus Pharmaceuticals, Inc., 2012 Equity Incentive Plan, as amended, for grants made to non-management directors (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 27, 2020. File No. 001-35518).
10.52	*	Form of Performance Share Unit Award Agreement, issued under the Amended and Restated Stock Incentive Plan, for grants made to Jack A. Khattar (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on February 27, 2020, File No. 001-35518).
10.53	††#*	Development and Option Agreement, dated April 21, 2020, by and between Navitor Pharmaceuticals, Inc. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Form 10-Q filed on August 17, 2020, File No. 001-35518).
10.54	††#*	Amended and Restated Distribution, Development, Commercialization and Supply Agreement, dated January 15, 2016, by and between Britannia Pharmaceuticals Limited and US WorldMeds, LLC (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed on August 17, 2020, File No. 001-35518).
10.55	††*	First Amendment to Amended and Restated Distribution, Development, Commercialization and Supply Agreement, dated February 19, 2020, by and between Britannia Pharmaceuticals Limited and US WorldMeds, LLC (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed on August 17, 2020, File No. 001-35518).
10.56	††#*	Letter Agreement Re: Memorandum of Understanding for the Supply of Pens, effective February 25, 2019 (incorporated by reference to Exhibit 10.4 to the Form 10-Q filed on August 17, 2020, File No. 001-35518).

Exhibit Number		Description
10.57	††*	Letter Agreement Re: Exclusive Supply of Pens, effective September 23, 2019 (incorporated by reference to Exhibit 10.5 to the Form 10-Q filed on August 17, 2020, File No. 001-35518).
10.58	††+*	Offer Letter to James P. Kelly (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on October 5, 2020, File No. 001-35518).
10.59	+*	Executive Retention Agreement, dated October 12, 2020, by and between James P. Kelly and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on October 5, 2020, File No. 001-35518).
10.60	††+*	Consulting Agreement, made as of November 18, 2020, by and between Supernus Pharmaceuticals, Inc. and Gregory S. Patrick (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on November 19, 2020, File No. 001-35518).
10.61	††+*	Consulting Agreement, made as of December 31, 2020, by and between Supernus Pharmaceuticals, Inc. and Stefan K.F. Schwabe (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on November 19, 2020, File No. 001-35518).
14	*	Code of Ethics (incorporated by reference to Exhibit 14 to the Company's Annual Report on Form 10-K for the period ended December 31, 2012, filed on March 15, 2013, File No. 001-35518).
21	**	Subsidiaries of the Registrant.
23.1	**	Consent of KPMG LLP.
31.1	**	Certification of Chief Executive Officer.
31.2	**	Certification of Chief Financial Officer.
32.1	**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350
32.2	**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350
101	**	The following financial information from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, formatted in Inline XBRL: (i) Cover Page; (ii) Consolidated Statement of Earnings; (iii) Consolidated Statement of Comprehensive Earnings; (iv) Consolidated Balance Sheets; (v) Consolidated Statements of Equity; (vi) Consolidated Statements of Cash Flows; and (vii) the Notes to Consolidated Financial Statements, tagged in summary and detail.
104	**	The Cover Page of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, formatted in Inline XBRL (included with the Exhibit 101 attachments).

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

†† Certain portions of this exhibit that constitute confidential information have been omitted in accordance with Regulation S-K, Item 601(b)(10)(iv) because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

Exhibits and schedules have been omitted pursuant to Regulation S-K Item 601(a)(5) and will be furnished on a supplemental basis to the Securities and Exchange Commission upon 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 8, 2021

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 8, 2021
/s/ JAMES P. KELLY	Executive Vice-President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 8, 2021
/s/ CHARLES W. NEWHALL, III.	Director and Chairman of the Board	March 8, 2021
CARROLEE BARLOW, M.D., PH.D.	Director	March 8, 2021
/s/ GEORGES GEMAYEL, PH.D.	Director	March 8, 2021
/s/ FREDERICK M. HUDSON	Director	March 8, 2021
/s/ JOHN M. SIEBERT, PH.D.	Director	March 8, 2021

Exhibit 10.9

CERTAIN CONFIDENTIAL INFORMATION IDENTIFIED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

EXECUTION COPY

ASSET PURCHASE AND CONTRIBUTION AGREEMENT

dated as of

December 22, 2005

among

SUPERNUS PHARMACEUTICALS, INC.,

SHIRE LABORATORIES INC.

and

SHIRE PLC

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ASSET PURCHASE AND CONTRIBUTION AGREEMENT

AGREEMENT dated as of December 22, 2005 among Supernus Pharmaceuticals, Inc., a Delaware corporation ("**Supernus**"), Shire Laboratories Inc., a Delaware corporation ("**SLI**") and Shire plc, a company incorporated under the laws of England and Wales ("**Guarantor**").

W I T N E S S E T H :

WHEREAS, SLI conducts a business which develops pharmaceutical products using its oral drug delivery technologies for or in partnership with pharmaceutical companies and which consists of (i) predictive discovery lead selection and oral bioavailability screening, (ii) oral bioavailability enhancement, including solubility enhancement, permeation enhancement and efflux and protease protection, (iii) the development of oral controlled release formulations and (iv) the development of reduced abuse potential formulations (collectively, the "**Business**"); provided that the term "Business" shall not include the Retained Business (as defined herein);

WHEREAS, the parties desire to effect the contribution, sale and licensing of assets attributable to the Business currently conducted by SLI to Supernus, with a view towards Supernus carrying on the Business as a going concern in succession to SLI, in consideration for securities issued by Supernus and cash, upon the terms and subject to the conditions hereinafter set forth;

WHEREAS, concurrently herewith, Supernus, Shire LLC, an Affiliate (as defined herein) of SLI, and Guarantor have entered into (i) a License Agreement dated as of the date hereof relating to the license of Guanfacine (as defined herein) and (ii) a License Agreement dated as of the date hereof relating to the Compounds (as defined herein) being licensed to Shire LLC and its Affiliates (the licenses in clauses (i) and (ii), collectively, the "**Licenses**");

WHEREAS, concurrently herewith, Supernus, SLI and certain other parties have entered into a Series A Convertible Preferred Stock Purchase Agreement (the "**Stock Purchase Agreement**");

WHEREAS, concurrently herewith Supernus, Shire LLC and Guarantor have entered into an Ongoing Projects Agreement (as defined herein); and

WHEREAS, Guarantor has agreed to guarantee the obligations of SLI hereunder.

The parties hereto agree as follows:

Article 1.

DEFINITIONS

Section a. Definitions.

(i)The following terms, as used herein, have the following meanings:

"**Affiliate**" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by or is under common control with such Person, where "control" means the ownership of more than 50% of the issued share capital or other equity interest or the legal power to direct or cause the direction of such Person.

"**Amphetamine**" means (i) (±)-alpha-Methylbenzeneethanamine; (ii) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of (i); and (iii) any compound involving forming or breaking a bond or bonds with any of (i) or (ii) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of (i) or (ii).

"**Anagrelide**" means 6,7-Dichloro-1,5-dihydroimidazo-[2,1-b]quinazolin-2(3H)-one.

"**Business Day**" means a day, other than Saturday, Sunday or other day on which commercial banks in New York, New York are authorized or required by law to close.

"**Business Intellectual Property Rights**" means (i) the SLI Patents, (ii) the SLI Trademarks and Tradenames and (iii) the SLI Other Know-How.

"**Carbamazepine**" means (i) carbamazepine (5H-Dibenz{b,f}azepine-5-carboxyamide); (ii) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of (i); and (iii) any compound involving forming or breaking a bond or bonds with any of (i) or (ii) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of (i) or (ii); *provided* that the definition of Carbamazepine shall not include Oxcarbazepine.

"**Closing Date**" means the date of the Closing.

"**Code**" means the Internal Revenue Code of 1986, as amended.

"**Compound Fields**" means the research, development, formulation, testing, design, manufacture, use, offer to sell, sale, distribution, import and export of any pharmaceutical product containing any of the Compounds as an active ingredient.

"**Compounds**" means Amphetamine, Carbamazepine, Guanfacine, Lanthanum, and Mesalamine (each a "**Compound**" and collectively, the "**Compounds**").

"**Contract**" means any contract, agreement (including any confidential disclosure agreement), license, lease, sales or purchase order or other legally binding undertaking or commitment, whether written or oral.

"**Damages**" means any and all damage, loss and expense (including reasonable expenses of investigation and reasonable attorneys' fees and expenses in connection with any action, suit or proceeding whether involving a third party claim or solely between the parties hereto).

"**Effective Time**" means 12:01 a.m. (EST) on the Closing Date.

"**Environmental Laws**" means any statute, law (including common law), regulation, rule, judgment, order, injunction, permit or governmental restriction or requirement, in each case relating to the environment, or pollutants, contaminants, wastes or chemicals or any toxic, radioactive, ignitable, corrosive, reactive or otherwise hazardous substances, wastes or materials.

"**Environmental Liabilities**" means any and all liabilities, obligations or commitments arising in connection with or in any way relating to the Business (as currently or previously conducted), the Contributed Assets or any activities or operations occurring or conducted at the Real Property (including offsite disposal), whether accrued, contingent, absolute, determined, determinable or otherwise, which arise under or relate to any Environmental Law (and including any matter disclosed or required to be disclosed in Schedule 3.13).

"**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended and the rules and regulations promulgated thereunder.

"**ERISA Affiliate**" of any entity means any other entity which, together with such entity, would be treated as a single employer under Section 414 of the Code.

"**GAAP**" means generally accepted accounting principles in the United States.

"**Guanfacine**" means (i) guanfacine (N-(Aminoiminomethyl)-2,6-dichlorobenzeneacetamide); (ii) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of (i); and (iii) any compound

involving forming or breaking a bond or bonds with any of (i) or (ii) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of (i) or (ii).

"**IND**" means an Investigational New Drug Application.

"**Inventions**" means all writings, inventions, discoveries, improvements, Know-How, and other technology (including without limitation any proprietary biological or other materials, compounds or reagents and computer software), whether or not patentable or copyrightable, and any patent applications, patents or copyrights based thereon relating, in whole or in part, to the Compounds.

"**Intellectual Property Rights**" means patents, trademarks, service marks, trade names, internet domain names, rights in designs, copyright (including rights in computer software databases) and moral rights, utility models and other intellectual property rights, and all rights in and to Know-How, in each case whether registered or unregistered and including any applications for the grant of any such rights and all rights and forms of protection having an equivalent or similar effect anywhere in the world.

"**Know-How**" means any non-public information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including without limitation databases; ideas; discoveries; inventions; trade secrets; practices; methods; tests; assays; techniques; specifications; processes; formulations; formulae; knowledge; skill; experience; materials including pharmaceutical, chemical and biological materials; products; compositions; scientific, technical, or test data including without limitation pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, and stability data; studies; procedures; drawings; plans; designs; diagrams; sketches; technology; documentation; and patent-related and other legal information or descriptions.

"**Knowledge of SLI**," "**SLI's knowledge**" or any other similar knowledge qualification in this Agreement means to the actual knowledge of the individuals listed in Schedule 1.01(a).

"**Knowledge of Supernus**," "**Supernus' knowledge**" or any similar knowledge qualification in this Agreement means to the actual knowledge of the individuals listed in Schedule 1.01(b).

"**Lanthanum**" means (i) lanthanum; (ii) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of (i); and (iii) any compound involving forming or breaking a bond or bonds with any of (i) or (ii) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of (i) or (ii).

"**Lien**" means, with respect to any property or asset, any mortgage, lien, pledge, charge, security interest or encumbrance in respect of such property or asset.

"**Material Adverse Effect**" means a material adverse effect on the business, assets or results of operations of the Business, except any such effect resulting from or arising in connection with (i) this Agreement or the transactions contemplated hereby, (ii) changes or conditions affecting the pharmaceutical industry generally or (iii) changes in economic, regulatory or political conditions generally.

"**Mesalamine**" means (i) mesalamine (5-Amino-2-hydroxybenzoic acid); (ii) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of (i); and (iii) any compound involving forming or breaking a bond or bonds with any of (i) or (ii) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of (i) or (ii).

"**NDA**" means a New Drug Application.

"**Oxcarbazepine**" means 10,11-Dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide.

"**Ongoing Projects Agreement**" means the Ongoing Projects and Royalty Agreement between Supernus, Shire Development Inc. and Guarantor dated the date hereof.

"**Person**" means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

"**Pre-Closing Receivables**" means an amount in respect of any accounts, notes or other receivables arising from the conduct of the Business or the Retained Business that SLI or any of its Affiliates had invoiced to a third party prior to the Effective Time and which remain outstanding as of such time.

"**QA Agreement**" means the Quality Assurance Agreement among Supernus, Shire Development Inc. and Shire Pharmaceuticals Development Limited dated the date hereof.

"**Retained Business**" means the business of SLI and its Affiliates related to the research, development and commercialization of the Compounds or products based on the Compounds, including all Intellectual Property Rights of SLI and its Affiliates related to the Compounds (other than, for the avoidance of doubt, the SLI Other Know-How and other than the patent families identified as: (i) [[1]*], including US patent number [**]; and (ii) [**] and form part of the Business Intellectual Property Rights).

"**SLI Compound Know-How**" means Know-How relating, in whole or in part, to any of the Compounds, including their formulation development, stability, bioanalytics, testing, pharmacodynamics, pharmacokinetics, preclinical and clinical performance, manufacture, use, sale or design, and in which SLI or any of its Affiliates has any right or title as of the Effective Time.

"**SLI Other Know-How**" means Know-How, other than the SLI Compound Know-How, relating to the Business and in which SLI has any right or title as of the Effective Time.

"**SLI Patents**" means the patents and patent applications set forth on Schedule 3.10(a) together with all foreign equivalents thereof held in SLI's name.

"**SLI Trademarks and Tradenames**" means the trademarks, service marks, trade names, internet domain names, rights in designs and copyright (including rights in computer software databases) held in SLI's name and set forth on Schedule 3.10(a), together with the goodwill associated therewith.

"**Subsidiary**" means, with respect to any Person, any entity of which securities or other ownership interests having ordinary voting power to elect a majority of the board of directors or other persons performing similar functions are at the time directly or indirectly owned by such Person.

"**Supernus Consideration Shares**" means 4,000,000 shares of Supernus Preferred Stock.

"**Supernus Common Stock**" means the common stock, par value $.001 per share, of Supernus.

"**Supernus Preferred Stock**" means the Series A Convertible Preferred Stock, par value $.001 per share, of Supernus.

"**Transaction Documents**" means, collectively, (i) the Stock Purchase Agreement, (ii) the Ongoing Projects Agreement, (iii) the QA Agreement and (iv) the Licenses.

(ii)Each of the following terms is defined in the Section set forth opposite such term:

[[1]*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Term	Section
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Section b. Other Definitional and Interpretative Provisions

. Unless specified otherwise, in this Agreement the obligations of any party consisting of more than one person are joint and several. The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. References to Articles, Sections, Exhibits and Schedules are to Articles, Sections, Exhibits and Schedules of this Agreement unless otherwise specified. All Exhibits and Schedules annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. "Writing", "written" and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof. References to any Person include the successors and permitted assigns of that Person. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively.

Article 2.

TRANSACTIONS AT CLOSING

Section a. Contribution of Assets

. Except as otherwise provided below, upon the terms and subject to the conditions of this Agreement, SLI agrees to contribute, sell, convey, transfer, assign and deliver, or cause to be contributed, sold, conveyed, transferred, assigned and delivered, to Supernus at the Closing, free and clear of all Liens, other than Permitted Liens, all of SLI's right, title and interest in, to and under the following assets and properties, as the same shall exist at the Effective Time (the "Contributed Assets"):

(i)the Business Intellectual Property Rights; and

(ii)the other assets and properties of the Business owned, used or held for use by SLI that are not Intellectual Property Rights, including all right, title and interest of SLI in, to and under the following assets to the extent owned, used or held for use exclusively in the conduct of the Business:

(1) all personal property (including office and laboratory equipment) and interests therein;

(2) all raw materials, supplies and other inventories;

(3) all rights under all Contracts to which SLI is a party other than those relating to the Retained Assets, including those set forth on Schedule 3.06;

(4) all accounts, notes and other receivables arising after the Effective Time;

(5) all transferable licenses, permits or other governmental authorizations;

(6) all books, records, files and papers, whether in hard copy or computer format; provided that SLI shall be entitled to make and maintain copies of such books, records, files and papers; and

(7) all goodwill associated with the Contributed Assets, together with the right to represent to third parties that Supernus is the successor to the Business; provided that in no event shall the Contributed Assets include any Retained Asset.

Section b. Retained Assets

. Supernus expressly understands and agrees that the following assets and properties of SLI (the "**Retained Assets**") shall be retained by SLI and its Affiliates and not included in the Contributed Assets:

(i)all cash and cash equivalents, including any marketable securities, on hand and in banks and any security deposits in respect of any Retained Asset or Contributed Asset;

(ii)insurance policies relating to the Business or the Contributed Assets and all claims, credits, causes of action or rights thereunder;

(iii)all Intellectual Property Rights other than the Business Intellectual Property Rights (the "**Retained Intellectual Property Rights**"), including for the avoidance of doubt but without limiting the foregoing the patents and patent applications, together with all foreign equivalents thereof, and other items set forth on Schedule 2.02 and the SLI Compound Know-How;

(iv)the other property and assets of the Retained Business set forth on Schedule 2.02;

(v)all books, records, files and papers, whether in hard copy or computer format (i) used or held for use in the Retained Business or relating to any of the other Retained Assets, including all data, regulatory filings, quality assurance records, processes and manufacturing materials relating to the Compounds, (ii) related to the matters set forth on Schedules 3.07 or 6.01, including all documents and attorney work papers related thereto or (iii) prepared in connection with this Agreement or the transactions contemplated hereby;

(vi)all minute books and corporate records of SLI and its Affiliates;

(vii) the Pre-Closing Accrued Income and the Pre-Closing Receivables;

(viii)all Tax refunds or credits of the Business relating to the Pre-Closing Tax Period, whether received prior to or after the Effective Time; *provided* that SLI or its Affiliates paid the Tax in respect of such refund or credit;

(ix)all rights of SLI arising under this Agreement or any other Transaction Document to which it is a party or the transactions contemplated hereby or thereby;

(x)the Lease Agreement dated November 1, 2002 between ARE Acquisitions, LLC and SLI for the premises located at 1330 Piccard Drive, Rockville, Maryland; and

(xi)all prepaid expenses, including *ad valorem* taxes, leases and rentals (collectively, "**Prepaid Expenses**").

Section c. Assumed Liabilities

. Upon the terms and subject to the conditions of this Agreement, Supernus agrees, effective at the time of the Closing, to assume all liabilities and obligations of any kind, character or description (whether known or unknown, absolute, contingent or otherwise) relating to or arising out of the Contributed Assets or the conduct of the Business and, in each case, arising after the Effective Time, except for the Retained Liabilities (the "**Assumed Liabilities**").

Section d. Retained Liabilities

. Notwithstanding any provision in this Agreement or any other writing to the contrary, Supernus is assuming only the Assumed Liabilities and is not assuming any other liability or obligation of SLI or its Affiliates of whatever nature, whether in existence prior to the Effective Time or arising thereafter, including any liability or obligation set forth on Schedule 2.04, relating to the Retained Business or the Retained Assets or relating to the Contributed Assets or the Business and arising prior to the Effective Time. All such other liabilities and obligations shall be retained by and remain obligations and liabilities of SLI (all such liabilities and obligations not being assumed being herein referred to as the "**Retained Liabilities**").

Section e. Assignment of Contracts and Rights

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(i)Subject to the terms and conditions of this Agreement, promptly after the Closing, Supernus will use its reasonable best efforts to obtain the consent of any third party required to assign the Contributed Assets to Supernus and, if Supernus so requests, SLI shall use its reasonable best efforts to assist Supernus in obtaining such third party consents; provided that SLI shall not be required to make any payment or incur any liability in connection therewith other than in respect of a Retained Liability.

(ii)Notwithstanding any other provision of this Agreement to the contrary, this Agreement shall not constitute an agreement to assign any Contributed Asset or any right thereunder if an attempted assignment, without the consent of a third party, would constitute a breach or in any way adversely affect the rights of Supernus or SLI thereunder. If such consent is not obtained, SLI and Supernus will, if possible, (i) cooperate in a mutually agreeable arrangement under which Supernus would obtain the benefits and assume the obligations thereunder in accordance with this Agreement or (ii) take such other action or enter into such other arrangement in respect of such Contributed Asset as they may mutually agree.

Section f. Consideration; Allocation of Consideration.

(i)The consideration for the contribution of the Contributed Assets is (i) the Supernus Consideration Shares and (ii) $1,500,000 in cash (the "**Supernus Consideration Amount**" and, together with the Supernus Consideration Shares, the "**Supernus Consideration**"). The Supernus Consideration shall be delivered to SLI as provided in Section 2.07.

(ii)Supernus and SLI agree that the Supernus Consideration (plus Assumed Liabilities, to the extent properly taken into account under Section 1060 of the Code) shall be allocated in accordance with Schedule 2.06 (b).

SLI and Supernus agree to (i) be bound by the allocation set forth on Schedule 2,06 (b) and (ii) act in accordance with such allocation in the preparation, filing and audit of any Tax return (including filing Form 8594 with its federal income Tax return for the taxable year that includes the date of the Closing). Not later than 30 days prior to the filing of their respective Forms 8594 relating to this transaction, each party required to file such form shall deliver to the other parties hereto a copy of such form.

Section g. Closing

. The closing of the contribution of the Contributed Assets, the assumption of the Assumed Liabilities, the issuance of the Supernus Consideration Shares and the payment of the Supernus Consideration Amount hereunder (the "**Closing**") shall take place at the offices of Davis Polk & Wardwell, 450 Lexington Avenue, New York, New York, on the date hereof. At the Closing:

(i)Supernus shall issue to SLI certificates for the Supernus Consideration Shares pursuant to the Stock Purchase Agreement and shall register such shares in its corporate books.

(ii)Supernus shall deliver to SLI the Supernus Consideration Amount in immediately available funds by wire transfer to an account of SLI with a bank previously designated by SLI in writing to Supernus; provided that, at the request of SLI, the amount of such payment shall be less the amount payable by SLI to Supernus pursuant to a certain letter agreement dated the date hereof relating to the leased property at 1550 East Gude Drive, Rockville, Maryland.

(iii)SLI and Supernus shall enter into (i) an Assignment and Assumption Agreement substantially in the form attached hereto as Exhibit A, (ii) an Assignment of SLI Patents substantially in the form attached hereto as Exhibit B and (iii) subject to the provisions hereof, SLI shall deliver to Supernus such bills of sale, endorsements, consents, assignments and other good and sufficient instruments of conveyance and assignment as the parties and their respective counsel shall deem reasonably necessary to vest in Supernus all right, title and interest of SLI in, to and under the Contributed Assets, free and clear of any Liens, other than Permitted Liens.

(iv)Each of SLI and Supernus shall execute and deliver each Transaction Document to which it is a party to each other party to such Transaction Document.

(v)SLI shall deliver a certification signed under penalties of perjury that it is not a "foreign person" as defined in Section 1445 of the Code.

(vi)(i) Supernus shall have received all documents it may reasonably request relating to the existence of SLI and the authority of SLI to enter into this Agreement and consummate the transactions contemplated hereby, all in form and substance reasonably satisfactory to Supernus and (ii) SLI shall have received all documents it may reasonably request relating to the existence of Supernus and the authority of Supernus to enter into this Agreement and consummate the transactions contemplated hereby, all in form and substance reasonably satisfactory to SLI.

Section h. License to the SLI Compound Know-How

. SLI hereby grants to Supernus and its Affiliates, a paid-up, worldwide, irrevocable, exclusive (except as to SLI and its Affiliates) license under the SLI Compound Know-How relating to the Business for any use outside the Compound Fields to conduct any business with respect to any compounds other than the Compounds. The grant of the license in this Section 2.08 includes the right to grant sublicenses to third parties and to appoint distribution and independent sales organizations or representatives under the rights granted to Supernus or its Affiliates. Such grant to Supernus and its Affiliates, and the right to grant sublicenses, is subject to the restrictions and obligations set forth in Section 6.04. As used in this Section 2.08, an "exclusive (except as to SLI and its Affiliates) license" means that SLI shall not grant any other entity any license under such SLI Compound Know-How other than in respect of the Compounds, but that SLI and its Affiliates retain all of their rights, including but not limited to any rights to practice the rights and ownership of such SLI Compound Know-How, in all fields. It is understood and

agreed that this Section 2.08 does not grant Supernus or its Affiliates any right other than as specified in this Section 2.08 in any intellectual property of SLI or its Affiliates, nor the right to sue.

Section i. Access for Possession of Retained Assets

. As soon as practicable after the Closing, Supernus will afford to SLI, its Affiliates and their respective authorized representatives such access to Supernus' offices, properties, books, records, employees and auditors as may be reasonably necessary or appropriate to permit SLI and its Affiliates to obtain possession of all Retained Assets, including those referred to in Section 2.02(e).

Article 3.

REPRESENTATIONS AND WARRANTIES OF SLI

Except as set forth in the Disclosure Schedules to this Agreement, SLI represents and warrants to Supernus as of the date hereof that:

Section a. Corporate Existence and Power

. SLI is a corporation duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation.

Section b. Corporate Authorization

. The execution, delivery and performance by SLI of this Agreement and each Transaction Document to which it is a party and the consummation of the transactions contemplated hereby and thereby are within SLI's corporate powers and have been duly authorized by all necessary corporate action on the part of SLI. This Agreement and each Transaction Document to which it is a party constitutes a valid and binding agreement of SLI.

Section c. Governmental Authorization

. The execution, delivery and performance by SLI of this Agreement and each Transaction Document to which it is a party and the consummation of the transactions contemplated hereby and thereby require no action by or in respect of, or filing with, any governmental body, agency or official other than (i) in relation to NDAs and INDs in SLI's name, notifications to be made to the U. S. Food and Drug Administration (and competent regulatory authorities in other counties) of the transaction and consequent change of principal office address of SLI, (ii) any such actions or filings as to which the failure to make or obtain would not have, or would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect and (iii) any filings or notices not required to be made or given until after the Closing Date.

Section d. Noncontravention

. The execution, delivery and performance by SLI of this Agreement and each Transaction Document to which it is a party and the consummation of the transactions contemplated hereby and thereby do not and will not (i) violate the certificate of incorporation or bylaws of SLI, (ii) assuming compliance with the matters referred to in Section 3.03, violate any applicable law, (iii) assuming the obtaining of all Required Consents, to SLI's knowledge, constitute a default under or give rise to any right of termination, cancellation or acceleration of any right or obligation or to a loss of any benefit relating to the Business to which SLI is entitled under any provision of any agreement or other instrument binding upon SLI or (iv) result in the creation or imposition of any Lien on any Contributed Asset, except in the case of clause (ii), (iii) or (iv) for such matters as would not have, individually or in the aggregate, a Material Adverse Effect.

Section e. Required Consents

. Schedule 3.05 sets forth each Contract binding upon SLI requiring a consent or other action by any Person as a result of the execution, delivery and performance of this Agreement, except such consents or actions that would not have, or would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect if not received or taken by the Closing Date (the "**Required Consents**").

Section f. Material Contracts.

(i)Except for the Contracts disclosed in Schedule 3.06 (collectively, the "Material Contracts"), with respect to the Business, SLI is not a party to or bound by:

(1) any lease (whether of real or personal property) providing for annual rentals of S 50,000 or more that cannot be terminated on not more than 60 days' notice without payment by SLI of any material penalty;

(2) any agreement for the purchase of materials, supplies, goods, services, equipment or other assets providing for either (A) annual payments by SLI of $50,000 or more or (B) aggregate payments by SLI of $50,000 or more, in each case that cannot be terminated on not more than 60 days' notice without payment by SLI of any material penalty;

(3) any sales, distribution or other similar agreement providing for the sale by SLI of materials, supplies, goods, services, equipment or other assets that provides for annual payments to SLI of $100,000 or more;

(4) any material partnership, joint venture or other similar agreement;

(5) any agreement relating to the acquisition or disposition of any business (whether by merger, sale of stock, sale of assets or otherwise);

(6) any agreement relating to indebtedness for borrowed SLI money or the deferred purchase price of property (in either case, whether incurred, assumed, guaranteed or secured by any asset), except any such agreement with an aggregate outstanding principal amount not exceeding $50,000;

(7) any agreement, other than this Agreement and the Transaction Documents, that limits in any material respect the freedom of SLI or the Business to compete in any line of business or with any Person or in any area; or

(8) any material agreement with or for the benefit of any Affiliate of SLI.

(ii)Each Material Contract required to be disclosed pursuant to this Section is a valid and binding agreement of SLI and is in full force and effect, and none of SLI or, to the Knowledge of SLI, any other party thereto is in default or breach in any respect under the terms of any such Material Contract, except for any such defaults or breaches which would not have, or would not be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

Section g. Litigation

. Except for the matters disclosed in Schedule 3.07, there is no action, suit, investigation or proceeding pending against, or to the Knowledge of SLI, threatened against or affecting, SLI or the Business before any court or arbitrator or any governmental body, agency or official which is reasonably likely to have a Material Adverse Effect or which in any manner challenges or seeks to prevent, enjoin, alter or materially delay the transactions contemplated by this Agreement.

Section h. Compliance with Laws and Court Orders

. SLI is not in violation of any law, rule, regulation, judgment, injunction, order or decree applicable to the Contributed Assets or the conduct of the Business, except for violations that have not had and would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect,

Section i. Properties.

(i)Schedule 3.09(a) correctly describes all real property used or held for use exclusively in the Business which SLI owns, leases, operates or subleases (the "**Real Property**").

(ii)SLI has good title to, or in the case of any leased Real Property or personal property has valid leasehold interests in, all Contributed Assets, except for properties and assets where the failure to have such good title or valid leasehold interests is not material to such properties or assets or to the Business. No Contributed Asset is subject to any Lien, except:

(1) Liens disclosed on Schedule 3.09(b);

(2) Liens for taxes, assessments and similar charges that arc not yet due or are being contested in good faith;

(3) mechanic's, materialman's, carrier's, repairer's and other similar Liens arising or incurred in the ordinary course of business or that are not yet due and payable or arc being contested in good faith; or

(4) Liens incurred in the ordinary course of business (clauses (i) through (iv) of this Section 3.09(b) are, collectively, the "**Permitted Liens**").

Section j. Intellectual Property.

(i)Schedule 3.10(a) contains a list of the SLI Patents and the SLI Trademarks and Tradenames included in the Business Intellectual Property Rights.

(ii)Schedule 3.10(b) sets forth a list of all agreements (excluding customer agreements entered into in the ordinary course of business) as to which SLI is a party and pursuant to which any Person is authorized to use any material Business Intellectual Property Right.

(iii)To the Knowledge of SLI, except for the Retained Intellectual Property Rights, the Business Intellectual Property Rights and the license to the SLI Compound Know-How granted pursuant to Section 2.08 together constitute all the Intellectual Property Rights necessary for the conduct of the Business as currently conducted, other than rights in respect of third party commercial computer software.

(iv)SLI has not received any written notice of infringement of or conflict with the rights of others with respect to the use of any of the Business Intellectual Property Rights.

(v)No Business Intellectual Property Right is subject to any outstanding judgment, injunction, order or decree restricting the use thereof by SLI with respect to the Business.

Section k. Insurance Coverage

. SLI has made available to Supernus a list of, and true and complete copies of, all insurance policies and fidelity bonds relating to the Contributed Assets, the Business and its officers and employees.

Section l. Employee Benefit Plans.

(i)SLI has made available to Supernus a list and copies of each material "employee benefit plan", as defined in Section 3(3) of ERISA, each employment, severance or similar contract, plan arrangement or policy and each other plan or arrangement providing for compensation, bonuses, profit-sharing, stock option or other stock related rights or other forms of incentive or deferred compensation, vacation benefits, insurance (including any self-insured arrangements), health or medical benefits, employee assistance program, disability or sick leave benefits, workers' compensation, supplemental unemployment benefits, severance benefits and post-employment or retirement benefits (including compensation, pension, health, medical or life insurance benefits) which is maintained, administered or contributed to by SLI or any of its ERISA Affiliates and covers any individual employed by SLI. Such plans are referred to collectively herein as the "**SLI Plans**".

(ii)Except as otherwise provided in this Agreement, no facts or circumstances exist which would reasonably be expected to impose upon Supernus any liability or obligation with respect to any current or former employee benefit plan sponsored, maintained or contributed to SLI or any ERISA Affiliate of SLI or any predecessor thereof.

Section m. Environmental Compliance

. Except as disclosed on Schedule 3.13 and as to matters that would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect:

(i)(i) no written notice, order, request for information, complaint or penalty has been received by SLI, and (ii) there are no judicial, administrative or other actions, suits or proceedings pending or threatened, in the case of each of (i) and (ii), which allege a violation of any Environmental Law and relate to the Contributed Assets or Real Property;

(ii)SLI has obtained or caused to be obtained all environmental permits necessary for the operation of the Contributed Assets and the Real Property to comply with all applicable Environmental Laws (as in effect on the date hereof) and SLI is in compliance with the terms of such permits and, with respect to the operation of the Contributed Assets and the Real Property, with all other applicable Environmental Laws (as in effect on the date hereof); and

(iii)there has been no written environmental audit conducted within the past five years by SLI of any Contributed Asset or any of the Real Property which has not been made available to Supernus prior to the date hereof.

Section n. Title to the Contributed Assets

. Upon consummation of the transactions contemplated hereby, Supernus will have acquired good title in and to, or a valid leasehold interest in, each of the Contributed Assets, free and clear of all Liens, except for Permitted Liens, and the right to use the Contributed Assets, subject to the terms and conditions of this Agreement, the Transaction Documents and Contracts with third parties that are in respect of or relate to the Contributed Assets.

Article 4.

REPRESENTATIONS AND WARRANTIES OF SUPERNUS

In addition to the representations and warranties being made by Supernus to the Purchasers (as defined in the Stock Purchase Agreement) in the Stock Purchase Agreement, Supernus represents and warrants to SLI as of the date hereof that:

Section a. Corporate Existence and Power

. Supernus is a corporation duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation and has all corporate powers and all material governmental licenses, authorizations, permits, consents and approvals required to carry on its business as now conducted.

Section b. Corporate Authorization

. The execution, delivery and performance by Supernus of this Agreement and each Transaction Document to which it is a party and the consummation of the transactions contemplated hereby and thereby are within the corporate powers of Supernus and have been duly authorized by all necessary corporate action on the part of Supernus. This Agreement and each Transaction Document to which it is a party constitutes a valid and binding agreement of Supernus.

Section c. Governmental Authorization

. The execution, delivery and performance by Supernus of this Agreement and each Transaction Document to which it is a party and the consummation of the transactions contemplated hereby and thereby require no material action by or in respect of, or material filing with, any governmental body, agency or official.

Section d. Noncontravention

. The execution, delivery and performance by Supernus of this Agreement and each Transaction Document to which it is a patty and the consummation of the transactions contemplated hereby and thereby do not and will not (i) violate the certificate of incorporation or bylaws of Supernus or (ii) assuming compliance with the matters referred to in Section 4.03, violate any applicable law, rule, regulation, judgment, injunction, order or decree.

Section e. Capitalization; Issuance of Supernus Consideration Shares.

(i)The authorized capital stock of Supernus consists of 52,000,000 shares of Supernus Common Stock and 39,000,000 shares of Supernus Preferred Stock. Immediately prior to the consummation of the transactions contemplated hereby and by the Stock Purchase Agreement, there are outstanding 6,500,000 shares of Supernus Common Stock and no shares of Supernus Preferred Stock.

(ii)All outstanding shares of capital stock of Supernus have been duly authorized and validly issued and are fully paid and non-assessable. Except as set forth in this Section 4.05, there are no outstanding (i) shares of capital stock or voting securities of Supernus, (ii) securities of Supernus convertible into or exchangeable for shares of capital stock or voting securities of Supernus or (iii) options or other rights to acquire from Supernus, or other obligation of Supernus to issue, any capital stock, voting securities or securities convertible into or exchangeable for capital stock or voting securities of Supernus (the items in Sections 4.05(b)(i), 4.05(b)(ii) and 4.05(b)(iii) being referred to collectively as the "**Supernus Securities**"). There are no outstanding obligations of Supernus to repurchase, redeem or otherwise acquire any Supernus Securities.

(iii)Schedule 4.05(c) lists, for each holder of any Supernus Securities (i) the identity of such holder, (ii) the type and amount of Supernus Securities held by such holder and (iii) the percentage of such holder's fully diluted equity interest in Supernus, in each case, immediately after the consummation of the transactions contemplated hereby and by the Stock Purchase Agreement.

(iv)Upon issuance of the Supernus Consideration Shares, the Supernus Consideration Shares shall be duly authorized and validly issued and will be fully paid and non-assessable.

Section f. Litigation

. There is no action, suit, investigation or proceeding pending against, or to the Knowledge of Supernus threatened against or affecting, Supernus before any court or arbitrator or any governmental body, agency or official which in any manner challenges or seeks to prevent, enjoin, alter or materially delay the transactions contemplated by this Agreement or any Transaction Document to which it is a party.

Section g. No Prior Activities

. Supernus has not engaged in any activities or incurred any liabilities other than in connection with its incorporation, this Agreement and the other Transaction Documents to which it is a party and the transactions contemplated hereby and thereby.

Section h. Representations of SLI

. Neither Supernus nor any of its Affiliates has any knowledge, or any reason to believe, that any representation or warranty made by SLI pursuant to this Agreement is not true and correct.

Section i. Inspections; No Other Representations

. Supernus, together with its expert advisors, is an informed and sophisticated purchaser, experienced in the evaluation and purchase of property and assets such as the Contributed Assets as contemplated hereunder. Supernus, together with its expert advisors has undertaken such investigation and has been provided with and has evaluated such documents and information as it has deemed necessary to enable it to make an informed and intelligent decision with respect to the execution, delivery and performance of this Agreement. Supernus acknowledges that SLI has given Supernus complete and open access to the key employees, documents and facilities of the Business. Supernus agrees to accept the Contributed Assets and the Business in the condition they are in on the Closing Date based on its own inspection, examination and determination with respect to all matters and without reliance upon any express or implied representations or warranties of any nature made by or on behalf of or imputed to SLI, except as expressly set forth in this Agreement. Without limiting the generality of the foregoing, Supernus acknowledges that no representation or warranty is made by either SLI or any of its Affiliates with respect to (i) any projections, estimates or budgets delivered to or made available to Supernus of future revenues, future results of operations (or any component thereof), future cash flows or future financial condition (or any component thereof) of the Business or the future business and operations of the Business or (ii) any other information or documents made available to Supernus or its counsel, accountants or advisors with respect to the Business, except as expressly set forth in this Agreement.

Article 5.

COVENANTS OF SLI

Section a. Access to Information

. On and after the Closing Date, SLI will afford to Supernus and its agents reasonable access to its books of account, financial and other records (including accountant's work papers), information, employees and auditors to the extent necessary for Supernus in connection with any audit, investigation, dispute or litigation or any other reasonable business purpose relating to the Business or the Contributed Assets; provided that any such access by Supernus shall not unreasonably interfere with the conduct of the business of SLI or its Affiliates.

Section b. SLI Trademarks and Tradenames

. After the Closing, SLI shall cooperate with Supernus to effect the transfer of the SLI Trademarks and Tradenames to Supernus.

Section c. Confidentiality.

(i)After the Closing, SLI and its Affiliates will hold, will cause their respective officers, directors and employees to hold, and will use their best efforts to cause their respective accountants, counsel, consultants, advisors and agents to hold, in confidence, all confidential documents and information as of the Effective Time concerning the Business or relating to any of the Contributed Assets (including all data, regulatory filings, quality assurance records, processes, and manufacturing materials relating to the Contributed Assets or the Business), whether furnished to SLI or its Affiliates in connection with the transactions contemplated by this Agreement or any Transaction Document or in the possession of, or known by, any current employee of any Affiliate of SLI who had previously worked at SLI prior to the Closing Date, except to the extent that such information (i) can be shown to

have been in the public domain through no fault of SLI or any of its Affiliates, (ii) can be shown to have been later lawfully acquired by SLI or any of its Affiliates from sources other than Supernus, (iii) relates to the Retained Business or the Retained Assets or any continuing business of SLI and its Affiliates; provided that, if any such information is the subject of a separate written confidentiality obligation between Supernus and any Affiliate of SLI, any obligations of SLI and its Affiliates regarding such information shall be governed by the terms of such other confidentiality obligation, (iv) relates to any Retained Liability and may reasonably be necessary in the satisfaction of or resolution of any dispute involving such Retained Liability and (v) relates to any past, present or future products of SLI or any of its Affiliates and may reasonably be necessary or may be required in connection with the development, manufacturing, offer for sale, sale, distribution, importation or exportation of such products or may reasonably be requested or may be required by any governmental agency or authority (collectively, "**Supernus Confidential Information**"). SLI shall be responsible for any failure to treat any Supernus Confidential Information confidentially by such Persons.

(ii)Notwithstanding the restriction set forth in Section 5.03(a) to the contrary, SLI may disclose Supernus Confidential Information (i) to its Affiliates, potential and actual sublicensees, consultants, outside contractors, clinical investigators, and other third parties, on a need-to-know basis; provided that such Persons shall only use the Supernus Confidential Information for purposes specifically authorized by this Agreement, (ii) to its attorneys, accountants, and advisors who are bound by a professional duty of confidentiality (it being understood that any sublicensee referred to in clause (i) above may disclose the relevant Supernus Confidential Information to its attorneys, accountants, and advisors who are bound by a professional duty of confidentiality), (iii) to government or other regulatory authorities to the extent that such disclosure is reasonably necessary to obtain intellectual property protection or authorizations to conduct clinical trials of, and to commercially market, products; provided that SLI or its Affiliates requests confidential treatment, if it is available, with respect to such Supernus Confidential Information, and (iv) pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demands issued by a court or governmental agency or as otherwise required by applicable law or regulation (including the rules of any national securities exchange or listing authority to which it or its Affiliates are subject or submit); provided that SLI shall, where legally permissible, notify Supernus promptly upon receipt thereof, giving Supernus, where legally permissible, sufficient advance notice to permit it to seek a protective order or other similar order with respect to such Supernus Confidential Information; and provided, further, that SLI shall furnish only that portion of such Supernus Confidential Information which it is advised by counsel is legally required whether or not a protective order or other similar order is obtained by Supernus.

Section d. Non-Solicit

. SLI agrees that for a period of four years after the Closing Date, neither it nor any of its Affiliates shall solicit for employment any employee of Supernus or any of its Subsidiaries or induce any such employee to terminate his or her employment with Supernus or any of its Subsidiaries; provided that general advertisement for employment in newspapers, magazines, trade publications or other public media (including the Internet) shall not be considered solicitation for employment.

Article 6.

COVENANTS OF SUPERNUS

Section a. Access; Cooperation

. On and after the Closing Date, Supernus will afford to SLI, its Affiliates and their respective counsel, auditors and other authorized representatives reasonable access to its offices, properties, books, records, employees and auditors to the extent relating to the Retained Assets or the Retained Liabilities or necessary to permit SLI to determine any matter relating to its rights and obligations for the period ending on or prior to the Closing Date; provided that any such access by SLI shall not unreasonably interfere with the conduct of the business of Supernus. Without limiting the foregoing, Supernus will, and will cause its employees, officers and advisers to, cooperate with and provide assistance to SLI and its Affiliates in connection with (i) determining any amounts owed to SLI pursuant to Section 7.05 and (ii) the litigation matters set forth on Schedule 6.01, including preserving and retaining records, and furnishing records, information and testimony, and attending conferences, discovery proceedings,

hearings, trials or appeals; provided that, with respect to clause (ii) above, Supernus shall be reimbursed by SLI or one of its Affiliates for the time reasonably spent by any of its employees cooperating with or providing assistance to SLI and its Affiliates in connection with such litigation, at the FTE Rate (as defined in the Ongoing Projects Agreement) for such time, and for any out-of-pocket expenses reasonably incurred by Supernus or its employees in connection therewith.

Section b. Trademarks; Tradenames.

(i)Except as set forth in Section 6.02(b), after the Closing, Supernus and its Affiliates shall not use any of the trademarks, service marks or tradenames that are part of the Retained Intellectual Property Rights.

(ii)Supernus shall have the right to use existing packaging, labeling, containers, supplies, logos and advertising materials bearing the name "Shire Laboratories" or "SLI" for a period not to exceed six months following the Closing Date. All goodwill from such use by Supernus shall accrue to the benefit of SLI and its Affiliates, and all such use shall conform to any trademark usage guidelines provided by SLI. Supernus shall comply with all applicable laws in any use of packaging or labeling containing the name "Shire Laboratories" or "SLI".

(iii)If Supernus violates any provision of this Section 6.02 or if, in the reasonable view of SLI or its Affiliates, Supernus deviates from the permissible scope of use in connection with or the manner and nature of the permitted use of the names "Shire Laboratories" or "SLI", SLI or its Affiliates shall provide Supernus written notice of the violation and/or deviation from the permissible standard and allow Supernus ten Business Days from receipt of the written notice to cure such violation and/or deviation. If, after ten Business Days from receipt of the written notice of the violation and/or deviation, Supernus has not cured such violation and/or deviation to the reasonable satisfaction of SLI or its Affiliate that provided the notice, SLI or its Affiliates may immediately terminate Supernus's right to use such names and Supernus shall permanently and immediately discontinue all use of such names. The parties acknowledge and agree that a violation of any provision of this Section 6.02 will cause SLI and its Affiliates irreparable injury and that if Supernus does not cure the violation within the specified time period, SLI and its Affiliates shall be entitled to seek emergency relief from a federal or state court to enforce the terms of this Agreement.

Section c. Confidentiality.

(i)After the Closing, Supernus and its Affiliates will hold, will cause their respective officers, directors and employees to hold, and will use their best efforts to cause their respective accountants, counsel, consultants, advisors and agents to hold, in confidence, all confidential documents and information concerning the Retained Business or relating to any of the Retained Assets (including all data, regulatory filings, quality assurance records, processes, dissolution methodologies and manufacturing materials relating to the Compounds), whether furnished to Supernus or its Affiliates in connection with the transactions contemplated by this Agreement or any Transaction Document or in the possession of, or known by, any Transferred Employee on or prior to the Closing Date, except to the extent that such information can be shown to have been (i) in the public domain through no fault of Supernus, its Affiliates or any Transferred Employee, (ii) later lawfully acquired by Supernus from sources other than SLI, any Transferred Employee or any other current or former employee of SLI or its Affiliates or (iii) relates solely to the Business or the Contributed Assets and not in any respect to the Retained Business or the Retained Assets; provided that, if any such information is the subject of a separate written confidentiality obligation between Supernus and any Affiliate of SLI, any obligations of Supernus and its Affiliates regarding such information shall be governed by the terms of such other confidentiality obligation (collectively, "**SLI Confidential Information**"). Supernus shall be responsible for any failure to treat SLI Confidential Information confidentially by such Persons.

(ii)Notwithstanding the restriction set forth in Section 6.03(a) to the contrary, Supernus may disclose SLI Confidential Information related to the SLI Compound Know-How (i) to its Affiliates, potential and actual sublicensees, consultants, outside contractors, clinical investigators, and other third parties, on a need-to-know basis; provided that such Persons shall only use any such SLI Confidential Information for purposes specifically authorized by this Agreement, (ii) to its attorneys, accountants, and advisors who are bound by a professional duty

of confidentiality (it being understood that any sublicensee referred to in clause (i) above may disclose such SLI Confidential Information to its attorneys, accountants, and advisors who are bound by a professional duty of confidentiality), (iii) to government or other regulatory authorities to the extent that such disclosure is reasonably necessary to obtain authorizations to conduct clinical trials of, and to commercially market, products; provided that Supernus requests confidential treatment, if it is available, with respect to such SLI Confidential Information, (iv) pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demands issued by a court or governmental agency or as otherwise required by applicable law or regulation (including the rules of any national securities exchange or listing authority to which it or its Affiliates are subject or submit); provided that Supernus shall, where legally permissible, notify SLI promptly upon receipt thereof, giving SLI, where legally permissible, sufficient advance notice to permit it to seek a protective order or other similar order with respect to such SLI Confidential Information; and provided, further, that Supernus shall furnish only that portion of such SLI Confidential Information which it is advised by counsel is legally required whether or not a protective order or other similar order is obtained by SLI and (v) related to improvements to the Business for the purpose of filing patent applications; provided that such disclosure does not disclose confidential information concerning the Retained Business or relating to any of the Retained Assets (including all data, regulatory filings, quality assurance records, processes, dissolution methodologies and manufacturing materials relating to the Compounds).

Section d. Restriction on Use

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(i)Supernus agrees that, except for activities conducted pursuant to contracts or agreements with SLI or any of its Affiliates, from time to time, neither Supernus nor any of its Restricted Affiliates shall engage in any research, formulation development, testing, manufacture, offer for sale, sale, distribution, importation, exportation, design, analytical testing, technology assessment or oral bioavailability screening, enhancement or other activities that relate, in whole or in part, to any of the Compounds in any field of use, either directly or indirectly, including as a principal or for its own account or solely or jointly with others, or as a stockholder in any corporation or joint stock association, as a partner, member, joint venturer, joint researcher, joint sponsor, joint promoter, joint marketer, joint developer, collaborator or other equity interest holder in a partnership, a limited liability company or other Person, or as a licensor of Intellectual Property Rights (or otherwise aid or assist any Person in connection with any of the foregoing); provided, however, subject to Section 6.04(g), Supernus may provide services to, license Intellectual Property Rights in the ordinary course of business to, or otherwise work with, providing such services, license or work is unrelated to any of the Compounds, any Person who has, without any prior contact with or assistance from Supernus, any of its Affiliates or any Transferred Employee, independently engaged in (or who has the present intention to engage in) any research, formulation development, testing, manufacture, offer for sale, sale, distribution, importation, exportation, design, analytical testing, technology assessment or oral bioavailability screening, enhancement or other activities that relate, in whole or in part, to any of the Compounds in any field of use, either directly or indirectly ("**Independent Compound Activities**"), so long as (i) Supernus, its Affiliates and the Transferred Employees are and remain in compliance with Section 6.03 and this Section 6.04, and the provision of such services or such other work does not contravene Section 6.03 or this Section 6.04, (ii) Supernus and its Affiliates comply with Section 6.04(b) and (iii) also, in the case of a license, the scope and terms of the license between Supernus and such Person are sufficient to ensure that the licensee cannot use the Business Intellectual Property Rights in a manner inconsistent with Section 6.03 or this Section 6.04. For purposes of this Section 6.04(a) and Section 6.05, "**Restricted Affiliates**" means Affiliates of Supernus other than investors who are investing in Supernus pursuant to the Stock Purchase Agreement and future financial investors in equity or debt of Supernus, in either case, who are not or who do not become a Successor Business Entity.

(ii)Supernus hereby agrees that, from and after the Closing, it shall not provide any services to, license any Business Intellectual Property Rights to, or otherwise perform any work for, any Person (each such Person, a "**Customer**") unless the contract or agreement relating to such services, license or work (each such contract or agreement, a "**Customer Contract**") between Supernus and the Customer contains the provisions set forth in Exhibit D (the "**Shire-Related Customer Provisions**"). Supernus further agrees that, from and after the Closing, (i) it shall not amend or waive, in whole or in part, any of the Shire-Related Customer Provisions in any Customer Contract, without the prior written consent of Shire, (ii) it shall from time to time and upon the request of

SLI (or such other entity as may be designated by Guarantor) provide SLI and its Affiliates, for monitoring purposes, with a list of all Customers, (iii) if SLI or any of its Affiliates in its sole discretion believes that there may be, or may have been, a breach or threatened breach of the Shire-Related Customer Provisions under any Customer Contract, at the written request of SLI (or such other entity as may be designated by Guarantor), Supernus shall provide SLI and its Affiliates with an executed copy of the relevant Customer Contract and (iv) it shall indemnify and hold harmless SLI and its Affiliates against any and all Damages suffered by SLI and its Affiliates as a result of a breach of the Shire-Related Customer Provisions by any Customer, if and to the extent that any of Shire-Related Customer Provisions in the Customer Contract that SLI or any of its Affiliates is seeking to enforce shall for any reason be held invalid, illegal or unenforceable in any respect. SLI and its Affiliates agree to keep the information in any Customer Contract confidential in accordance with the provisions of Section 5.03, except to the extent reasonably necessary or appropriate for SLI or any of its Affiliates to enforce its rights and/or pursue its remedies under or with respect to such Customer Contract.

(iii)Supernus may sell, assign, or otherwise transfer any Business Intellectual Property Rights to any of its Subsidiaries so long as such Subsidiary expressly agrees in writing with SLI or such other entity as designated by Guarantor as a prior condition to such sale, assignment or other transfer to be bound by the terms of Section 6.03 and this Section 6.04.

(iv)Supernus or any of its Affiliates may, subject to Section 6.04(g), enter into and consummate any transaction involving a direct or indirect sale, assignment, transfer or other disposition of all or any part of the Business or the Business Intellectual Property Rights (a "**Subsequent Transaction**"), provided that, as a condition to entering into any such Subsequent Transaction, any acquiror, successor, assignee or direct or indirect transferee of all or such part of the Business or the Business Intellectual Property Rights (each such acquiror, successor, assignee or direct or indirect transferee, a "**Successor Business Entity**") shall have expressly agreed in writing with SLI or such other entity as designated by Guarantor that such Successor Business Entity shall comply with, and, as applicable, shall cause Supernus (or its successor), the Subsidiaries of Supernus, if any, in existence immediately prior to such Subsequent Transaction, and the Affiliates of the Successor Business Entity to comply with, the terms of Section 6.03 and this Section 6.04. The provisions of this Section 6.04 shall apply mutatis mutandis to each Subsequent Transaction and any and all Successor Business Entities as if it were Supernus hereunder.

(v)Supernus shall, and as a further condition to entering into any Subsequent Transaction each Successor Business Entity shall have expressly agreed in writing with SLI (or such other entity as may be designated by Guarantor) that such Successor Business Entity shall, provide to SLI (or such other entity as may be designated by Guarantor) on an annual basis within 30 days of the end of the calendar year a certificate signed by its chief executive officer, chief financial officer or general counsel certifying the compliance of Supernus and its Affiliates or such Successor Business Entity and its Affiliates, as the case may be, with all of their obligations under Section 6.03 and this Section 6.04.

(vi)For the avoidance of doubt, to the extent that any Successor Business Entity or any Affiliate of a Successor Business Entity (an "**SBE Affiliate**") is, prior to closing of any Subsequent Transaction, without any prior assistance from Supernus, any of its Affiliates or any Transferred Employee, independently engaged in (or who has the present intention to engage in) any Independent Compound Activities, the Independent Compound Activities of such Successor Business Entity or SBE Affiliate shall not constitute a breach of Section 6.03 or this Section 6.04 so long as (i) the Business and the Business Intellectual Property Rights are held separate by the Successor Business Entity or SBE Affiliate from, and are not used in connection with, any Independent Compound Activities, (ii) all non-public information concerning the Business Intellectual Property Rights relating to the Compounds is kept confidential from any Successor Business Entity or SBE Affiliate engaged in any Independent Compound Activities and is not used in any manner by any Successor Business Entity or SBE Affiliate in connection with any Independent Compound Activities and (iii) SLI (or such other entity as may be designated by Guarantor) has received in a timely manner the certification required by Section 6.04(e). The parties hereto agree that the obligation to "hold separate" shall not require a separate physical location provided that the Successor Business Entity or SBE Affiliate has otherwise taken all steps necessary and appropriate to ensure compliance with Section 6.03 and this Section 6.04.

(vii)Notwithstanding any other provisions of this Section 6.04, for a period of seven years from the Closing Date, Supernus agrees that neither Supernus nor any of its Subsidiaries shall, directly or indirectly (i) provide any services to or on behalf of, license any Intellectual Property Rights to, or otherwise work with or for, any of the Persons set forth on Schedule 6.04(g) (the "**Specified Persons**"), their successors or any of their Affiliates or (ii) enter into any business combination or merge or consolidate with, be acquired by, or enter into any joint venture, joint research, joint sponsorship, joint promotion, joint development, collaboration or Subsequent Transaction with any of the Specified Persons, their successors or any of their Affiliates.

Section e. Waiver

. Except as otherwise specifically set forth in this Agreement (including Supernus' right of indemnification pursuant to Section 10.02(a)), Supernus agrees not to, and agrees to cause its Restricted Affiliates not to, either alone or in cooperation with any third party, sue or to bring any cause of action in any court, patent office or other forum (including those for any type of infringement invalidity, or unenforceability of any Intellectual Property Rights), against SLI or any of its Affiliates or any of their respective officers, directors, employees, agents, representatives, distributors, salespersons, customers, licensees, and/or end-users to prevent, inhibit, financially affect or encumber in any manner any of the activities of SLI or any of its Affiliates related, in whole or in part, to the research, development, manufacture, use, offer to sell, sale, distribution, import, and export of any compound(s), composition(s), article(s), material(s), method(s), use(s), or product(s) relating, in whole or in part, to the Compounds. For the avoidance of doubt, the provisions of this Section 6.05 shall not affect the rights and obligations of Supernus or any of its Affiliates under the Ongoing Projects Agreement or the Licenses in the event of an alleged breach of any of these agreements by SLI or any of its Affiliates.

Section f. First Right Regarding [[2]].*

(i)Supernus hereby grants to SLI or its designated Affiliate the first right to enter into a license under all Intellectual Property Rights of Supernus and its Affiliates relating to any oral formulation for [**] which Supernus or any of its Affiliates proposes to commercialize or to grant rights in to any third party. If Supernus or any of its Affiliates proposes to commercialize or grant any rights to any third party relating to any oral formulation of [**], Supernus shall notify SLI in writing of such proposal. The notice shall (i) provide details about such oral formulation and the proposed commercialization or granting of rights, and any material commercial terms associated therewith and (ii) offer to provide or make available such other information as may be reasonably requested by SLI or its designated Affiliate to the extent it is available to Supernus and is not a trade or business secret of a third party. During the 90-day period following receipt of such written notice, SLI or its designated Affiliate shall have the right to enter into negotiations with Supernus regarding such oral formulation and, if SLI or its designated Affiliate shall so elect, Supernus shall negotiate, exclusively and in good faith, during such 90-day period, with SLI or such designated Affiliate commercially reasonable terms for the commercialization or granting of rights with respect to such oral formulation to SLI or such designated Affiliate.

(ii)If SLI or its designated Affiliate does not elect to enter into negotiations with Supernus during such 90-day period, (i) neither SLI nor any of its Affiliates shall have any further right, claim or interest under this Section 6.06 or in any oral formulation of [[3]*] developed by Supernus or any of its Affiliates and (ii) Supernus shall be free to negotiate the commercialization or granting of rights with respect to [**] or any oral formulation of [**] developed by Supernus or any of its Affiliates with a third party without any further obligations under this Section 6.06 to SLI or any of its Affiliates.

(iii)If SLI or its designated Affiliate has entered into negotiations with Supernus and, by the end of such 90-day period, SLI or such designated Affiliate and Supernus have not been able to reach agreement on the terms for the commercialization or granting of rights to SLI or such designated Affiliate with respect to such oral formulation, Supernus shall be free to negotiate with a third party so long as the terms and conditions of such third party agreement or arrangement are at least as favorable to Supernus as those proposed by SLI or such designated

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[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Affiliate. If the terms and conditions of such proposed third party agreement or arrangement are the same as or less favorable to Supernus than those previously proposed by SLI or its designated Affiliate, before the execution of any agreement(s) with such third party, Supernus shall provide SLI or such designated Affiliate with a copy of the relevant agreement(s) and, for a period of 30 days from the receipt of copies of the relevant agreement(s), SLI or such designated Affiliate shall have the right to enter into an agreement (or agreements) with Supernus on the same terms and conditions. Should SLI or such designated Affiliate not enter into any such agreement(s) with Supernus during such 30-day period, at the end of such 30-day period, (i) neither SLI nor any of its Affiliates shall have any further right, claim or interest under this Section 6.06 or in any oral formulation of [**] developed by Supernus or any of its Affiliates and (ii) Supernus shall be free to negotiate the commercialization or granting of rights with respect to [**] or any oral formulation of [**] developed by Supernus or any of its Affiliates with a third party without any further obligations under this Section 6.06 to SLI or any of its Affiliates.

Section g. First Right Regarding [**].

(i)Supernus hereby grants to SLI or its designated Affiliate the first right to enter into a license under all Intellectual Property Rights of Supernus and its Affiliates relating to any oral formulation for [**] which Supernus or any of its Affiliates proposes to commercialize or to grant rights in to any third party. If Supernus or any of its Affiliates proposes to commercialize or grant any rights to any third party relating to any oral formulation of [**], Supernus shall notify SLI in writing of such proposal. The notice shall (i) provide details about such oral formulation and the proposed commercialization or granting of rights, and any material commercial terms associated therewith and (ii) offer to provide or make available such other information as may be reasonably requested by SLI or its designated Affiliate to the extent it is available to Supernus and is not a trade or business secret of a third party. During the 90-day period following receipt of such written notice, SLI or its designated Affiliate shall have the right to enter into negotiations with Supernus regarding such oral formulation and, if SLI or its designated Affiliate shall so elect, Supernus shall negotiate, exclusively and in good faith, during such 90-day period, with SLI or such designated Affiliate commercially reasonable terms for the commercialization or granting of rights with respect to such oral formulation to SLI or such designated Affiliate.

(ii)If SLI or its designated Affiliate does not elect to enter into negotiations with Supernus during such 90-day period, (i) neither SLI nor any of its Affiliates shall have any further right, claim or interest under this Section 6.07 or in any oral formulation of [**] developed by Supernus or any of its Affiliates and (ii) Supernus shall be free to negotiate the commercialization or granting of rights with respect to [**] or any oral formulation of [**] developed by Supernus or any of its Affiliates with a third party without any further obligations under this Section 6.07 to SLI or any of its Affiliates.

(iii)If SLI or its designated Affiliate has entered into negotiations with Supernus and, by the end of such 90-day period, SLI or such designated Affiliate and Supernus have not been able to reach agreement on the terms for the commercialization or granting of rights to SLI or such designated Affiliate with respect to such oral formulation, Supernus shall be free to negotiate with a third party so long as the terms and conditions of such third party agreement or arrangement are at least as favorable to Supernus as those proposed by SLI or such designated Affiliate. If the terms and conditions of such proposed third party agreement or arrangement are the same as or less favorable to Supernus than those previously proposed by SLI or its designated Affiliate, before the execution of any agreement(s) with such third party, Supernus shall provide SLI or such designated Affiliate with a copy of the relevant agreement(s) and, for a period of 30 days from the receipt of copies of the relevant agreement(s), SLI or such designated Affiliate shall have the right to enter into an agreement (or agreements) with Supernus on the same terms and conditions. Should SLI or such designated Affiliate not enter into any such agreement(s) with Supernus during such 30-day period, at the end of such 30-day period, (i) neither SLI nor any of its Affiliates shall have any further right, claim or interest under this Section 6.07 or in any oral formulation of [4*] developed by Supernus or any of its Affiliates and (ii) Supernus shall be free to negotiate the commercialization or granting of rights with respect to [**] or any oral formulation of [**] developed by Supernus or any of its Affiliates with a third party without any further obligations under this Section 6.07 to SLI or any of its Affiliates.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Section h. Business

. Supernus confirms that it is its intention as of the date of this Agreement to continue the conduct of its business as a going concern for the foreseeable future.

Article 7.

COVENANTS OF SUPERNUS AND SLI

Section a. Reasonable Best Efforts; Further Assurance

. Subject to the terms and conditions of this Agreement, Supernus and SLI will use their reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary or desirable under applicable laws and regulations to consummate the transactions contemplated by this Agreement. Subject to Section 2.05, SLI and Supernus agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be necessary or desirable in order to (i) consummate or implement expeditiously the transactions contemplated by this Agreement, (ii) vest in Supernus good title to the Contributed Assets and (iii) ensure title and rights with respect to the Retained Assets remain with SLI or its Affiliates, as applicable, and are not affected by this Agreement or the transactions contemplated hereby.

Section b. Certain Filings

. SLI and Supernus shall cooperate with one another (i) in determining whether any action by or in respect of, or filing with, any governmental body, agency, official or authority is required in connection with the consummation of the transactions contemplated by this Agreement and (ii) in taking such actions or making any such filings, furnishing information required in connection therewith and seeking to obtain any such actions, consents, approvals or waivers in a timely manner.

Section c. Public Announcements

. The parties agree to work together to prepare a mutually acceptable press release regarding the transaction contemplated by this Agreement. The parties agree to consult with each other before issuing any other press release or making any other public statement with respect to this Agreement or the transactions contemplated hereby and, except for any press releases and public statements the making of which may be required by applicable law or any listing agreement with any national securities exchange, will not issue any such press release or make any such public statement prior to such consultation. The parties acknowledge and agree that nothing in this Section 7.03 shall preclude any of the parties from disclosing this Agreement and the transactions contemplated hereby to customers, potential customers, suppliers, potential sources of financing and any third party whose consent may be required to effect the transactions contemplated hereby.

Section d. Quality Assurance Services

. For a period of three months following the Closing Date, SLI or one or more of its Affiliates shall provide Supernus with quality assurance services and, as reasonably required by Supernus, shall assist Supernus in establishing its own internal quality assurance capability.

Section e. Receivables, Retained Liabilities and Prepaid Expenses; Set-off.

(i)Promptly after the Closing, Supernus shall mail invoices in respect of any accounts, notes or other receivables, other than the Pre-Closing Receivables, arising from the conduct of the Business or the Retained Business (including any work in progress) that had accrued to SLI or any of its Affiliates prior to the Effective Time (such amounts, the "**Pre-Closing Accrued** Income") to each third party that owes any such amount, with appropriate instructions for such amounts to be paid directly to SLI. After the Closing, Supernus shall promptly pay, subject to Section 7.05(d), to a bank account designated by SLI or any of its Affiliates, any Pre-Closing Receivables or Pre-Closing Accrued Income it receives from any third party. Supernus shall use its reasonable best efforts to

assist SLI and its Affiliates to collect any Pre-Closing Receivables or Pre-Closing Accrued Income from third parties. After the Closing, SLI shall promptly pay, subject to Section 7.05(d), to a bank account designated by Supernus, any amounts it receives from third parties in respect of accounts, notes or other receivables arising from the conduct of the Business after the Effective Time.

(ii)Promptly after the Closing, subject to Section 7.05(d), Supernus shall pay to a bank account designated by SLI or any of its Affiliates an amount equal to all Prepaid Expenses that SLI or any Affiliate of SLI has paid, or is owed, with respect to the Business, any Contributed Asset or any Assumed Liability. If at any time after the Closing, SLI notifies Supernus regarding any other Prepaid Expense to which it is entitled under this Agreement, or if Supernus discovers any other Prepaid Expenses to which SLI is entitled pursuant to this Agreement, Supernus shall, subject to Section 7.05(d), promptly pay such amount to a bank account designated by SLI or any of its Affiliates. Any amounts payable pursuant to this 7.05(b) shall bear interest from and including the Closing Date to but excluding the date of payment at a rate per annum equal to 4.75% for the first 75 days from the Closing Date and 5% above the U.S. Federal Funds rate thereafter.

(iii)After the Closing, Supernus agrees to pay all amounts owed to any third party in respect of any Contributed Asset; provided that if any such amount includes any Retained Liability, Supernus shall notify SLI of the Retained Liability, which notice shall include documentation substantiating such liability together with proof of payment by Supernus and, subject to Section 7.05(d), SLI shall promptly pay such amount to a bank account designated by Supernus.

(iv)After the Closing, each of SLI and Supernus shall have the right to deduct any amount the other owes to it pursuant to this Section 7.05 from any payment such party is obligated to make to the other party pursuant to this Section 31 7.05; provided that, in each case, the party claiming any right to deduct any amount hereunder receives the prior written consent of the party that owes such amount.

(v)The parties hereto agree that any payment made pursuant to this Section 7.05 shall be treated for all Tax purposes as an adjustment to the Supernus Consideration.

(vi)Any amounts properly invoiced by either Supernus or SLI for payment by the other party pursuant to Section 7.05(c) or Article 9 shall be paid by the other party within 15 days from the date of the receipt of the invoice. Interest shall be chargeable on any amounts overdue, from the due date for payment of the unpaid sum (i.e., the 15th day from the date of the receipt of the relevant invoice) to the date of actual payment of the full amount, at a rate equal to 5% above the U.S. Federal Funds rate from time to time, such interest to accrue daily and to be compounded on the last day of each calendar month.

Section f. Closing Financial Statements.

(i)As promptly as practicable, but in no event later than 75 days after the Closing Date, Supernus agrees to prepare and deliver to SLI (i) financial statements for SLI (including a balance sheet as of the Closing Date and a statement of income and cash flows for the period from January 1, 2005 through the Closing Date, but, in each case, before giving effect to the transactions contemplated by this Agreement) and (ii) a certificate based on such financial statements setting forth Supernus's calculation of each of the amounts arising under Section 7.05, which certificate shall fairly present the accounts receivables, accrued liabilities and Prepaid Expenses arising under the Business as at the Effective Time, in each case, consistent with the methodologies used by SLI and its Affiliates to prepare financial statements and record such amounts prior to the Closing Date.

(ii)If after SLI's review of the documents referred to in Section 7.06(a) SLI disagrees with Supernus's calculation of the financial statements or amounts set forth in the certificate delivered pursuant to Section 7.06(a), SLI may, within 30 days after delivery of such documents, deliver a notice to Supernus disagreeing with such calculation and setting forth SLI' s calculation of such financial statements or amount, as applicable.

(iii)If a notice of disagreement shall be duly delivered pursuant to Section 7.06(b), SLI and Supernus shall, during the 30 days following such delivery, use their best efforts to reach agreement on the disputed items or

amounts. If during such period, SLI and Supernus are unable to reach such agreement, either SLI or Supernus by notice to the other party may initiate the process whereby they shall promptly jointly retain a nationally recognized accounting firm (the "**Accounting Referee**") and cause it to promptly review this Agreement and the disputed items or amounts and to resolve the disputed items or amounts. The Accounting Referee shall deliver to SLI and Supernus, as promptly as practicable, a report setting forth its calculation of the disputed items or amounts. Such report shall be final and binding upon SLI and Supernus and any amount set forth therein that is payable to a party hereto pursuant to Section 7.05, shall promptly be paid to such party by the party hereto obligated to make such payment pursuant to Section 7.05. The cost of such review and report shall be borne (i) by Supernus if the amount it owes SLI pursuant to such report is greater than the amount reflected on the certificate delivered pursuant to Section 7.06(a), (ii) by SLI if the amount Supernus owes SLI pursuant to such report is less than the amount reflected on the certificate delivered pursuant to Section 7.06(a) and (iii) otherwise equally by SLI and Supernus.

(iv)SLI and Supernus agree that they will, and agree to cause their respective independent accountants to, cooperate and assist in the preparation of the financial statements and the certificate delivered pursuant to Section 7.06(a) and in the conduct of the reviews referred to in this Section 7.06, including the making available to the extent necessary of books, records, work papers and personnel.

Section g. Notices From Third Parties

. After the Closing, (a) Supernus shall promptly send to SLI any notices or claims it receives in respect of the Retained Assets, Retained Liabilities, Retained Business or any other notice from any third party relating to (i) any asset to which SLI or any of its Affiliates have a right or (ii) any liability to which SLI or any of its Affiliates is subject (including any notices under any provisions of the Hatch Waxman Act or requests under Section 287, Title 35 U.S.C., product liability claims and notices from the U.S. Food and Drug Administration) and (b) SLI shall promptly send to Supernus any notices or claims it receives in respect of the Business, the Contributed Assets or the Assumed Liabilities.

Section h. Reports

. For so long as SLI or any of its Affiliates owns any Supernus Preferred Stock or Supernus Common Stock, Supernus agrees to furnish to SLI (or such other Affiliate of SLI as may be designated by either SLI or Guarantor) the reports and other information to be provided to holders of Supernus Preferred Stock or Supernus Common Stock pursuant to the Investor Rights Agreement dated as of the date hereof entered into by Supernus and the holders of Supernus Preferred Stock.

Section i. Warranty Disclaimer; Exclusion of Damages

. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER SLI NOR ANY OF ITS AFFILIATES MAKE ANY REPRESENTATION OR EXTEND ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY CONTRIBUTED ASSETS OR ASSUMED LIABILITIES TRANSFERRED HEREUNDER, OR ANY MATERIAL OR INFORMATION PROVIDED TO SUPERNUS UNDER THIS AGREEMENT, OR WITH RESPECT TO ANY PRODUCTS OR SERVICES OF SUPERNUS OR ITS AFFILIATES. FURTHERMORE, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE BUSINESS OR THE CONTRIBUTED ASSETS ARE VALID OR ENFORCEABLE OR THAT USE BY SUPERNUS OR ITS AFFILIATES OF SUCH CONTRIBUTED ASSETS, OR ANY MATERIALS OR INFORMATION PROVIDED TO SUPERNUS UNDER THIS AGREEMENT, DOES NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 10 REGARDING INDEMNIFICATION, NO PARTY HERETO SHALL BE LIABLE TO ANY OTHER PARTY HERETO FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING

WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

Article 8.

TAX MATTERS

Section a. Tax Definitions

. The following terms, as used herein, have the following meanings:

"**Pre-Closing Tax Period**" means (i) any Tax Period ending on or before the Closing Date and (ii) with respect to a Tax Period that commences before but ends after the Closing Date, the portion of such period up to and including the Closing Date.

"**Tax**" means (i) any tax or other like assessment or charge of any kind whatsoever (including withholding on amounts paid to or by any Person), together with any interest, penalty, addition to tax or additional amount imposed by any governmental authority (a "**Taxing Authority**") responsible for the imposition of any such tax (domestic or foreign), or (ii) liability for the payment of any amounts of the type described in (i) as a result of being party to any agreement or any express or implied obligation to indemnify any other Person.

Section b. Tax Matters

. SLI hereby represents and warrants to Supernus that:

(i)SLI has paid all material Taxes which will have been required to be paid prior to the Effective Time, the non-payment of which would result in a Lien on any Contributed Asset.

(ii)SLI has established, in accordance with GAAP applied on a basis consistent with that of preceding periods, adequate reserves for the payment of, and will pay, all material Taxes which arise from or with respect to the Contributed Assets or the operation of the Business and are incurred in or attributable to the Pre-Closing Tax Period, the non-payment of which would result in a Lien on any Contributed Asset.

Section c. Tax Cooperation; Allocation of Taxes.

(i)Supernus and SLI agree to furnish or cause to be furnished to each other, upon request, as promptly as practicable, such information and assistance relating to the Business and the Contributed Assets (including access to books and records) as is reasonably necessary for the filing of all Tax returns, the making of any election relating to Taxes, the preparation for any audit by any taxing authority, and the prosecution or defense of any claim, suit or proceeding relating to any Tax. Supernus and SLI shall retain all books and records with respect to Taxes pertaining to the Assets for a period of at least six years following the Closing Date. On or after the end of such period, each party shall provide the other with at least 30 days prior written notice before destroying any such books and records, during which period the party receiving such notice can elect to take possession, at its own expense, of such books and records. SLI and Supernus shall cooperate with each other in the conduct of any audit or other proceeding relating to Taxes involving the Contributed Assets or the Business, at the cost and expense of the party being audited.

(ii)All real property taxes, personal property taxes and similar ad valorem obligations levied with respect to the Contributed Assets for a taxable period which includes (but does not end on) the Closing Date (collectively, the "**Apportioned Obligations**") shall be apportioned between SLI and Supernus based on the number of days of such taxable period included in the Pre-Closing Tax Period and the number of days of such taxable period after the Closing Date (any such portion of such taxable period, the "**Post-Closing Tax Period**"). SLI shall be liable

for the proportionate amount of such taxes that is attributable to the Pre-Closing Tax Period, and Supernus shall be liable for the proportionate amount of such taxes that is attributable to the Post-Closing Tax Period.

(iii)All excise, sales, use, value added, registration stamp, recording, documentary, conveyancing, franchise, property, transfer, gains and similar Taxes, levies, charges and fees (collectively, "**Transfer Taxes**") incurred in connection with the transactions contemplated by this Agreement shall be borne by SLI. Supernus and SLI shall cooperate in providing each other with any appropriate resale exemption certifications and other similar documentation.

(iv)Apportioned Obligations and Taxes described in Section 8.03(b) or 8.03(c) shall be paid in a timely manner, and all applicable filings, reports and returns shall be filed, as provided by applicable law. The paying party shall be entitled to reimbursement from the non-paying party in accordance with Section 8.03(b) or 8.03(c), as the case may be. Upon payment of any such Apportioned Obligation or Tax, the paying party shall present a statement to the non-paying party setting forth the amount of reimbursement to which the paying party is entitled under Section 8.03(b) or 8.03(c), as the case may be together with such supporting evidence as is reasonably necessary to calculate the amount to be reimbursed. The non-paying party shall make such reimbursement promptly but in no event later than 10 days after the presentation of such statement. Any payment not made within such time shall bear interest at a rate per annum equal to the Prime rate as published in the Wall Street Journal, Eastern Edition, in effect from time to time, for each day until paid.

Article 9.

EMPLOYEE BENEFITS

Section a. Employment Offers and Terms.

(i)Supernus shall offer employment to each employee listed on Schedule 9.01(a) (the "**Scheduled Employees**") effective as of the Closing in a position which provides a status, base salary and health and welfare benefits no less favorable to the employee than those provided to the employee by SLI and its Affiliates as of the Closing (the "**Employment Terms**"). Each offer of employment by Supernus to a Scheduled Employee shall be conditioned upon such Scheduled Employee's execution of a confidentiality and proprietary rights agreement in the form set forth in Exhibit C hereto. Each Scheduled Employee who accepts Supernus's offer of employment shall hereinafter be referred to as a "**Transferred Employee**" and the "**Transfer Date**" with respect to such Transferred Employee shall be the Closing Date. Notwithstanding the foregoing, any Scheduled Employee who is not actively at work as of the Closing Date shall not be deemed a Transferred Employee unless he or she reports to work for Supernus after the Closing Date and the Transfer Date for such Scheduled Employee shall be the date on which such Scheduled Employee reports to work for Supernus after the Closing Date. Supernus may retract its offer of employment to any Scheduled Employee who is not actively at work as of the Closing Date and does not report to work for Supernus within 9 months following the Closing Date.

(ii)During the six-month period following the Closing, Supernus shall not terminate or constructively terminate the employment of any Transferred Employee without just cause. Nothing in this Agreement shall restrict the ability of Supernus to modify the Employment Terms with respect to any Transferred Employee any time following such Transferred Employee's Transfer Date. The Parties agree that modifications of the Employment Terms with respect to any Transferred Employee following such Transferred Employee's Transfer Date are not intended to give such Transferred Employee any rights or recourse under any benefit plans of SLI or its Affiliates or any rights or recourse against SLI or its Affiliates. If, however, any such Transferred Employee successfully asserts any right or recourse under any benefit plan of SLI or its Affiliates or against SLI or its Affiliates as a result of a modification of the Employment Terms with respect to such Transferred Employee following such Transferred Employee's Transfer Date, Supernus shall reimburse SLI and its Affiliates for all Damages incurred by SLI and its Affiliates arising from the assertion of such rights or recourse by such Transferred Employee.

(iii)The Scheduled Employees set forth on Schedule 9.01(c) have declined the Supernus employment offer (collectively, the "**Resigning Employees**") and have entered into termination agreements with SLI pursuant to which such Resigning Employees shall receive the special resignation benefits described in Schedule 9.01(c) (the

"**Special Resignation Benefits**"). SLI shall bear full responsibility for the cost of the Special Resignation Benefits payable to the Resigning Employees under such termination agreements.

Section b. Employee Liabilities.

(i)Schedule 9.02(a) sets forth the names of employees of SLI (the "**Redundant Employees**") whose employment terminated prior to the Closing and who have been determined by SLI to be entitled to severance benefits (the "**Severance Benefits**") under the Shire severance policy covering the SLI employees. Supernus agrees that effective as of Closing it shall assume responsibility for the payment of the Severance Benefits to the Redundant Employees as directed by SLI in writing and shall pay such Severance Benefits through the Supernus payroll, making all necessary deductions, withholding and payroll tax payments relating to such Severance Benefits. Supernus shall furnish to SLI itemized written monthly statements of the amounts of such Severance Benefits paid by Supernus and within thirty (30) days after receiving each such written statements SLI shall reimburse to Supernus in readily available funds the aggregate amount of such Severance Benefit payments. Notwithstanding the foregoing, if Supernus or any Affiliate of Supernus retains any Redundant Employee as an employee or consultant during the period that such Terminated Employee is entitled to receive Severance Benefits: (i) Supernus shall promptly notify SLI in writing, setting forth the name of such Redundant Employee and the date such Redundant Employee was retained by Supernus or its Affiliate, (ii) Supernus shall cease all payments of Severance Benefits to such Redundant Employee in respect of the period following the date such Redundant Employee was retained by Supernus or its Affiliate and (iii) SLI shall not be required to reimburse Supernus for any severance benefits or other amounts (including any Severance Benefits) in respect of the period following the date such Redundant Employee was retained by Supernus or its Affiliate.

(ii)Except as otherwise provided in this Article 9 and any corresponding schedules hereto, SLI shall retain, and shall indemnify and hold harmless Supernus and its Affiliates with respect to, all liabilities relating to the SLI Plans, including, without limitation, all liabilities arising under any such SLI Plans for health, medical and dental benefits and disability and workers compensation benefits and accrued and unpaid bonus and incentive compensation for any year (or portion thereof) with respect to any employee of SLI including any Transferred Employee prior to the Transferred Employee's Transfer Date. Except as expressly provided in this Article 9, SLI shall retain, and shall indemnify and hold harmless Supernus from, all employment-related liabilities (i) with respect to each employee and former employee of the Business who does not become a Transferred Employee and (ii) with respect to each Transferred Employee to the extent that such liabilities arise, accrue or are incurred before the Transfer Date of such Transferred Employee.

(iii)Except as otherwise provided in this Article 9 and any corresponding schedules hereto, Supernus shall assume, and shall indemnify and hold harmless SLI and its Affiliates with respect to, all employment-related liabilities with respect to each Transferred Employee to the extent that such liabilities arise, accrue or are incurred on or after the Transfer Date of such Transferred Employee.

Section c. Sponsorship of Welfare Benefit Plans

. Effective as of the Closing, Supernus shall convert sponsorship of the SLI Plans listed on Schedule 9.03 to Supernus plans (the "**Transferred Plans**"). SLI and Supernus shall, and shall cause their respective Affiliates to, take all actions necessary to effect the transfer to and assumption by Supernus of the Transferred Plans on the terms set forth in Schedule 9.03. From and after the Closing, Supernus shall assume all responsibility for the benefits payable from and after the Effective Time under the Transferred Plans to all participants, beneficiaries and dependents covered by the Transferred Plans. To the extent that any former employee of the SLI business who is not an employee of the SLI business as of the Closing Date or any partner or dependent of any such employee has elected or elects COBRA continuation coverage under any Transferred Plan (each a "**Pre-Closing COBRA Participant**"): (i) Supernus shall cause such COBRA continuation coverage to be provided to such Pre-Closing COBRA Participant under such Transferred Plan for the full elected duration applicable under COBRA and (ii) to the extent that SLI has provided pursuant to any agreement or arrangement that any such Pre-Closing COBRA Participant shall be entitled to a continuation of a company-paid contribution toward the premium for coverage under any such Transferred Plan during the COBRA continuation period, Supernus shall continue to fund such

company-paid contribution after the Closing; provided that Supernus shall furnish to SLI itemized written monthly statements of the amounts of such company-paid contributions funded by Supernus and within thirty (30) days after receiving each such written statement SLI shall reimburse to Supernus in readily available cash funds the aggregate amount of such company-paid contributions. The reimbursement provisions above in this section shall not apply with respect to any Resigning Employee or any partner or dependent of any Resigning Employee and instead any company-paid contributions toward the COBRA benefits of any such individual shall be paid and reimbursed by the Parties pursuant to Section 9.01(c).

Section d. Spin-off of 401(k) Plan.

(i)SLI shall cause each Transferred Employee who is or has at any time been a participant in the SLI 401(k) Plan to be 100% vested in their account balance thereunder, if any, as of the Closing Date.

(ii)Effective as of the Closing Date, Supernus has adopted a prototype, non-standardized, defined contribution plan intended to qualify under Section 401(a) and Section 401(k) of the Code (the "**Supernus 401(k) Plan**") in which Transferred Employees shall be eligible to participate on and after the Closing Date and that is substantially comparable to the SLI 401(k) Plan, provided that such Supernus 401(k) Plan shall not permit future investments in or hold securities of SLI or its Affiliates except as provided below in this Section 9.04. The prototype plan on which the Supernus 401(k) Plan is based has received a favorable qualification opinion letter.

(iii)As soon as practicable after the Closing Date, SLI shall cause to be transferred to the Supernus 401(k) Plan, cash or, to the extent provided below, other assets as the parties may agree, having a fair market value equal to the aggregate value of the account balances in the SLI 401(k) Plan as of the date of the plan asset transfer for Transferred Employees. Such plan asset transfer shall include any notes evidencing loans to Transferred Employees from their account balances, marketable securities acceptable to Supernus, shares of common stock of SLI or any of its Affiliates, if any, held in any Transferred Employee's account and the balance in cash, and shall also include all qualified domestic relations orders, within the meaning of Section 414(p) of the Code, applicable to Transferred Employees. Supernus shall assume exclusive responsibility for the administration of the transferred assets from and after the transfer of those assets, including, without limitation, responsibility for: (i) all duties and obligations associated with those assets and the investment alternatives made available for those assets while those assets are held under the Supernus 401(k) Plan or any successor plan, (ii) the proper distribution of benefits relating to the transferred assets and (iii) any future transfer of the assets out of any trust or account maintained under the Supernus 401(k) Plan.

Section e. Credit for Prior Service

. Each Transferred Employee will receive service credit for all periods of employment with SLI or any Affiliate of SLI or any predecessor thereof prior to the Closing Date to the same extent and for all purposes under any employee benefit plan of Supernus or any Affiliate of Supernus in which such employee participates after the Closing (including the Transferred Plans), to the extent that such service was recognized under any analogous plan of SLI or any Affiliate of SLI in effect immediately prior to the Closing (including the Transferred Plans). For the avoidance of doubt, Supernus may establish any service requirements for any employee benefit plans implemented after Closing which are additional and not analogous to any plan of SLI or any Affiliate of SLI in effect immediately prior to the Closing, including any additional equity-based or non-qualified deferred compensation plans. In addition, Supernus reserves the right to change all employee benefit plan rules, except as prohibited by law and as limited under Section 9.01.

Section f. Health Plan Exclusions, Deductibles and Co-Pays

. If on or after the Closing Date, any Transferred Employee becomes covered under any benefit plan of Supernus or any Affiliate of Supernus providing medical, dental, health, pharmaceutical or vision benefits (a "**Successor Plan**") to replace benefits of a similar type provided under a plan of SLI or an Affiliate of SLI immediately prior to Closing Date (a "**Prior Plan**"), such Successor Plan shall not include any restrictions or limitations with respect to any pre-existing condition exclusions and actively-at-work requirements (except to the

extent such exclusions or requirements were applicable under the corresponding Prior Plan), and any eligible expenses incurred by such Transferred Employee and his or her covered dependents during the calendar year in which the Transferred Employee becomes covered under any Successor Plan shall be taken into account under any such Successor Plan for purposes of satisfying all deductible, coinsurance and maximum out-of-pocket requirements applicable to such employee and/or his or her covered dependents for that year, to the extent that such expenses were incurred during a period in which the Transferred Employee or covered dependent was covered under a corresponding Prior Plan.

Section g. Vacation

. Effective as of the-Closing Date, SLI shall pay to each Transferred Employee, within 30 days after the Closing Date, all accrued but unused vacation days under the SLI vacation policy.

Section h. Annual Bonus

. SLI shall pay to each Transferred Employee, within 30 days after the Closing Date, such Scheduled Employee's 2005 annual bonus entitlement under the SLI annual bonus plan for the full calendar year 2005, based on 100% of each such Employee's target bonus.

Section i. Other

. Each Transferred Employee shall cease his or her participation, if any, in the Shire Employee Stock Purchase Plan, and Shire Deferred Bonus Plan effective as of the Closing and shall be paid his or her accrued balance or benefit under such plans in accordance with the terms of such plans and SLI and its Affiliates shall have no further obligation in respect of such amounts or benefits or any tax liabilities or attributes associated with such amounts or benefits. Under the Shire Supplemental Executive Retirement Plan (the "**Shire SERP**"), the transactions contemplated under this Agreement shall not be treated as a termination of the employment of any Transferred Employee participating in the Shire SERP for as long as SLI continues to hold a material voting interest in Supernus (or any successor). As of the Closing Date, Supernus shall establish a mirror plan to the Shire SERP (the "**Supernus SERP**") and, under the Supernus SERP, Supernus shall assume sole responsibility and liability for the benefits accrued by each Transferred Employee under the Shire SERP as of the Closing Date (each, a "**SERP Transferee**") and all matters and liabilities relating to such benefits (including, without limitation, the administration of such benefits before, on and after the Closing Date, the transfer of such benefits as provided above, the payment of such benefits and any taxes and withholding related thereto and the administration and updating of the Supernus SERP (collectively, the "**Transferred SERP Liability**")). As soon as practicable following the Closing Date (but within 30 days following the Closing Date), SLI shall transfer to Supernus in readily available cash funds, an amount equal to the aggregate benefit liability under the Shire SERP as of the Closing Date in respect of the benefits accrued under the Shire SERP by the SERP Transferees as of the Closing Date. Subject to such transfer, neither SLI nor any Affiliate of SLI (other than Supernus and its successors) shall have any further liability or obligation with respect to the Transferred SERF Liability. As of the Closing Date, Supernus shall deliver to SLI an indemnity agreement {in a form reasonably acceptable to SLI) executed by each SERP Transferee, indemnifying SLI and its Affiliates (other than Supernus and its successors) against the Transferred SERP Liability associated with such SERP Transferee's benefit under the Shire SERP and the Supernus SERP.

Article 10.

SURVIVAL; INDEMNIFICATION

Section a. Survival

. The representations and warranties of the parties hereto contained in this Agreement shall expire on the Closing Date; provided that the representations and warranties contained in Sections 3.01, 3.02, 3.03, 3.14, 4.01, 4.02, 4.03 and 4.05 shall survive until the latest date permitted by applicable law. The covenants and agreements of the parties hereto contained in this Agreement shall survive the Closing indefinitely or for the shorter period explicitly specified therein, except that for such covenants and agreements that survive for such shorter period,

breaches thereof shall survive indefinitely or until the latest date permitted by applicable law. Notwithstanding the preceding sentence, any breach of covenant, agreement, representation or warranty in respect of which indemnity may be sought under this Agreement shall survive the time at which it would otherwise terminate pursuant to the preceding sentence, if notice of the inaccuracy thereof giving rise to such right of indemnity shall have been given to the party against whom such indemnity may be sought prior to such time.

Section b. Indemnification.

(i)Effective at and after the Closing, SLI hereby indemnifies Supernus and its Affiliates against and agrees to hold each of them harmless from any and all Damages actually suffered by Supernus or any of its Affiliates arising out of:

(1) any misrepresentation or breach of Section 3.01, 3.02, 3.03 or 3.14;

(2) any breach of covenant or agreement made or to be performed by SLI pursuant to this Agreement; or

(3) any Retained Liability; provided that with respect to indemnification by SLI pursuant to Section 10.02(a)(i), SLI's maximum aggregate liability for all such misrepresentations or breaches shall not exceed $1,500,000.

(ii)Effective at and after the Closing, Supernus hereby indemnifies SLI and its Affiliates against and agrees to hold each of them harmless from any and all Damages actually suffered by SLI or any of its Affiliates arising out of:

(1) any misrepresentation or breach of Section 4.01, 4.02, 4.03 or 4.05;

(2) any breach of covenant or agreement made or to be performed by Supernus pursuant to this Agreement; or

(3) any Assumed Liability; provided that with respect to indemnification by Supernus pursuant to Section 10.02(b)(i), Supernus's maximum aggregate liability for all such misrepresentations or breaches shall not exceed $1,500,000.

Section c. Procedures.

(i)The party seeking indemnification under Section 10.02 (the "**Indemnified Party**") agrees to give prompt notice to the party against whom indemnity is sought (the "**Indemnifying Party**") of the assertion of any claim, or the commencement of any suit, action or proceeding in respect of which indemnity may be sought under such Section and will provide the Indemnifying Party such information with respect thereto that the Indemnifying Party may reasonably request. The Indemnified Party's failure to so notify the Indemnifying Party shall not relieve the Indemnifying Party of its obligations hereunder, except to the extent such failure shall have adversely prejudiced the Indemnifying Party.

(ii)The Indemnifying Party shall be entitled to participate in the defense of any Claim asserted by any third party ("**Third Party Claim**") and, subject to the limitations set forth in this Section, shall be entitled to control and appoint lead counsel for such defense, in each case at its own expense.

(iii)If the Indemnifying Party shall assume the control of the defense of any Third Party Claim in accordance with the provisions of this Section 10.03, (i) the Indemnifying Party shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of such Third Party Claim, if the settlement does not release the Indemnified Party from all liabilities and obligations with respect to such Third Party Claim or the settlement imposes injunctive or other equitable relief against the Indemnified Party, and (ii) the Indemnified Party shall be entitled to participate in the defense of such Third Party

Claim and to employ separate counsel of its choice for such purpose. The fees and expenses of such separate counsel shall be paid by the Indemnified Party.

(iv)Each party shall cooperate, and cause their respective Affiliates to cooperate, in the defense or prosecution of any Third Party Claim and shall furnish or cause to be furnished such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials or appeals, as may be reasonably requested in connection therewith.

Section d. Calculation of Damages.

(i)The amount of any Damages payable under Section 10.02 by the Indemnifying Party shall be net of any (i) amounts recovered or recoverable by the Indemnified Party under applicable insurance policies, or from any other Person alleged to be responsible therefor and (ii) Tax benefit realized by the Indemnified Party arising from the incurrence or payment of any such Damages. In computing the amount of any such Tax benefit, the Indemnified Party shall be deemed to fully utilize, at the highest applicable marginal tax rate then in effect, all Tax items arising from the incurrence or payment of any indemnified Damages. If the Indemnified Party receives any amounts under applicable insurance policies, or from any other Person alleged to be responsible for any Damages, subsequent to an indemnification payment by the Indemnifying Party, then such Indemnified Party shall promptly reimburse the Indemnifying Party for any payment made or expense incurred by such Indemnifying Party in connection with providing such indemnification payment up to the amount received by the Indemnified Party, net of any expenses incurred by such Indemnified Party in collecting such amount.

(ii)The Indemnifying Party shall not be liable under Section 10.02 for any (i) consequential or punitive Damages or (ii) Damages for lost profits.

Section e. Assignment of Claims

. If the Indemnified Party receives any payment from an Indemnifying Party in respect of any Damages pursuant to Section 10.02 and the Indemnified Party could have recovered all or a part of such Damages from a third party (a "**Potential Contributor**") based on the underlying Claim asserted against the Indemnifying Party, the Indemnified Party shall assign such of its rights to proceed against the Potential Contributor as are necessary to permit the Indemnifying Party to recover from the Potential Contributor the amount of such payment; provided that the Indemnified Party shall not be required to assign any right to proceed against a Potential Contributor if the Indemnified Party determines in its reasonable discretion that such assignment would be materially detrimental to its reputation or future business prospects.

Section f. Exclusivity

. After the Closing, Section 10.02 will provide the exclusive remedy for any misrepresentation, breach of warranty, covenant or other agreement or other claim (other than those arising out of a breach of Sections 5.01, 5.02, 5.03, 6.01, 6.02, 6.03, 6.04, 6.05, 6.06 and 6.07 (collectively, the "**Specified Covenants**")) arising out of this Agreement or the transactions contemplated hereby, other than in the case of fraud.

Article 11.

MISCELLANEOUS

Section a. Notices

. All notices, requests and other communications to any party hereunder shall be in writing (including facsimile transmission) and shall be given,

if to Supernus, to:

Supernus Pharmaceuticals, Inc.
1550 East Gude Drive
Rockville, Maryland 20850
Attention: Jack Khattar
Telephone No.: (301) 838-2500
Facsimile No.: (301) 424-1364

with a copy to:

Schmeltzer, Aptaker & Shepard, P.C.
2600 Virginia Avenue, N.W.
Suite 1000
Washington, D.C. 20037
Attention: Mark I. Gruhin, Esq.
Telephone No.: (202) 342-3444
Facsimile No.: (202) 342-3434

if to SLI, to:

Shire Laboratories Inc.
11200 Gundry Lane
Owings Mills, Maryland 21117
Attention: Richard Couch
Telephone No.: (410) 413-2002
Facsimile No.: (443) 471-2470

with a copy to:

Davis Polk & Wardwell
99 Gresham Street
London EC2V 7NG
England
Attention: John K. Knight
Facsimile No.: +44 207 710 4839

and, in the case of Sections 7.05, 7.06, 7.08 and 8.03, with a copy to:

Shire plc
Hampshire International Business Park
Chineham
Basingstoke
Hampshire RG24 8EP
England
Attention: Simon Gibbins
Facsimile No.: +44 1256 894713

or such other address or facsimile number as such party may hereafter specify for the purpose by notice to the other parties hereto. All such notices, requests and other communications shall be deemed received on the date of receipt by the recipient thereof if received prior to 5:00 p.m. in the place of receipt and such day is a Business Day in the place of receipt. Otherwise, any such notice, request or communication shall be deemed not to have been received until the next succeeding Business Day in the place of receipt.

Section b. Amendments and Waivers.

(i)Any provision of this Agreement may be amended or waived if, but only if, such amendment or waiver is in writing and is signed, in the case of an amendment, by each party to this Agreement, or in the case of a waiver, by the party against whom the waiver is to be effective.

(ii)No failure or delay by any party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

Section c. Expenses

. Except as otherwise provided herein, all costs and expenses incurred in connection with this Agreement shall be paid by the party incurring such cost or expense. SLI agrees to reimburse Supernus for an amount of its reasonable legal fees and expenses up to, but not to exceed, $100,000.

Section d. Successors and Assigns

. The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns; provided that, except as otherwise expressly provided in this Agreement, no party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the consent of each other party hereto. For the avoidance of doubt, (i) the limitations on assignment, delegation or other transfer under this Section 11.04 relate to the parties' rights and obligations under this Agreement and are not otherwise intended to limit or restrict the ability of Supernus to sell or dispose of its assets so long as it complies with its obligations under Article 6 and (ii) any such sale or disposition shall not affect the rights of Supernus under Article 10.

Section e. Governing Law

. This Agreement shall be governed by and construed in accordance with the law of the State of Delaware, without regard to the conflicts of law rules of such state.

Section f. Jurisdiction

.

(i)Each party hereto hereby irrevocably and unconditionally submits, for itself and its property, to the non-exclusive jurisdiction of any Delaware State or Federal court sitting in New Castle County, Delaware and any appellate court from any thereof; in any suit, action, or proceeding arising out of or relating to this Agreement, or for recognition or enforcement of any judgment, and each of the parties hereto hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such Delaware State court, or, to the extent permitted by applicable law, in such Federal court. Each of the parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by applicable law. Without limiting the foregoing, each party agrees that service of process on such party as provided in Section 11.01 shall be deemed effective service of process on such party.

(ii)Each of the parties hereto hereby irrevocably and unconditionally waives, to the fullest extent it may legally and effectively do so, any objection which it may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement in any court referred to in Section 11.06(a).

(iii)Each of the parties hereto hereby irrevocably waives, to the fullest extent it may legally and effectively do so, the defense of an inconvenient forum to the maintenance of such suit, action, or proceeding in any

such court, and agrees not to plead the same, and agrees that nothing herein will limit the right to sue in any other jurisdiction if a Delaware State or Federal court of competent jurisdiction sitting in New Castle County, Delaware rules or orders that it will not exercise jurisdiction over any such action or proceeding.

(iv)To the extent that a party hereto has or hereafter may acquire any immunity from jurisdiction of any court or from any legal process (whether through service of notice, attachment prior to judgment, attachment in aid of execution or execution, on the ground of sovereignty or otherwise) with respect to itself or its property, it hereby irrevocably waives, to the fullest extent it may legally and effectively do so, such immunity in respect of its obligations under this Agreement.

(v)Each of the parties hereto hereby acknowledges that a breach of a Specified Covenant may cause irreparable harm to the non-breaching party and that the remedy or remedies at law for any such breach may be inadequate. Each of the parties hereto hereby agrees that, in the event of any such breach, in addition to all other available remedies hereunder, the non-breaching party shall have the right to obtain equitable relief to enforce the provisions of this Agreement.

Section g. Waiver of Jury Trial

. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY,

Section h. Counterparts; Effectiveness; Third Party Beneficiaries

. This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other party hereto. Until and unless each party has received a counterpart hereof signed by the other party hereto, this Agreement shall have no effect and no party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication). No provision of this Agreement is intended to confer any rights, benefits, remedies, obligations, or liabilities hereunder upon any Person other than the parties hereto and their respective successors and assigns.

Section i. Entire Agreement

. This Agreement and the Transaction Documents constitute the entire agreement between the parties with respect to the subject matter of this Agreement and supersedes all prior agreements and understandings, both oral and written, between the parties with respect to the subject matter of this Agreement. For the avoidance of doubt, this Agreement and each of the Transaction Documents shall be treated as a stand-alone agreement unless otherwise expressly provided for herein or therein.

Section j. Bulk Sales Laws

. Supernus and SLI each hereby waive compliance by SLI with the provisions of the “bulk sales,” “bulk transfer” or similar laws of any state.

Section k. Severability

. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other authority to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party. Upon such a determination, the parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner

in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

Section l. Guarantor

. Guarantor hereby guarantees to Supernus the prompt and full discharge by SLI of all of SLI's covenants, agreements, indemnities, obligations and liabilities under this Agreement including the due and punctual payment of all amounts which are or may become due and payable by SLI hereunder, when and as the same shall become due and payable, in accordance with the terms hereof.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the day and year first above written.

SHIRE LABORATORIES INC.

By: /s/ Scott Applebaum
Name: Scott Applebaum
Title: Secretary

SUPERNUS PHARMACEUTICALS, INC.

By: /s/ Jack Khattar
Name: Jack Khattar
Title: President & CEO

SHIRE PLC

By: /s/ Matthew Emmens
Name: Matthew Emmens
Title: Director

EXHIBIT A

ASSIGNMENT AND ASSUMPTION AGREEMENT

ASSIGNMENT AND ASSUMPTION AGREEMENT, dated as of December 22, 2005, between Shire Laboratories Inc., a Delaware corporation ("**SLI**") and Supernus Pharmaceuticals, Inc., a Delaware corporation ("**Supernus**").

W I T N E S S E T H :

WHEREAS, Supernus and SLI have concurrently herewith consummated the purchase by Supernus of the Contributed Assets pursuant to the terms and conditions of the Asset Purchase and Contribution Agreement dated as of December 22, 2005 among Supernus, SLI and Shire plc (the "**Asset Purchase Agreement**"; capitalized terms defined in the Asset Purchase Agreement and not otherwise defined herein being used herein as therein defined);

WHEREAS, pursuant to the Asset Purchase Agreement, Supernus has agreed to assume certain liabilities and obligations of SLI with respect to the Contributed Assets and the Business.

NOW, THEREFORE, in consideration of the sale of the Contributed Assets and in accordance with the terms of the Asset Purchase Agreement, Supernus and SLI agree as follows:

i.(a) SLI does hereby sell, transfer, assign and deliver to Supernus all of the right, title and interest of SLI in, to and under the Contributed Assets; provided that no sale, transfer, assignment or delivery shall be made of any or any material portion of any Contributed Asset if an attempted sale, assignment, transfer or delivery, without the consent of a third party, would constitute a breach or other contravention thereof or in any way adversely affect the rights of Supernus or SLI thereunder.

(b) Supernus does hereby accept all the right, title and interest of SLI in, to and under all of the Contributed Assets (except as aforesaid) and Supernus assumes and agrees to pay, perform and discharge promptly and fully when due all of the Assumed Liabilities and to perform all of the obligations of SLI to be performed under the Contracts that comprise the Contributed Assets except to the extent liabilities thereunder constitute Retained Liabilities.

ii.This Agreement shall be governed by and construed in accordance with the law of the State of Delaware, without regard to the conflicts of law rules of such state.

iii.This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

SHIRE LABORATORIES INC.

By: _____
Name:
Title:

SUPERNUS PHARMACEUTICALS, INC.

By:_____
Name:
Title:

EXHIBIT B

ASSIGNMENT OF PATENTS

WHEREAS SHIRE LABORATORIES INC., a corporation incorporated under the laws of Delaware whose principal office is situated at 1550 East Gude Drive, Rockville, Maryland ("**Shire**") (hereinafter "**ASSIGNOR**") in consideration of the sum of Ten Dollars ($10.00), or the equivalent thereof, and other good and valuable consideration, the sufficiency of which and receipt of which are hereby acknowledged, paid to it by Supernus Pharmaceuticals, Inc, a corporation incorporated under the laws of Delaware whose principal office is at 1550 East Gude Drive, Rockville, Maryland ("**Supernus**"); (hereinafter "**ASSIGNEE**"), does hereby sell and assign to the said ASSIGNEE, its successors and assigns, the below indicated right, title, and interest throughout the world, in and to the patents and patent applications listed on Schedule A attached hereto, which patents and patent applications are owned by it, and all patents, divisions, reissues, continuations and any extensions thereof and rights of priority therein, said interest being its entire ownership interest in the same, to be held and enjoyed by said ASSIGNEE, its successors, assigns, or other legal representatives, to the full end of the term thereof, except as expressly provided herein, as fully and entirely as the same would have been held and enjoyed by ASSIGNOR if this assignment and sale had not been made;

WHEREAS, in connection with the sale and assignment by ASSIGNOR to said ASSIGNEE of the patents and patent applications listed on Schedule A attached hereto, said ASSIGNEE and ASSIGNOR have entered into two License Agreements dated as of December 22, 2005 pursuant to which said ASSIGNEE has granted to ASSIGNOR and its affiliates an irrevocable, exclusive license, including the right to sue and grant sublicenses, under such patents and patent applications to research, develop, formulate, test, design, have manufactured, manufacture, use, offer to sell, sell, distribute, import and export any pharmaceutical product containing at least one of the Compounds (as defined below) as an active ingredient anywhere in the world.

And for the consideration aforesaid, ASSIGNOR hereby covenants and agrees to and with said ASSIGNEE, its successors and assigns, that whenever ASSIGNEE, its counsel or representative, or the counsel or representative of its successors or assigns, shall advise that an amendment to, or a division of, or any other proceeding or action in connection with any patent applications listed on Schedule A attached hereto, including interference proceedings, is lawful and desirable, or that a reissue or continuation or extension of such application or patent issuing therefrom is lawful and desirable, ASSIGNOR will, through an authorized representative, have all papers and drawings signed, have all rightful oaths and affidavits taken, and have all acts done that are necessary or required to be done for the procurement of all lawful rights associated with the patents and patent applications listed on Schedule A attached hereto, or for the reissue or continuation or extension of the same, will, through an authorized representative, have done all acts necessary or required to secure in said ASSIGNEE, its successors and assigns, the title to and full benefit of all rights hereby assigned, without charge to said ASSIGNEE or its successors or assigns, but at its or their expense and ASSIGNOR hereby appoints every present or future officer of said ASSIGNEE as its agent to sign all such papers and to do all such necessary acts on its behalf, to the fullest extent permitted by law;

And ASSIGNOR hereby authorizes and requests the Commissioner of Patents and Trademarks and any other granting authority to issue any Letters Patent resulting from said patent applications listed on Schedule A attached hereto concerning same to said ASSIGNEE;

And ASSIGNEE hereby covenants and agrees to and with said ASSIGNOR, its successors and assigns, such covenant to run with and attach to each patent and patent application assigned to ASSIGNEE by ASSIGNOR in this assignment, that the owner of any patents or patent applications listed on Schedule A attached hereto shall not use, directly or indirectly, solely or jointly with others or in cooperation with a third party, or as a licensor of intellectual property, any of the intellectual property rights covered by such patents and/or patent applications in any research, development, formulation, testing, design, manufacture, use, offer for sale, sale, distribution, importation or exportation, that relates, in whole or in part, to any of the Compounds in any field of use, other than for or on behalf of ASSIGNOR and its affiliates. For purposes hereof, "**Compounds**" means any and all of (a)(i) (+)-alpha-Methylbenzeneethanamine; (ii) carbamazepine (5H-Dibenz{b,f} azepine-5-carboxyamide), (iii) guanfacine (N-

(Aminoiminomethyl)-2,6-dichlorobenzeneacetamide), (iv) lanthanum and (v) mesalamine (5-Amino-2-hydroxybenzoic acid), (b) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of any of clause (a); and (c) any compound involving forming or breaking a bond or bonds with any of clause (a) or (b) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of clause (a) or (b), other than, in the case of clauses (a), (b) and (c), 10,11-Dihydro-10-oxo-5H-debenz[b,f]azepine-5-carboxamide.

This assignment shall have an effective date of December 22, 2005.

I declare under penalty of perjury under the laws of the United States of America, and under penalty of the laws of any other jurisdiction before which this document may be presented, that I am an officer of the above identified ASSIGNOR, that I have signed this document on behalf of ASSIGNOR with the full authority of its board of directors, and that all of the foregoing is true and correct.

Dated: December 22, 2005

By: _____
Name: _____
Title: _____

ACCEPTANCE BY ASSIGNEE

I hereby accept this assignment on behalf of said ASSIGNEE. I declare under penalty of perjury under the laws of the United States of America, and under penalty of the laws of any other jurisdiction before which this document may be presented, that I am an officer of the above-identified ASSIGNEE, that I have signed this document on behalf of ASSIGNEE with the full authority of its board of directors, and that all of the foregoing is true and correct.

Dated: December 22, 2005

By: _____
Name: _____
Title: _____

EXHIBIT C

SHIRE LABORATORIES INC.

Confidentiality and Proprietary Rights Agreement

In consideration of my employment by Shire Laboratories Inc. ("**Shire**" or "**SLI**") (which together with Shire plc and any affiliated companies and any predecessors thereof shall hereinafter be referred to as the "**Company**") and in consideration of my transfer of employment to Supernus Pharmaceuticals, Inc. ("**Supernus**") and the compensation and benefits made available to me by the Company and Supernus, I understand, acknowledge and agree that:

i.The Company intends to sell the Business to Supernus pursuant to the terms and conditions of an Asset Purchase and Contribution Agreement dated as of December 22, 2005 among Supernus, the Company and Shire plc (the "**Purchase Agreement**") and in so doing will assign to Supernus certain patents, trademarks and tradenames of SLI and certain know how not pertaining to the Compounds (collectively, the "**Business Intellectual Property Rights**"). However, the Company has not agreed to assign or transfer to Supernus any intellectual property rights other than the Business Intellectual Property Rights. The intellectual property, proprietary property, assets and information retained by the Company include the following types of property and information: (i) client lists, financial information, proprietary scientific methods and protocols, scientific results, market research and product ideas which do not pertain to the Business; (ii) all other knowledge or information of a proprietary, private, confidential or secret nature which in any way relates to the business of the Company or the design, construction, manufacture or sale of the Company's products or services which do not pertain to the Business, and (iii) any confidential business plans, budgets, financial information, legal information, records or similar information of the Company, other than such information that has been assigned or transferred by the Company to Supernus and made available to you for use in the context of your employment with Supernus. This is not an exhaustive list, but rather it is intended to illustrate those types of information or materials that the Company deems protected by this Agreement. The intellectual property, proprietary property, assets and information retained by the Company shall hereinafter be referred to as the "**Retained Intellectual Property**".

ii.I shall not, publish, disclose, or make use of, or authorize anyone else to publish, disclose or otherwise make use of any of the Retained Intellectual Property, except as may be expressly permitted by the Purchase Agreement. I shall not disclose or cause others to disclose any of the Retained Intellectual Property to Supernus or any other party, or induce Supernus or any other party to use any information or material which is the property of the Company or its affiliates or other individuals or companies (other than Supernus) and which is of a proprietary or confidential nature. If I have any doubt as to whether any information or material includes any of the Retained Intellectual Property I will consult with senior management of Supernus who, in turn, will consult with officials of Shire plc to resolve such doubt.

iii.All documents, written information and other items including, but not limited to, notes, sketches, manuals, blueprints, notebooks, products, tools, fixtures, records and information made or obtained by me while employed by the Company which constitute part of the Retained Intellectual Property or which include any of the Retained Intellectual Property shall be the exclusive property of the Company and, upon the request of the Company, I shall promptly deliver such material to the Company without retaining any copies thereof, whether in written, electronic, oral, visual or other form.

iv.My interest in (a) any and all inventions, improvements, and ideas (whether or not patentable) which I have made or conceived, either solely or jointly with others, at any time during the period of my employment with the Company, and (b) any suggestions, proposals, writings and the like, of any sort whatsoever, including any interest in any copyright, which I have developed and with which my work for the Company was concerned during my employment with the Company, or which relate or are applicable directly or indirectly to any phase of the Company's business shall be the exclusive property of the Company or the Company's rightful successor, assignee, or nominee with respect thereto, except to the extent it is part of the Business Intellectual Property in which case it shall be the exclusive property of Supernus. The items defined in (a) and (b) above will hereinafter be referred to

collectively as "**Proprietary Subject Matter**". I have made full and prompt disclosure in writing to an official of the Company of all Proprietary Subject Matter made or conceived during the term of my employment with the Company. At the request and expense of the Company, but without further compensation to me, I shall do such acts, and execute, acknowledge and deliver all such papers, including without limitation patent applications, as may be necessary or desirable in the sole discretion of the Company to obtain, maintain, protect or vest in applications, patents, copyrights or other proprietary rights of any kind relating thereto, in all countries of the world; including rendering such assistance as the Company may request in any contemplated or pending litigation, patent office proceeding, or other proceeding.

v. Excepted from this Agreement are only such inventions, improvements, ideas, suggestions, proposals, writings and the like relating to any phase of the Company's business made or conceived by me prior to my employment with the Company which are (a) embodied in a United States Letters Patent, Copyright Registration or an application for United States Letters Patent or Copyright Registration filed prior to the commencement of my employment; (b) in the physical possession of a former employer who owns them; or (c) disclosed in detail in an attachment hereto signed by the Company.

vi. The terms "**Business**", "**Business Intellectual Property Rights**", "**Compounds**" and "**Retained Intellectual Property Rights**", as used in this Agreement, are intended to have the same meanings given to those terms in the Purchase Agreement. In the event of any inconsistency or conflict between the meaning of any such term in this Agreement and in the Purchase Agreement, the meaning given to such term in the Purchase Agreement shall control. A copy of the relevant provisions of the Purchase Agreement will be made available during normal business hours at the offices of the Company or Supernus in the event of any questions concerning the meanings of any of these terms or the scope of the confidentiality provisions contained therein.

vii. This Agreement is to be made under and shall be construed in accordance with the laws of the State of Maryland.

_____ _____

Signature of Witness Print Name of Witness

IN WITNESS WHEREOF, I have hereunto set my hand this day of in the year 200

Signature of Witness	Print Name of Witness

EXHIBIT D

CUSTOMER CONTRACT/LICENSE AGREEMENT PROVISIONS

Section . *Certain Arrangements of Supernus with Shire; Third Party Beneficiary Rights.*

1. Customer acknowledges that Supernus has certain contractual agreements with subsidiaries of Shire plc ("**Shire**") pursuant to which (i) Supernus has granted to Shire and its subsidiaries an irrevocable, exclusive license, including the right to sue, in intellectual property rights (including without limitation patents, patent applications and know-how) owned by Supernus to research, develop, formulate, test, design, have manufactured, manufacture, use, offer to sell, sell, distribute, import and export any pharmaceutical product containing at least one of the Compounds (as defined below) as an active ingredient anywhere in the world and (ii) Supernus has agreed not to engage, directly or indirectly, including as a principal or for its own account or solely or jointly with others or in cooperation with a third party, or as a licensor of intellectual property, in any research, formulation development, testing, manufacture, offer for sale, sale, distribution, importation, exportation, design, technology assessment or oral bioavailability screening or enhancement that relates, in whole or in part, to any of the Compounds in any field of use, or otherwise aid or assist any third party in connection with any of the foregoing. For purposes hereof, "**Compounds**" means any and all of: (A)(I) (+)-alpha-Methylbenzeneethanamine, also known as "amphetamine", (II) carbamazepine (5H-Dibenz{b,f}azepine-5-carboxyamide), (III) guanfacine (N-(Aminoiminomethyl)-2,6-dichlorobenzeneacetamide), (IV) lanthanum, and (V) mesalamine (5-Amino-2-hydroxybenzoic acid), (B) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of clause (A), and (C) any compound involving forming or breaking a bond or bonds with any of clause (A) or (B) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of clause (A) or (B), but excluding 10,11-Dihydro-10-oxo-5H-debenz[b,f]azepine-5-carboxamide, also known as "oxcarbazepine".

2. Customer hereby agrees that it shall not use any of the services or Confidential Information[5] provided to it, or work performed on its behalf, by Supernus pursuant to this Agreement, or the results therefrom, or any intellectual property rights licensed to it by Supernus in any activity that is outside the Purpose[6] and, in particular, in any activity that, directly or indirectly, relates, in whole or in part, to any of the Compounds in any field of use. The provisions of this Section (i) are intended to benefit, and shall be enforceable by, Shire and its subsidiaries, (ii) shall survive any termination or expiration of this Agreement and (iii) shall not be amended or waived, in whole or in part, without the prior written consent of Shire. Supernus has agreed to provide Shire with a list of its customers' names from time to time for monitoring purposes and Customer hereby agrees to its name being provided to Shire. Shire has agreed to keep the list and the terms of this Agreement confidential in accordance with the terms of a confidentiality agreement with Supernus, except to the extent reasonably necessary for Shire to investigate any alleged violation of, or to enforce its rights under, the provisions of this Section. Customer acknowledges that Supernus has agreed with Shire that if Shire or any of its subsidiaries in its sole discretion believes that there may be, or may have been, a breach or threatened breach of the provisions of this Section, at the written request of Shire, Supernus shall provide Shire and its subsidiaries with an executed copy of this Agreement, and Customer hereby consents to Supernus providing such copy to Shire or any of its subsidiaries.

3. In the event Customer breaches or threatens to breach the provisions of this Section , should the breach or threatened breach relate directly or indirectly to any activities relating to any of the Compounds then, in addition to any rights that Supernus may have against Customer, Customer acknowledges and agrees that Shire or any of its subsidiaries shall have the right to bring a suit, action or proceeding against Customer for any and all damages suffered or incurred by Shire and its subsidiaries as a result of Customer's breach or threatened breach, whether or not Supernus is a party to the suit, action or proceeding. If any legal action or other proceeding is brought by Shire for the enforcement of this Section, and such action is successful, Shire shall be entitled to recover its reasonable attorney's fees, court costs and reasonable expenses, even if not taxable or assessable as court costs

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[5] To be separately defined based on information to be provided or shared as part of the customer arrangements.

[6] To be separately defined based on scope of the customer arrangements.

(including, without limitation, all such fees, costs and expenses incident to appeal) incurred in that action or proceeding in addition to any other relief to which Shire may be entitled. If any legal action or other proceeding is brought by Shire for the enforcement of this Section, and such action is unsuccessful, Customer shall be entitled to recover its reasonable attorney's fees, court costs and reasonable expenses, even if not taxable or assessable as court costs (including, without limitation, all such fees, costs and expenses incident to appeal) incurred in that action or proceeding in addition to any other relief to which Customer may be entitled. Customer further acknowledges that a breach or threatened breach of these provisions may cause irreparable harm to Shire and its subsidiaries and that the remedy or remedies at law for any such breach or threatened breach may be inadequate. Customer agrees that, in the event of any such breach or threatened breach, in addition to all other available remedies they may have available to them, Shire and its subsidiaries shall have the right to obtain equitable relief.

4. Customer agrees that Shire and its subsidiaries shall not be liable for any claim or counterclaim (equitable, statutory, contractual or otherwise) that could be asserted by Customer against Supernus and that no such claims or counterclaims shall be asserted against Shire or any of its subsidiaries. Customer further agrees to waive against Shire and its subsidiaries any such claims or counterclaims (equitable, statutory, contractual or otherwise) and also agrees that in any action by Shire or any of its subsidiaries it will not assert and will waive any defense, bar or other similar matter (equitable, statutory, contractual or otherwise) based on or relating to the actions, inactions or status of Supernus. To the extent that the assertion of any such claims, counterclaims, defenses, bars or similar matters is compulsory, Supernus may be joined in the action and such claims, counterclaims, defenses, bars or other matters asserted against Supernus (but only against Supernus) and Supernus hereby agrees to such joinder.

5. [This Agreement] [the provisions of this Section] shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law rules of such State. Each of the parties hereto acknowledges and agrees that this Agreement has been entered into in express reliance upon 6 Del. C. § 2708 and hereby waives, to the fullest extent permitted by law, any and all objections to the laws of the State of Delaware governing this Agreement.

6. Each of the parties hereto irrevocably and unconditionally submits to the jurisdiction of the courts of the State of Delaware and of the Federal courts sitting in the State of Delaware any Delaware State or Federal court sitting in New Castle County, Delaware and any appropriate appellate courts therefrom in any suit, action or proceeding arising out of or relating to [this Agreement] [the provisions of this Section] and irrevocably consents to the jurisdiction of such courts and any appropriate appellate courts therefrom in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. Each of the parties hereto irrevocably and unconditionally agrees that (i) to the extent such party is not otherwise subject to service of process in the State of Delaware, to appoint and maintain an agent in the State of Delaware as such party's agent for acceptance of legal process and to notify the other party of the name and address of such agent and (ii) to the fullest extent permitted by law, service of process may also be made on such party by prepaid certified mail with a validated proof of mailing receipt constituting evidence of valid service, and that service made pursuant to (i) or (ii) above shall, to the fullest extent permitted by law, have the same legal force and effect as if served upon such party personally within the State of Delaware. For purposes of implementing the parties' agreement to appoint and maintain an agent for service of process in the State of Delaware, each party that has not as of the date hereof already duly appointed such an agent does hereby appoint [name to be inserted], as such agent.

7. EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO [THIS AGREEMENT] [THE PROVISIONS OF THIS SECTION].

Exhibit 10.10

CERTAIN CONFIDENTIAL INFORMATION IDENTIFIED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

GUANFACINE LICENSE AGREEMENT

THIS GUANFACINE LICENSE AGREEMENT ("Agreement"), effective on the 22nd day of December, 2005, ("Effective Date") is entered into by and between Supernus Pharmaceuticals, Inc. ("Supernus"), a corporation incorporated under the laws of Delaware with its principal place of business at 1550 East Gude Drive, Rockville, Maryland; Shire LLC, (Shire") a limited liability company organized under the laws of Kentucky with its principal place of business in Florence, Kentucky; and Shire plc, a company incorporated in England and Wales ("Guarantor").

RECITALS

WHEREAS Supernus has acquired certain patents and Know-How (as defined below) from an Affiliate (as defined below) of Shire;

WHEREAS concurrently herewith, Supernus, an Affiliate of Shire certain other parties have entered into a Series A Convertible Preferred Stock Purchase Agreement ("the Stock Purchase Agreement");

WHEREAS concurrently herewith, Supernus, Guarantor, and an Affiliate of Shire have entered into an Asset Purchase Agreement (as defined below);

WHEREAS concurrently herewith, Supernus, Guarantor, and an Affiliate of Shire have entered into an Ongoing Projects Agreement (as defined below);

WHEREAS concurrently herewith, Supernus, Guarantor, and Shire have entered into a General License Agreement ("the General License");

WHEREAS Supernus owns all right, title, and interest in the Guanfacine Patents (as defined below) and Guanfacine Know-How (as defined below);

WHEREAS Shire is desirous of obtaining and Supernus is desirous of granting a license under the Guanfacine Patents and Guanfacine Know-How to research, develop, formulate, test, design, have manufactured, manufacture, use, offer to sell, sell, distribute, import, and export Licensed Products (as defined below) in the Guanfacine Field (as defined below) in the Territory (as defined below) under the terms and conditions set forth herein; and

WHEREAS, Guarantor has agreed to guarantee the obligations of SLI hereunder.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants contained herein, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties (as defined below) hereto, intending to be legally bound, hereby agree as follows.

ARTICLE 1 - DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

a. "Affiliate" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by or is under common control with such Person, where "control" means the ownership of more than 50% of the issued share capital or other equity interest or the legal power to direct or cause the direction of such Person.

b. "Asset Purchase Agreement" means the Asset Purchase and Contribution Agreement between, *inter alia*, Supernus and Shire Laboratories Inc. dated the date hereof.

c. "Business Day" means any day other than (1) Saturday or Sunday or (2) any other day on which banks in New York, New York, United States or London, England are permitted or required to be closed.

d. "Calendar Quarter" means for each Calendar Year, each of the three month periods ending March 31, June 30, September 30 and December 31; *provided*, *however*, that the first Calendar Quarter for the first Calendar Year shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter.

e. "Calendar Year" means, for the first Calendar Year, the period commencing on the Effective Date and ending on December 31 of the Calendar Year during which the Effective Date occurs, and each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31.

f. "Combination Product" means any product that contains one or more pharmaceutically-, therapeutically-, prophylactically- or diagnostically-active ingredients in addition to Guanfacine.

g. "Commercial Sale" means the transfer of title to a Licensed Product by Shire, its Affiliates, or its sublicensees to a Third Party for consideration in any arm's length transaction in any country following governmental approval for commercial sale in such country. If governmental approval is not necessary in order to sell a Licensed Product in a particular country, then Commercial Sale shall mean the transfer of title to a Licensed Product by Shire, its Affiliates, or its sublicensees to a Third Party for consideration in any arm's length transaction in such country.

a. "Control" means, with respect to any intellectual property right or other intangible property, that a Party or one of its Affiliates owns any right, title, or interest or has a license or sublicense to such item or right, and has the ability to grant access, license, or sublicense, in whole or in part, in or to such right without violating the terms of any agreement or other arrangement with any Third Party.

b. "Effective Date" means the date first written above.

c. "First Commercial Sale" means the first Commercial Sale.

d. "Guanfacine" means (i) guanfacine (N-(Aminoiminomethyl)-2,6-dichlorobenzeneacetamide), (ii) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of (i); and (iii) any compound involving forming or breaking a bond or bonds with any of (i) or (ii) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of (i) or (ii)..

e. "Guanfacine Field" means the research, development, formulation, testing, design, manufacture, use, offer to sell, sale, distribution, import, and export of any pharmaceutical product containing Guanfacine as an active ingredient.

f. "Guanfacine Know-How" means any Know-how in which Supernus has acquired or acquires any right, title, interest or Control under the Asset Purchase Agreement.

g. "Guanfacine Patents" means the following patent application and patents:

U.S. Patent Nos. 6,287,599 and 6,811,794 [**] and the patent application identified as [**], filed in the U.S. Patent and Trademark Office on [**], entitled [**]; continuation and divisional applications of any of the foregoing; any patents granted on any of the foregoing; re-examinations, reissues, renewals, extensions, supplementary protection certificates and term restorations, any confirmation patent or registration patent or patent of addition based on any such patent; and all foreign counterparts of any of the foregoing.

h. "Intellectual Property Rights" means patents, trade marks, service marks, trade names, internet domain names, rights in designs, copyright (including rights in computer software databases) and moral rights, utility models and other intellectual property rights, and all rights in and to Know-How, in each case whether registered or unregistered and including any applications for the grant of any such rights and all rights and forms of protection having an equivalent or similar effect anywhere in the world.

i. "Know-How" means any non-public information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including without limitation, databases; ideas; discoveries; inventions; trade secrets; practices; methods; tests; assays; techniques; specifications; processes; formulations; formulae; knowledge; skill; experience; materials including pharmaceutical, chemical and biological materials; products; compositions; scientific, technical, or test data including without limitation pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, and stability data; studies; procedures; drawings; plans; designs; diagrams; sketches; technology; documentation; and patent-related and other legal information or descriptions.

j. "Licensed Product" means any pharmaceutical product containing Guanfacine as an active ingredient.

k. "Net Sales" means, with respect to a Licensed Product, the amount received by Shire, its Affiliates, or its sublicensees for Commercial Sales of such Licensed Product to a Third Party less:

i. transportation charges, freight and insurance;

ii. taxes (other than taxes based on income), tariffs, customs duty, excise or other duty and any other governmental charges, all to the extent imposed upon the sale, transportation or delivery of such Licensed Product and paid by the seller;

iii. trade, quantity discounts, cash discounts, rebates or chargebacks actually granted, allowed or incurred in the ordinary course of business in connection with the sale of such Licensed Product, including any credits, volume rebates, charge-back and prime vendor rebates, fees, reimbursements or similar payments granted or given to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations or other institutions or health care organizations;

iv. adjustments, allowances or credits to customers, including on account of price adjustments, governmental requirements, billing errors, rejection, damage, recalls or return of such Licensed Product, in each case, in the ordinary course of business; and

v. payments or rebates paid in connection with sales of Licensed Products to any government or governmental authority in respect of any state or federal Medicare, Medicaid or similar programs.

For the purposes of determining Net Sales in the event a Licensed Product is a Combination Product, the Net Sales of any such Combination Product shall be determined by multiplying the Net Sales of the Combination Product by the fraction A/(A+B), where A is the weighted (by sales volume) average sale price of the Licensed Product when sold separately in finished form and B is the weighted (by sales volume) average sale price of the other product(s) sold separately in finished form. In the event that such average sale price cannot be determined for both the Licensed

Product and the other product(s) in combination, Net Sales for purposes of determining royalties shall be mutually agreed by the Parties based on the relative value contributed by each component.

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Notwithstanding the foregoing, the disposition of, or the use of, a Licensed Product in clinical studies, compassionate use, named patient use, test marketing, or any non-registrational studies where the Licensed Product is supplied without charge or at cost shall not result in any Net Sales. Additionally, amounts received by Shire or its Affiliates or sublicensees for the sale of Licensed Products among Shire and its Affiliates and sublicensees for resale shall not be included in the computation of Net Sales hereunder.

For the avoidance of doubt, Net Sales shall not include any upfront fees or milestones.

l. "Ongoing Projects Agreement" means the Ongoing Projects and Royalty Agreement among Supernus, Guarantor, and Shire Development Inc. dated the date hereof

m. "Parties" means Supernus, Guarantor, and Shire.

n. "Party" means Supernus, Guarantor, or Shire.

o. "Person" means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

p. "Representatives" means Affiliates of the Parties and the respective officers, directors, employees, agents, advisors, representatives, distributors, salespersons, customers, licensees, subcontractors and end-users of each Party and its Affiliates.

q. "Term" means, on a country-by-country basis, the later of (i) [1*] or (ii) [**], absent this Agreement, would be infringed by the research, development, formulation, testing, design, manufacture, use, offer to sell, sale, distribution, import, and export of a Licensed Product.

r. "Territory" means the world.

s. "Third Party" means any entity including for-profit and non-profit institutions other than Supernus and Shire and Shire's Affiliates.

t. "Transaction Documents" means, collectively, (i) the Asset Purchase Agreement, (ii) the Stock Purchase Agreement, (iii) the Ongoing Projects Agreement, (iv) the Quality Assurance Agreement among Supernus, Shire Pharmaceuticals Development Ltd. and Shire Development Inc. dated the date hereof, (v) this Agreement, and (vi) the General License.

u. "Valid Claim" means a claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal.

v. Other Terms. Each of the following terms is defined in the Section set forth opposite such term:

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Term	Section
Actions	5.5
Agreed Rate	4.8
Agreement	Preamble
Effective Date	Preamble
General License	Recitals
Guarantor	Preamble
Liabilities	5.4

Term	Section
Royalty Term	4.4
Shire	Preamble
Stock Purchase Agreement	Preamble
Supernus	Preamble

w. Other Definitional and Interpretative Provisions. Unless specified otherwise, in this Agreement the obligations of any party consisting of more than one person are joint and several. The words “hereof”, “herein” and “hereunder” and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. References to Articles and Sections are to Articles and Sections of this Agreement unless otherwise specified. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words “include”, “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation”, whether or not they are in fact followed by those words or words of like import. “Writing”, “written” and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof. References to any Person include the successors and permitted assigns of that Person. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively.

ARTICLE 2 - ARTICLE 2 - GRANT OF RIGHTS

a. Grant of License to Shire. Subject to the terms and conditions of this Agreement, Supernus hereby grants to Shire and its Affiliates, in the Guanfacine Field, an irrevocable, exclusive license under the Guanfacine Patents and the Guanfacine Know-How to research, develop, formulate, test, design, have manufactured, manufacture, use, offer to sell, sell, distribute, import, and export Licensed Products in the Territory.

b. Sublicenses. The grant of the license in this Article 2 includes the right to grant sublicenses to Third Parties and to appoint distribution and independent sales organizations or representatives under the rights granted to Shire and its Affiliates pursuant to Section 2.1. All sublicense agreements entered into by Shire or its Affiliates shall be consistent with the terms and conditions of this Agreement.

c. No Other Technology Rights. It is understood and agreed that this Guanfacine License Agreement does not grant either Party any license or other right in the Intellectual Property Rights of the other Party other than as specified in this Article 2.

d. Covenant Not to Sue. Supernus and its Affiliate(s) individually and jointly hereby covenant and agree not, either alone or in cooperation with any Third Party, to sue or to bring any cause of action including those for any type of infringement of any Intellectual Property Rights, against Shire or any of its Representatives to prevent,

inhibit, financially affect or encumber in any manner any of the activities of any of Shire or any of its Affiliates related, in whole or in part, to the research, development, testing, design, formulation, manufacture, use, offer to sell, sale, distribution, import, and export of any compound(s), composition(s), article(s), material(s), method(s), use(s), or product(s) relating, in whole or in part, to Guanfacine or Licensed Products. This covenant shall not prevent Supernus from enforcing its rights under any of the Transaction Documents, including, in the case of this Agreement, indemnification under Section 5.4.

e. Covenant for Intellectual Property. Supernus hereby covenants and agrees, at its own expense, to file, prosecute, and maintain, on a Guanfacine Patent-by-Guanfacine Patent and country-by-country basis, the Guanfacine Patents, *provided however*, that Supernus may decide, in its sole discretion, not to file, prosecute, maintain any of the Guanfacine Patents in any country. In the event that Supernus decided not to file, prosecute, or maintain any of the Guanfacine Patents in any country, Supernus shall provide to Shire sufficient notice of such decision to permit Shire to decide whether Shire desires to file, prosecute, or maintain such Guanfacine Patent(s) in such country and if Shire so desires, Supernus shall assign to Shire, at no cost to Shire, all right, title, and interest in such Guanfacine Patent(s) in such country with sufficient time for Shire to file, prosecute, or maintain such Guanfacine Patent(s) in such country.

f. Mutual Covenant. Neither Party has entered into, and neither Party shall, during the term of this Agreement, enter into, any agreements, contracts, or other arrangements that will be inconsistent with its obligations under this Agreement.

g. Access to Documentation. During the Term of this Agreement, Supernus and its Affiliates will continuously provide Shire and its Affiliates access to, if such access is not a violation by Supernus or any of its Affiliates of any obligations of confidentiality of Supernus or its Affiliates to any Third Party, at Shire's sole cost and subject to any obligations of confidentiality of Supernus or its Affiliates that would not be such a violation, originals or copies of Supernus's research and development documentation relating, in whole or in part, to Guanfacine.

h. Availability of Supernus Personnel. Personnel of Supernus and its Affiliates, designated by Supernus and subject to Shire's approval will be made available to Shire and its Affiliates, during Supernus's regular business hours and upon reasonable advance notice to Supernus, at Shire's sole cost for the purpose of consulting with Shire on the scientific development of the Guanfacine Patents and the Guanfacine Know-How including assisting Shire and its Affiliates in understanding or interpreting the documentation provided to Shire and its Affiliates under Section 2.7.

i. Confirmatory Recording. On the Effective Date, Supernus shall execute a confirmatory license in the form attached hereto as Exhibit A solely for recordation as Shire may deem necessary or desirable. It shall not be a violation or breach of any agreement to which Supernus and Shire are parties, to record such confirmatory license. Such confirmatory license shall not amend, modify, cancel, or supersede the terms of this Agreement. In the event of any inconsistencies between this Agreement and such confirmatory license, this Agreement shall prevail.

ARTICLE 3 - ENFORCEMENT OF PATENT RIGHTS

a. Notification of Third Party Infringement. Each Party shall promptly notify the other Party in writing of any claim or evidence of possible Third Party infringement or misappropriation of any the Guanfacine Patents or Guanfacine Know-How insofar as such infringement or misappropriation relates to Guanfacine.

b. Right to Respond. Shire or its Affiliates shall have the first right, but not any obligation, to take any action against any infringement, misappropriation, or allegation of invalidity or unenforceability of any Guanfacine Patents insofar as such infringement, misappropriation, or allegation of invalidity or unenforceability relates to Guanfacine by a Third Party with counsel to be chosen by Shire or its Affiliates *provided* that, to the extent practicable and not materially detrimental to Shire, Shire notifies Supernus prior to its response and allows Supernus sufficient opportunity to contribute to such action if Supernus determines that Shire's action will have an effect on other Supernus' licensees. Shire shall also have the sole right, and at its sole discretion, to settle or compromise any such

action in any manner. The expense and costs of counsel in such action by Shire shall be borne entirely by Shire. Supernus shall be permitted to retain its own counsel in an action by Shire at Supernus' own expense and costs, and Shire shall have no obligation to reimburse Supernus for such expense or costs. If Shire does not take any action against such infringement, misappropriation, or allegation of invalidity or unenforceability of the Guanfacine Patents and Supernus chooses to act at its own election, the expense and costs of such action shall be borne entirely by Supernus, but Shire shall be permitted to retain its own counsel in such action at Shire's own expense and costs and Supernus shall have no obligation to reimburse Shire for such expense or costs.

Supernus or its Affiliates shall have the sole right, but not any obligation, to take any action against any infringement, misappropriation, or allegation of invalidity or unenforceability of any Guanfacine Patents insofar as such infringement, misappropriation, or allegation of invalidity or unenforceability does not relate to Guanfacine by a Third Party with counsel to be chosen by Supernus or its Affiliates, *provided* that, to the extent practicable and not materially detrimental to Supernus, Supernus notifies Shire prior to its response and allows Shire sufficient opportunity to contribute to such action. Supernus shall also have the sole right, and at its sole discretion, to settle or compromise any such action in any manner. The expense and costs of counsel in such action by Supernus shall be borne entirely by Supernus. Shire shall be permitted to retain its own counsel in an action by Supernus at Shire's own expense and costs, and Supernus shall have no obligation to reimburse Shire for such expense or costs.

Supernus shall not take any direct or indirect actions and shall not assist any Third Party or any Affiliate of Supernus in any action asserting that any Guanfacine Patent is invalid, is not enforceable, or is not infringed.

c. Recovery. Any and all monetary damages recovered from a Third Party in connection with any action by Shire regarding infringement, misappropriation, invalidity, or unenforceability of any of the Guanfacine Patents shall be used to reimburse Shire for the expense and costs of Shire's counsel. Any excess over such reimbursement shall be treated as Net Sales under this Agreement. Any and all monetary damages recovered from a Third Party in connection with any action by Supernus regarding infringement, misappropriation, invalidity, or unenforceability of any of the Guanfacine Patents shall be used to reimburse Supernus for the expense and costs of Supernus's counsel. Shire shall receive the equivalent of the then applicable royalty rate payable by Supernus under Section 4.2 of any excess over such reimbursement.

ARTICLE 4 - MILESTONE, ROYALTIES, AND REPORTING

a. Milestone and Milestone Payment. Shire shall, upon the First Commercial Sale in the United States of the first Licensed Product, pay to Supernus [2*] dollars (US$[**]). This milestone payment shall accrue and be paid for the first Licensed Product only, and shall be made only once when this milestone is achieved for the first time under this Agreement regardless of how many times such milestone is achieved for the first Licensed Product. Shire shall pay any such milestone payment to Supernus within ten (10) Business Days of the date the payment becomes due. No payment shall be owed unless the milestone is achieved.

b. Royalty Rate on Licensed Products. During the Royalty Term (as defined in section 4.4, below) Shire shall pay to Supernus a running royalty of [**] ([**]%) of Net Sales of each Licensed Product that, absent this Agreement, would infringe a Valid Claim of a Guanfacine Patent in the country in which such Licensed Product is sold and that is not researched, developed, formulated, or manufactured for Shire or its Affiliates by or on behalf of Supernus. If the term of such Guanfacine Patent that would be infringed absent this Agreement expires during the Royalty Term for such Licensed Product, Shire shall pay to Supernus a running royalty of [**] ([**]%) of Net Sales of such Licensed Product for the remainder of the Royalty Term for such Licensed Product. The foregoing notwithstanding, no running royalties shall be due to Supernus under any Guanfacine Patents or Guanfacine Know-How assigned to Shire pursuant to Section 2.5.

c. One Royalty. Only one royalty shall be due for the Net Sales of any Licensed Product, no matter what Intellectual Property Rights are incorporated into such product. Furthermore, Shire's obligation to pay royalties shall

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only be imposed once with respect to the same unit of a Licensed Product, no matter how many times that unit may be sold.

d. Royalty Term. Royalties due under this Article 4 will be due on a country-by-country until the later of (i) [**] or (ii) [**], absent this Agreement, would be infringed by the sale of such Licensed Product in such country ("the Royalty Term"). After expiration of the Royalty Term for any Licensed Product, the licenses granted in this Agreement shall become permanent, irrevocable, and fully paid-up with respect to such Licensed Product.

e. Payments. Shire shall within thirty (30) days following the conclusion of each Calendar Quarter after the First Commercial Sale of a Licensed Product for which a royalty is due, deliver to Supernus a written report showing the information and basis on which the payment under Section 4.2 due for such Calendar Quarter is calculated. Supernus shall within ten (10) days following the receipt of such information issue to Shire an invoice for the payment of such amount due under Section 4.2. Shire shall pay any amounts properly invoiced by Supernus within fifteen (15) days from the date of receipt of the invoice. Any such amounts shall be payable in United States dollars and shall be paid by bank wire transfer in immediately available funds to such bank account as designated in writing by Supernus.

f. Payment Currency. If Net Sales are in a currency other than U.S. dollars, then, for the purpose of determining the amount of royalties payable hereunder, such amount shall be converted into U.S. dollars at the exchange rate used by Shire consistent with its standard operating procedures as they relate to its income statement, for the purposes of consolidating its own net revenues. Such policies will be made available to Supernus upon request and are consistent with customary industry practices.

g. Withholding Taxes. All amounts payable by Shire pursuant to this Agreement shall be paid free and clear of, and without deduction for and on account of, tax unless Shire is required by law to make those payments subject to deduction or withholding of tax, in which case Shire will deduct or withhold such taxes in accordance with the applicable tax treaty, law or regulation and will pay such taxes to the appropriate taxing authorities. Shire shall make certificates of such tax payments available to Supernus to review and copy.

h. Interest. Subject to Section 4.7, interest shall be chargeable on any amounts overdue to Supernus at the Agreed Rate, from the due date for payment of the unpaid sum to the date of actual payment of the full amount. The Agreed Rate for these purposes is the rate of [3*] ([**]%) above the U.S. Federal Funds Rate from time to time, such interest to accrue daily and to be compounded on the last day of each calendar month.

i. Records and Audits. Shire, its Affiliates and its sublicensees shall keep and maintain complete and accurate records of their revenues received from sales of Licensed Product(s) for a period of three (3) years. Shire shall permit, and cause its Affiliates and sublicensees to permit, independent certified public accountants retained by Supernus and approved by Shire, such permission not to be unreasonably withheld or delayed, to have access to their records and books for the sole purpose of verifying Net Sales and any payment under Section 4.2 due thereon. Such independent certified public accountant must be under an obligation of confidentiality (a) not to use the information contained in the audited Party's records and books or the auditing results for any other purpose and (b) not to disclose the information contained in the audited Party's records and books or the auditing results except that the independent certified public accountant may disclose the auditing results to Supernus solely to confirm the accuracy of the information being audited and to identify any errors therein. The independent certified public accountant shall promptly forward the results of such audit to both Supernus and Shire upon completion of such audit. Such examination shall be conducted during regular business hours and upon reasonable notice and no more than once in each Calendar Year during the Term of this Agreement, and once during the Calendar Year following the termination of this Agreement and only for the two (2) Calendar Years preceding the date of such request for such audit. Any adjustment in the amount of payment under Section 4.2 due to Supernus on account of overpayment or underpayment of amounts due hereunder shall be made at the next date when payments are to be made under this Agreement. Supernus shall pay the fees and expenses of the accountant engaged to perform the audit unless such

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audit reveals an underpayment of [**] ([**]%) or more for the period examined, in which case the audited Party shall pay all reasonable fees and expenses of the accountant.

j. Legal Restrictions. If at any time legal restrictions prevent the remittance by Shire of all or any part of royalties on Net Sales in any country, Shire will have the right and option to make such payment by depositing the amount thereof in local currency to an account in the name of Supernus in a bank or other depository in such country. Shire will consult with Supernus regarding, and promptly notify Supernus of, any and all such arrangements.

k. Current Products. If there have been Net Sales of any product prior to or on the Effective Date, there shall be no royalties due to Supernus for any Net Sales of such product made after the Effective Date. For the avoidance of doubt, this Section 4.10 refers to all units of such product no matter when produced or sold.

l. Future Products. Shire has no obligation to Supernus or its Affiliates to make, use, offer to sell, sell, import, or commercialize any compounds or products under this Agreement, and therefore, there is no obligation or commitment to Supernus that any payments of any kind will ever accrue to Supernus under this Agreement. This Section 4.11 is not a grant of any license for Shire to make, use, offer to sell, sell, import, or commercialize any compounds or products under this Agreement.

ARTICLE 5 - REPRESENTATIONS, WARRANTIES, DISCLAIMERS, LIABILITY

a. Supernus's Representations and Warranties. Supernus represents and warrants that:

vi. Supernus is a corporation duly organized, validly existing, and in good standing under the laws of the State of Delaware;

vii. Supernus has the legal right, authority, and power to enter into this Agreement;

viii. Supernus has taken all necessary action to authorize the execution, delivery, and performance of this Agreement;

ix. upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Supernus, enforceable in accordance with its terms; and

x. the performance of Supernus's obligations under this Agreement will not conflict with its certificate of incorporation, as amended, or by-laws, or result in a breach of any agreements, contracts, or other arrangements to which it is a party.

b. Shire's Representations, and Warranties. Shire represents and warrants that:

xi. Shire is a limited liability company duly organized, validly existing, and in good standing under the laws of the State of Kentucky;

xii. Shire has the legal right, authority, and power to enter into this Agreement;

xiii. Shire has taken all necessary action to authorize the execution, delivery, and performance of this Agreement;

xiv. upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Shire, enforceable against Shire in accordance with its terms; and

xv. the performance of Shire's obligations under this Agreement will not conflict with its organizational documents or result in a breach of any agreements, contracts, or other arrangements to which it is a party.

c. WARRANTY DISCLAIMER; EXCLUSION OF DAMAGES; LIMITATIONS OF LIABILITY. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE GUANFACINE PATENTS, THE GUANFACINE KNOW-HOW, OR ANY LICENSE GRANTED BY EITHER PARTY HEREUNDER, OR ANY MATERIALS OR INFORMATION PROVIDED TO EITHER PARTY UNDER THIS AGREEMENT, OR WITH RESPECT TO ANY PRODUCTS OR SERVICES OF EITHER COMPANY OR THEIR RESPECTIVE AFFILIATES. FURTHERMORE, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE GUANFACINE PATENTS OR THE GUANFACINE KNOW- HOW ARE VALID OR ENFORCEABLE OR THAT USE BY EITHER PARTY OR THEIR RESPECTIVE AFFILIATES OF THE GUANFACINE PATENTS, THE GUANFACINE KNOW-HOW, OR ANY OTHER RIGHTS LICENSED HEREIN, OR ANY MATERIALS OR INFORMATION PROVIDED TO EITHER PARTY UNDER THIS AGREEMENT, DO NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 5 REGARDING INDEMNIFICATION, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER. ALL CONDITIONS, WARRANTIES OR OTHER TERMS, WHETHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCONSISTENT WITH THE PROVISIONS OF THIS SECTION ARE EXPRESSLY EXCLUDED.

The foregoing exclusion of damages (i) applies even if a Party had or should have had knowledge, actual or constructive, of the possibility of such damages, (ii) is a fundamental element of the basis of the bargain between the Parties and this Agreement would not be entered into without such limitations and exclusions, and (iii) shall apply whether a claim is based on breach of contract, breach of warranty, tort (including negligence), product liability, strict liability or otherwise, and notwithstanding any failure of essential purpose of any limited remedy herein. The foregoing exclusion of damages is intended to apply even if there is a total and fundamental breach of this Agreement. The essential purpose of the exclusion of damages clause is to limit the Parties' respective liabilities to each other hereunder.

d. Indemnification. Shire hereby agrees to defend, indemnify and hold harmless Supernus and each of its Representatives from and against any liabilities, claims, costs, expenses (including reasonable legal fees), loss or damage ("Liabilities") to the extent arising from Shire's or its Representatives' willful misconduct, gross negligence or material breach of its representations and warranties or its obligations under this Agreement, and except, in each case, to the extent that such Liability arises, in whole or in part, as a result of Supernus' or its Representatives' gross negligence, willful misconduct, or breach of this Agreement. For the avoidance of doubt and notwithstanding the immediately preceding sentence, this indemnity shall not include protection for any loss, claim, damage, or liability resulting, in whole or in part, directly or indirectly, from actions or omissions covered by the warranty disclaimers in Section 5.3 herein.

Supernus hereby agrees to defend, indemnify and hold harmless Shire and each of its Representatives from and against any Liabilities to the extent arising from Supernus' or its Representatives' wilful misconduct, gross negligence or material breach of its representations and warranties or its obligations under this Agreement, except, in each case, to the extent that such Liability arises, in whole or in part, as a result of Shire's or its Representatives' wilful misconduct, gross negligence, or breach of this Agreement. For the avoidance of doubt and notwithstanding the immediately preceding sentence, this indemnity shall not include protection for any loss, claim, damage, or liability resulting, in whole or in part, directly or indirectly, from actions or omissions covered by the warranty disclaimers in Section 5.3 herein.

e. Indemnification Procedure. The indemnified Party shall promptly notify the indemnifying Party, in writing, if it learns of any litigation, claim, administrative or criminal proceedings (collectively "Actions") asserted or threatened against the indemnified Party for which the indemnified Party is entitled to indemnification hereunder. With respect to any such Action, the indemnified Party shall cooperate with and provide such assistance to the indemnifying Party as such Party may reasonably request. Such assistance may include providing copies of all relevant correspondence and other materials that the indemnifying Party may reasonably request; *provided however,* that any information so provided which is confidential shall be treated in accordance with the confidentiality provisions of the Ongoing Projects Agreement.

In the event of any claim or notice of the commencement of any proceedings to which the indemnities in this Article 5 may apply, the indemnified Party shall permit the indemnifying Party to take control of the relevant proceedings and shall not make any admission or offer or make any settlement without the prior consent of the indemnifying Party. If the indemnifying Party shall assume the control of the relevant proceedings in accordance with the previous sentence, (a) the indemnifying Party shall obtain the prior written consent of the indemnified Party before entering into any settlement with respect to such proceedings if the settlement would not release the indemnified Party from all liabilities and obligations with respect to such proceedings or the settlement would impose injunctive or other equitable relief against the indemnified Party and (b) the indemnified Party shall be entitled to participate in such proceedings and to employ separate counsel of its choice for such purpose. The fees and expenses of such separate counsel shall, absent a conflict between the indemnifying Party and the indemnified Party, be paid by the indemnified Party. The failure or delay to deliver notice to the indemnifying Party within a reasonable time after the commencement of any such action, if irreparably prejudicial to the indemnifying Party's ability to defend such action, shall relieve the indemnifying Party of any liability to the indemnified Party under this Article 5 to the extent that is directly attributable in its entirety to such failure or delay, but the omission to deliver notice to the indemnifying Party will not relieve the indemnifying Party of any liability that the indemnifying Party may have to any indemnified Party otherwise. The indemnified Party shall cooperate fully with the indemnifying Party and its legal representatives in the investigation of any loss, action, claim, damage, or liability covered by this indemnification.

f. Compliance with Law. Each Party shall comply, and shall require its Affiliates and sublicensees to comply, with all applicable laws and regulations relative to its obligations hereunder.

ARTICLE 6 - TERMINATION

a. Term of the Licenses. The licenses granted to Shire by this Agreement shall become permanent, irrevocable, and paid-up, on a country-by-country basis and a Licensed Product-by-Licensed Product basis, upon the expiration of the Term in such country.

b. Term of Supernus's Covenant Not to Sue. Supernus's covenant not to sue set forth in Article 2 shall run for [[4]*] from the Effective Date.

c. No Termination by Supernus. The Agreement cannot be terminated by Supernus for any reason.

d. Termination by Shire - Financial. Shire shall have the right to terminate immediately (a) this entire Agreement, other than those provisions which shall survive pursuant to Section 6.6 or (b) any provisions of this Agreement other than those that shall survive this Agreement pursuant to Section 6.6, at Shire's sole discretion, if Supernus (i) applies for or consents to the appointment of a receiver, trustee, liquidator or custodian on behalf of itself or for all or a substantial part of its property, (ii) becomes unable, or admits in writing its inability, to pay its debts generally as they mature, (iii) makes a general assignment for the benefit of its creditors, (iv) is dissolved or liquidated in full or in part other than in a solvent reorganization merger, or other similar activity, (v) commences a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law now or hereafter in effect or consents to any such relief or to the appointment of or taking possession of its property by any official in an involuntary case or other proceeding

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[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

commenced against it under any bankruptcy, insolvency or other similar law, (vi) takes any action for the purpose of effecting any of the foregoing, (vii) becomes the subject of an involuntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law now or hereafter in effect that is not dismissed within ninety (90) calendar days of commencement, or (viii) ceases to carry on its business as a going concern during the six (6) month period following the Effective Date. Supernus shall not have any right to cure termination under this Section 6.4.

e. Termination by Shire without Cause. Shire may terminate this Agreement, in whole or in part, without cause at any time.

f. Survival. Termination or expiration of this Agreement for any reason shall not affect the accrued rights of Shire or Supernus arising in any way out of this Agreement and shall not release either Shire or Supernus from any liability which, at the time of such termination or expiration, has already accrued to Shire or Supernus, as applicable, or which is attributable to a period prior to such termination or expiration, nor preclude Shire or Supernus, as applicable, from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring prior to such termination or expiration. Additionally, Articles 5, 6, 7, and 8 and Sections 2.3, 2.4, 2.5, 2.6, and 3.3 of this Agreement shall survive the termination or expiration of this Agreement.

ARTICLE 7 - DISPUTE RESOLUTION

a. Negotiation. Without prejudice to any rights under Section 7.7, the Parties hereby agree that they will attempt in good faith to resolve promptly by negotiations, any controversy or claim between the Parties arising out of or relating to this Agreement. If a controversy or claim should arise hereunder, the matter shall be referred to a senior executive of Supernus and a senior executive of Shire (the “Mediators”). If the matter has not been resolved within fifteen (15) days of the referral to the Mediators, subject to rights to injunctive relief and specific performance, and unless otherwise specifically provided for herein, any controversy or claim arising out of or relating to this Agreement, or the breach thereof, may be brought in a court of competent jurisdiction as specified in Section 7.3.

b. Governing Law. The validity, construction, and interpretation of this Agreement and any determination of the performance which this Agreement requires will be governed by and construed in accordance with the laws of the State of Delaware applicable to contracts made and performed wholly within the State of Delaware.

c. Jurisdiction. Each Party hereby irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of any Delaware State or Federal court sitting in New Castle County, Delaware and any appellate court from any thereof; in any suit, action, or proceeding arising out of or relating to this Agreement, or for recognition or enforcement of any judgment, and each of the Parties hereto hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such Delaware State court, or, to the extent permitted by law, in such Federal court. Each of the Parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

d. Venue. Each of the Parties hereby irrevocably and unconditionally waives, to the fullest extent it may legally and effectively do so, any objection which it may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement in any court referred to in Section 7.3.

e. Inconvenient Forum. Each of the Parties hereby irrevocably waives, to the fullest extent it may legally and effectively do so, the defense of an inconvenient forum to the maintenance of such suit, action, or proceeding in any such court, and agrees not to plead the same, and agrees that nothing herein will limit the right to sue in any other jurisdiction if a Delaware State or Federal court of competent jurisdiction sitting in New Castle County, Delaware rules or orders that it will not exercise jurisdiction over any such action or proceeding.

f. Immunity Waiver. To the extent that a Party has or hereafter may acquire any immunity from jurisdiction of any court or from any legal process (whether through service of notice, attachment prior to judgment, attachment

in aid of execution or execution, on the ground of sovereignty or otherwise) with respect to itself or its property, it hereby irrevocably waives, to the fullest extent it may legally and effectively do so, such immunity in respect of its obligations under this Agreement.

g. Equitable Relief. Each of the Parties hereby acknowledges that a breach of their respective obligations under this Agreement may cause irreparable harm and that the remedy or remedies at law for any such breach may be inadequate. Each of the Parties hereby agrees that, in the event of any such breach, in addition to all other available remedies hereunder, the non-breaching Party shall have the right to seek equitable relief to enforce the provisions of this Agreement.

ARTICLE 8 - OTHER PROVISIONS

a. Headings. Headings and captions of the Articles and Sections hereof are for convenience only and are not to be used in the interpretation of this Agreement.

b. Assignment. Shire shall not be entitled to assign, transfer or charge all or any of its rights or obligations under this Agreement without the prior written consent of Supernus, such consent not to be unreasonably withheld or delayed; provided that Shire may transfer or assign, in whole or from time to time in part, all or any of its rights or obligations under this Agreement, without the prior written consent of Supernus (i) to an Affiliate or (ii) to any Third Party in connection with any sale or other disposition involving any assets or equity of Shire, by way of merger, business combination, asset sale, stock sale or otherwise.

Supernus shall have the right to assign, transfer, or charge its rights and obligations in their entirety under this Agreement without the consent of Shire only as part of a sale of the entire assets of Supernus to a single Third Party, and only if such assignment, transfer, or charge is to such single Third Party, such assets including all of those acquired by Supernus under the Transaction Documents. Supernus shall not have the right to assign, transfer, or charge any of its rights and obligations under this Agreement without the prior written consent of Shire under any circumstances other than such sale of its entire such assets, and Shire's consent may be withheld at Shire's sole discretion, *provided however,* that Supernus may assign, transfer, or charge its right to running royalties under Article 4 to any Third Party without the consent of Shire.

c. Notices. Any notice or other communication pursuant to this Agreement shall be sufficiently made or given on the date of mailing if sent to such party by facsimile, with confirmation of transmission, on such date, with paper copy being sent by certified first class mail, postage prepaid, or by next day express delivery service, addressed to it at its address below (or such address as it shall designate by written notice given to the other party).

if to Supernus, to:

Supernus Pharmaceuticals, Inc.
1550 East Gude Drive
Rockville, Maryland 20850
Attention: Jack Khattar
Telephone No.: (301) 838-2500
Facsimile No.: (301) 424-1364

with a copy to:

Schmeltzer, Aptaker & Shepard, P.C.
2600 Virginia Avenue, N.W. Suite 1000
Washington, D.C. 20037
Attention: Mark I. Gruhin, Esq.
Telephone No.: (202) 342-3444
Facsimile No.: (202) 342-3434
if to Shire or Guarantor, to:

if to Shire or Guarantor, to:

Shire LLC
c/o 725 Chesterbrook Boulevard
Wayne, Pennsylvania 19087-5637
Attention: Scott Applebaum
Telephone No.: (484) 595-8800
Facsimile No.: (484) 595-8900

with a copy to:

Davis Polk & Wardwell
99 Gresham Street
London EC2V 7NG
England
Attention: John K. Knight
Facsimile No.: +44 207 418 1400

and with a copy to:

Shire plc
Hampshire International Business Park
Chineham
Basingstoke
Hampshire RG24 8EP
Attention: Simon Gibbins
Facsimile No.: +44 1256 894713

d. Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including without limitation, fire, floods, embargoes, war, acts of war (whether war is declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; *provided*, *however*, that the Party so affected shall use commercially reasonable and diligent efforts to avoid or remove such causes of non-performance, and shall continue performance hereunder with reasonable dispatch wherever such causes are removed. Each Party shall provide the other Parties with prompt written notice of any delay or failure to perform that occurs by reason of *force majeure*. The Parties shall mutually seek a resolution of the delay or the failure to perform in good faith.

e. Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision. No waiver, modification, release or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by both Parties hereto.

f. Relationship of the Parties. It is expressly agreed that the relationship between Supernus and Shire shall not constitute a partnership, joint venture or agency. Supernus and Shire are independent contractors. Neither Supernus nor Shire shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party to do so.

g. Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument.

h. Severability. In performing this Agreement, the Parties shall comply with all applicable laws. Wherever there is any conflict between any provision of this Agreement and any law, the law shall prevail, but in such event the affected provision of this Agreement shall be limited or eliminated only to the extent necessary, and the remainder of this Agreement shall remain in full force and effect. In the event the terms of this Agreement are materially altered as a result of the foregoing, the parties shall renegotiate in good faith the terms of this Agreement to resolve any inequities.

i. Entire Agreement. This Agreement and the other agreements referenced herein constitute the entire agreement between the parties with respect to the subject matter hereof, and supersede any and all oral and/or written communications or understandings relating to the subject matter hereof. For the avoidance of doubt, the Agreement and each of the Transaction documents shall be treated as a stand alone agreement unless expressly provided for herein or therein.

j. Guarantor. Guarantor hereby guarantees to Supernus the prompt and full discharge by Shire of all of Shire's covenants, agreements, indemnities, obligations and liabilities under this Agreement including the due and punctual payment of all amounts which are or may become due and payable by Shire hereunder, when and as the same shall become due and payable, in accordance with the terms hereof.

IN WITNESS WHEREOF, the parties have caused their duly authorized officers to execute and deliver this Agreement as of the Effective Date.

SUPERNUS PHARMACEUTICALS, INC.

By:/s/ Jack Khattar

Name: Jack Khattar
Title: President CEO

SHIRE LLC

By:/s/ Mike Chapman

Name: Mike Chapman
Title: President

SHIRE LLC

By:/s/ Matthew Emmens

Name: Matthew Emmens
Title: Director

Exhibit A

CONFIRMATORY LICENSE AGREEMENT

THIS CONFIRMATORY LICENSE AGREEMENT ("Agreement"), effective on the 22nd day of December, 2005, ("Effective Date") is entered into by and between Supernus Pharmaceuticals, Inc. ("Supernus"), a corporation incorporated under the laws of Delaware with its principal place of business at 1550 East Gude Drive, Rockville, Maryland; Shire LLC, (Shire") a limited liability company organized under the laws of Kentucky with its principal place of business in Florence, Kentucky; and Shire plc, a company incorporated in England and Wales ("Shire plc").

RECITALS

WHEREAS Supernus has acquired and owns all right, title, and interest in the Guanfacine Patents (as defined below); and

WHEREAS Shire is desirous of obtaining and Supernus is desirous of granting a license under the Guanfacine Patents to research, develop, formulate, test, design, have manufactured, manufacture, use, offer to sell, sell, distribute, import, and export Licensed Products (as defined below) in all fields in the Territory (as defined below).

WHEREAS Supernus, Shire, and Shire plc have entered into a Guanfacine License that they wish to confirm herein, the terms stated below confirming, but not amending or restating, the terms of the Guanfacine License.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants contained herein, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties (as defined below) hereto, intending to be legally bound, hereby agree as follows.

ARTICLE 1 - DEFINITIONS

The Guanfacine License incorporates, *inter alia*, the following terms with initial letters capitalized, whether used in the singular or the plural, and have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

a. "Affiliate" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by or is under common control with such Person, where "control" means the ownership of more than 50% of the issued share capital or other equity interest or the legal power to direct or cause the direction of such Person.

b. "Effective Date" means the date first written above.

c. "Guanfacine" means (i) guanfacine (N-(Aminoiminomethyl)-2,6-dichlorobenzeneacetamide), (ii) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of (i); and (iii) any compound involving forming or breaking a bond or bonds with any of (i) or (ii) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of (i) or (ii).

d. "Guanfacine Field" means the research, development, formulation, testing, design, manufacture, use, offer to sell, sale, distribution, import, and export of any pharmaceutical product containing Guanfacine as an active ingredient.

e. "Guanfacine Know-How" means any Know-how in which Supernus has acquired or acquires any right, title, interest or Control under the Asset Purchase Agreement.

f. "Guanfacine Patents" means the following patent application and patents:

U.S. Patent Nos. 6,287,599 and 6,811,794 [**] and the patent application identified as [**], filed in the U.S. Patent and Trademark Office on [**], entitled [**]; continuation and divisional applications of any of the foregoing; any patents granted on any of the foregoing; re-examinations, reissues, renewals, extensions, supplementary protection certificates and term restorations, any confirmation patent or registration patent or patent of addition based on any such patent; and all foreign counterparts of any of the foregoing.

g. "Licensed Product" means any pharmaceutical product containing Guanfacine as an active ingredient.

h. "Parties" means Supernus, Shire, and Shire plc.

i. "Party" means Supernus, Shire, or Shire plc.

j. "Person" means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

a. "Territory" means the world.

b. Other Terms. Each of the following terms is defined in the Section set forth opposite such term:

Term	Section
Agreement	Preamble
Shire	Preamble
Shire plc	Preamble
Supernus	Preamble

a. Other Definitional and Interpretative Provisions. Unless specified otherwise, in this Agreement the obligations of any Party consisting of more than one person are joint and several. The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. References to Articles and Sections are to Articles and Sections of this Agreement unless otherwise specified. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. "Writing", "written" and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof. References to any Person include the successors and permitted assigns of that Person. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively.

ARTICLE 2 - GRANT OF RIGHTS

a. Grant of License to Shire. The grant of the Guanfacine License provides that subject to the terms and conditions of that agreement, Supernus grants to Shire and its Affiliates, in the Guanfacine Field, an irrevocable, exclusive license under the Guanfacine Patents to research, develop, formulate, test, design, have manufactured, manufacture, use, offer to sell, sell, distribute, import and export Licensed Products in the Territory.

b. Sublicenses. The grant of the Guanfacine License includes the right to grant sublicenses to Third Parties and to appoint distribution and independent sales organizations or representatives under the rights granted to Shire and its Affiliates pursuant to Section 2.1.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

IN WITNESS WHEREOF, the parties have caused their duly authorized officers to execute and deliver this Agreement as of the Effective Date.

SUPERNUS PHARMACEUTICALS, INC.

By:_____

Name:
Title:

SHIRE LLC

By:_____

Name:
Title:

SHIRE LLC

By:_____

Name:
Title:

AMENDMENT No. 1 TO THE

GUANFACINE LICENSE AGREEMENT

having an Effective Date of December 22nd, 2005

by and among Supernus Pharmaceuticals, Inc., Shire LLC and Shire plc

THIS AMENDMENT NO. 1 TO THE GUANFACINE LICENSE AGREEMENT effective on the 1st day of May, 2009, ("Guanfacine License Amendment") is entered into by and between Supernus Pharmaceuticals, Inc. ("Supernus"), a corporation incorporated under the laws of Delaware with its principal place of business at 1550 East Gude Drive, Rockville, Maryland; Shire LLC, (Shire") a limited liability company organized under the laws of Kentucky with its principal place of business at 9200 Brookfield Court, Florence, Kentucky; and Shire plc, a company organized and existing under the laws of England and Wales, now known as Shire Biopharmaceuticals Holdings ("Guarantor").

RECITALS

WHEREAS Supernus, Shire and Guarantor entered into a Guanfacine License Agreement having an Effective Date of December 22nd, 2005 (the "Guanfacine License Agreement") as part of a transaction on that same date which included a Stock Purchase Agreement, an Asset Purchase Agreement, an Ongoing Projects Agreement, and a General License Agreement;

WHEREAS the Guanfacine License Agreement provides for a royalty-bearing license under the Guanfacine Patents and Guanfacine Know-How;

WHEREAS Supernus, Shire and Guarantor are desirous of amending the Guanfacine License Agreement so that it is a paid-up, royalty-free license;

NOW, THEREFORE, in consideration of the above premises and the mutual covenants contained herein, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties (as defined below) hereto, intending to be legally bound, hereby agree as follows.

ARTICLE 1 - DEFINITIONS

The terms in this Guanfacine License Amendment with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth in the Guanfacine License Agreement, or the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

ARTICLE 2 - SPECIFIC AMENDMENTS TO THE GUANFACINE LICENSE AGREEMENT

a. The Guanfacine License Agreement is hereby amended as follows:

Article 1.18 of the Guanfacine License Agreement is deleted in its entirety.

b. The Guanfacine License Agreement is hereby amended as follows:

Article 4 of the Guanfacine License Agreement (inclusive of each of Articles 4.1 through and including 4.11) is deleted in its entirety and replaced with the following:

4.1 Within fifteen (15) days of entering into this Guanfacine License Amendment, Shire shall pay Supernus a one-time lump sum payment of thirty six million eight hundred seventy five thousand dollars ($36,875,000.00) by wire transfer to the account designated below. No other sums are payable to Supernus, now or in the future, for the licenses granted herein.

Bank Name: [5*]

Bank Address: [**]

Account Number: [**]

ABA Number: [**]

c. The Guanfacine License Agreement is hereby amended as follows:

Article 3.3 of the Guanfacine License Agreement is deleted in its entirety and replaced with the following:

3.3 Recovery. Any and all monetary damages recovered from a Third Party in connection with any action by Shire regarding infringement, misappropriation, invalidity, or unenforceability of any of the Guanfacine Patents shall belong to Shire. Any and all monetary damages recovered from a Third Party in connection with any action by Supernus regarding infringement, misappropriation, invalidity, or unenforceability of any of the Guanfacine Patents shall be used to reimburse Supernus for the expense and costs of Supernus' counsel. Shire shall receive any excess over such reimbursement to the extent such Supernus action is related to Guanfacine and not other Supernus products or licensed products. To the extent such Supernus action relates to other Supernus products or licensed products, Supernus shall receive any excess over such reimbursement.

d. The Guanfacine License Agreement is hereby amended as follows:

Article 6.1 of the Guanfacine License is deleted in its entirety and replaced with the following:

6.1 Term of the Licenses. The licenses granted to Shire by this Agreement are permanent, irrevocable, and paid-up during the Term of this Agreement and thereafter.

e. The Guanfacine License Agreement is hereby Amended as follows:

The last sentence of Article 8.2 of the Guanfacine License Agreement is deleted in its entirety and replaced with the following sentence:

Supernus shall not have the right to assign, transfer, or charge any of its rights and obligations under this Agreement without the prior written consent of Shire under any circumstances other than such sale of its entire assets, and Shire's consent may be withheld at Shire's sole discretion.

ARTICLE 3 - CONFIDENTIALITY

This Guanfacine License Amendment, and the terms thereof, shall be treated by Supernus as confidential and will not be disclosed or shared with any third parties. Notwithstanding the previous sentence, Supernus may disclose this Guanfacine License Amendment and the terms thereof (i) to its attorneys, accountants, and advisors who are bound by a professional duty of confidentiality, or (ii) pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demands issued by a court or governmental agency or as otherwise required by applicable law or regulation (including the rules of any national securities exchange or listing authority to which it or its Affiliates are subject or submit); *provided* that Supernus shall, where legally permissible, notify Shire promptly upon receipt thereof, giving Shire, where legally permissible, sufficient advance notice to permit it to seek a protective order or other similar order with respect to such information; and *provided*, *further,* that Supernus shall furnish only that portion of such information which it is advised by counsel is legally required whether or not a protective order or other similar order is obtained.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Except as expressly modified in this Guanfacine License Amendment, all terms of the Guanfacine License Agreement remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused their duly authorized officers to execute and deliver this Agreement as of the Effective Date.

SUPERNUS PHARMACEUTICALS, INC.

By:/s/ Jack Khattar
Name: Jack Khattar
Title: President CEO

SHIRE LLC

By:/s/ Mike Chapman

Name: Mike Chapman
Title: President

SHIRE BIOPHARMACEUTICALS HOLDINGS

By:/s/ Patrick Clements
Name: Patrick Clements
Title: SVP

Exhibit 10.11

CERTAIN CONFIDENTIAL INFORMATION IDENTIFIED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

June 6, 2006

EXCLUSIVE LICENSE AGREEMENT

Between

SUPERNUS PHARMACEUTICALS INC.

and

UNITED THERAPEUTICS CORPORATION

EFFECTIVE DATE: June 6, 2006

PARTIES:

(1) **SUPERNUS PHARMACEUTICALS INC.,** a Delaware corporation with its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850 (***"Supernus"***); and

(2) **UNITED THERAPEUTICS CORPORATION**, located at One Park Drive, Research Triangle Park, NC 27709 **(*"United Therapeutics"*).**

BACKGROUND

(A) Supernus is the owner of all right, title and interest in the Supernus Intellectual Property (as defined below) relating to its drug delivery and drug formulation technologies.

(B) United Therapeutics is the owner of all rights, title and interest in the United Therapeutics Intellectual Property (as defined below) relating to United Therapeutics' Compound.

(C) On July 1, 2004, Supernus and United Therapeutics entered into the first of a series of Feasibility Agreements (as defined below) to evaluate the application of the Supernus Technology (as defined below) to the Compound (as defined below).

(D) In accordance with the Feasibility Agreements, United Therapeutics has requested, and Supernus agrees to grant, an exclusive license under the Supernus Intellectual Property to make, have made, use, supply and sell Licensed Products and Licensed Combination Products (as defined below) in the Territory (as defined below) on the terms and conditions set out in this Agreement.

OPERATIVE PROVISIONS

1. INTERPRETATION

a. In this Agreement:

"Act" means the Federal Food Drug and Cosmetic Act of 1934, and the rules and regulations promulgated thereunder, as in effect from time to time;

"Affiliates" means corporations, firms, partnerships or other entities which directly or indirectly control, are controlled by, or are under common control with a Party to this Agreement. For the purpose of this definition, "control" of corporations, firms, partnerships or other entities means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies, whether through the ownership of voting stock, by contract or otherwise, and the terms "controlled" and "common control" will have correlative meanings;

"Business Day" means any day other than Saturday or Sunday on which the New York Stock Exchange is open for business;

"cGMP" means current good manufacturing practices as defined in 21 CFR Parts 210 and 211 promulgated by the FDA under the Act or corresponding applicable Laws in any jurisdiction;

"Clinical Development Data" means all data, charts, summaries, analyses, reports, know how and other information resulting or derived from any animal or human clinical trials or studies of the Compound or the Licensed Products or the Licensed Combination Products conducted under or in connection with any Development Plan relating to United Therapeutics Intellectual Property but excluding (i) any Non-Clinical Development Data, or (ii) any information, data and materials that refer to, relate to, incorporate or claim Supernus Intellectual Property;

"Commercial Sale" means any sale of a Licensed Product or a Licensed Combination Product to a Third Party in any country in the Territory in the Field; provided, however, that a transfer of Licensed Products or Licensed Combination Products (i) for research and development purposes, or (ii) prior to United Therapeutics' receipt of Product Approval for use of such Licensed Product or Licensed Combination Product in humans, shall not be considered a Commercial Sale;

"Compound" means treprostinil diethanolamine, known as UT-15C, for oral administration;

"Confidential Information" means any scientific, technical, formulation, process, analytical methods, manufacturing, clinical, non-clinical, regulatory and related documentation, marketing, financial or commercial information or data relating to the business, projects or products of either Party and provided by one Party to the other (by written, oral, electronic or other means) in connection with this Agreement;

"Development Costs" means the costs and expenses of a Development Plan due and payable to Supernus by United Therapeutics in accordance with such Development Plan;

"Development Patent" means any Patent that discloses or claims subject matter generated or derived from Non-Clinical Development Data generated under or in connection with any Development Plan, and which may include Clinical Development Data supplied by United Therapeutics to Supernus under this Agreement;

"Development Plan" means (i) any plan for the development of the Compound by Supernus as set out in clause 4 and (ii) the Feasibility Agreements as set out in Schedule 1;

"Development Team" means the team set up by the Parties in accordance with clause 4.7 and 4.8;

"EnSoTrol®" means Supernus' proprietary osmotic tablet technology including formulas, methods, techniques, Patents, and related information;

"FDA" means the United States Food and Drug Administration or any successor thereto;

"Feasibility Agreements" means those certain feasibility agreements between Supernus and United Therapeutics dated, as set out in Schedule 1, and any amendments expansions or extensions thereto;

"Field" means the treatment of any and all therapeutic indications and uses;

"First Commercial Sale" means the first sale of Licensed Product or Licensed Combination Product to any Third Party in any country in the Territory; provided, however, that a first transfer of Licensed Products or Licensed Combination Products (i) for research and development purposes, or (ii) prior to United Therapeutics' receipt of Product Approval for use of such Licensed Product or Licensed Combination Product in humans, shall not be considered a First Commercial Sale so long as United Therapeutics receives no financial consideration for same;

"GAAP" means generally accepted accounting principles in the United States;

"Improvement" means any and all improvements, enhancements or modifications, patentable or otherwise, relating to the Compound or Licensed Products or Licensed Combination Products including, without limitation, any change or modification in the manufacture, formulation, analytical methodology, ingredients, preparation, presentation or means of delivery, administration or dosage of the Compound or Licensed Products or Licensed Combination Products;

"IND" means an investigational new drug application and any amendments thereto relating to the development or use of Licensed Product or Licensed Combination Product in the United States or the equivalent application in any other jurisdiction in the Territory;

"Laws" means all federal, state, provincial and local laws, ordinances, rules and regulations in any jurisdiction applicable to this Agreement or the activities contemplated under this Agreement, whether such laws, ordinances, rules and regulations are now or hereafter in effect;

"Licensed Patents" means:

(i)all domestic and international Patents set out in Schedule 2 which are owned by or licensed to Supernus to the extent necessary to enable United Therapeutics to make, have made, use or sell Licensed Products or Licensed Combination Products, and which claim (i) a Licensed Product or Licensed Combination Product, (ii) the process of manufacture or use of a Licensed Product or Licensed Combination Product, or (iii) a congener, if any, described within the Patents set forth in Schedule 2 to this Agreement, together with any and all Patents that issue or in the future issue therefrom, including utility and design Patents and certificates of invention, or (iv) any Patent that claims an invention in the Supernus Intellectual Property;

(ii)any and all reissues, extensions, substitutions, confirmations, registrations, revalidations, renewals, supplementary protection certificates, additions, continuations, continuations-in-part, divisions, or foreign equivalents to any such Patents to the extent that they claim the subject matter set forth in (a) i, ii, iii or iv above;

(iii)the Development Patents, if any, to the extent they are necessary to enable UT to make, have made, use or sell Licensed Products and Licensed Combination Products; and

(iv)such other Patents as the Parties may agree in writing from time to time;

To the extent that any existing Patent, Patent disclosure or Supernus Improvement owned or licensed by Supernus is necessary to practice any Licensed Patent, then such necessary Patents, Patent disclosures, and Supernus Improvements will be included as Patents, to the extent that Supernus is capable to do so;

"Licensed Products" means pharmaceutical compositions comprised of the Compound as the therapeutically active ingredient and which uses or is developed or manufactured using or in connection with the Supernus Intellectual Property;

"Licensed Combination Products" means pharmaceutical compositions comprised of the Compound as a therapeutically active ingredient in combination with other active ingredients and which uses or is developed or manufactured using or in connection with the Supernus Intellectual Property.

"Milestone Event" means each event identified in clause 7 which trigger a Milestone Payment;

"Milestone Payments" means the payments by United Therapeutics to Supernus of the sum identified in clause 7 on the occurrence of a Milestone Event;

"NDA" means a New Drug Application and all supplements filed with the FDA, including all documents, data and other information concerning Licensed Products and Licensed Combination Products which are necessary for, or included in, a Product Approval to market Licensed Products and Licensed Combination Products in the United States of America, as more fully defined in the Act;

"Net Sales" means the amount invoiced by United Therapeutics, its Affiliates or its Sub-Licensees to Third Parties for the Commercial Sale of Licensed Products and Licensed Combination Products in the Territory commencing upon the date of First Commercial Sale, after deducting in accordance with GAAP, the following:

1. trade, quantity or ordinary discounts including without limitation prompt payment and volume discounts;

2. credits, allowances for Licensed Product and Licensed Combination Product returns, discounts and rebates to, and chargebacks from, the account of Third Parties for spoiled, damaged, obsolete, outdated, rejected or returned Licensed Products or Licensed Combination Products;

3. sales, use or excise taxes, VAT or other taxes; or governmental charges incurred in connection with the sale, exportation or importation, transportation, or delivery of Licensed Products or Licensed Combination Products in final form; and

4. rebates or similar payments made in connection with sales of Licensed Products and Licensed Combination Products to any governmental or regulatory authority in respect of any State or Federal Medicare, Medicaid or similar programs in any country of the Territory.

If United Therapeutics, its Affiliates or Sub-Licensees supply the Licensed Products or Licensed Combination Products to any Customer as part of a package of products or services then the Net Sales value of the Licensed Products or Licensed Combination Product shall be whichever is higher of:

1. the fair market value of such Licensed Product or Licensed Combination Product; or

2. the actual price at which United Therapeutics, its Affiliates or Sub-Licensees sold the Licensed Product or Licensed Combination Product to such Customer.

For the purposes of this clause, fair market value shall mean the value of Licensed Products or Licensed Combination Products sold to similar Third Parties in the Territory with similar pricing and reimbursement structures and for similar quantities. Any dispute as to the determination of fair market value that cannot be resolved through discussion between the Parties shall be referred to an expert in the pharmaceutical industry, knowledgeable in customary terms for such transactions and jointly chosen by the Parties, for resolution. In the absence of fraud or bad faith, the industry expert's determination will be binding.

Sales or other transfers between United Therapeutics and its Affiliates and Sub-Licensees shall be excluded from the computation of Net Sales, but Net Sales shall include the subsequent sales by such Affiliates and Sub-Licensees to any Third Parties.

"Non-Clinical Development Data" means all information, data, formulations, inventions, methods of manufacture, analytical methodology, charts, studies, summaries, analyses, reports, know how and other information generated, discovered or arising under any Development Plan relating to Supernus Technology, but excluding (i) any Clinical Development Data, or (ii) any information, data and materials that refer to, relate to, incorporate or claim United Therapeutics Intellectual Property;

"Party and Parties" means respectively Supernus or United Therapeutics, or as the case may be, being both parties to this Agreement;

"Patent" means a patent or patent application, including any and all divisions, continuations, continuations in part, extensions, substitutions, renewals, registrations, revalidations, reissues or other additions relating thereto including supplementary certificates of protection of or to any patent or patent application;

"Product Approval" means the grant of all necessary regulatory and governmental approvals required to manufacture, use, store, import, export, transport and/or sell Licensed Products or Licensed Combination Products in any country of the Territory;

"Product Launch" shall mean the date selected by United Therapeutics on which United Therapeutics first makes a Licensed Product or Licensed Combination Product available for commercial sale in each country of the Territory, after the receipt of all applicable Product Approvals required to be obtained by United Therapeutics or its suppliers prior to commercial sale of Licensed Products or Licensed Combination Products;

"*Quarter*" means a three-month period ending on the last day of March, June, September or December in any calendar year;

"*Royalty Term*" means, with respect to each Licensed Product or Licensed Combination Product in each country of the Territory, the period of 12.5 years from the date of the First Commercial Sale of each Licensed Product or Licensed Combination Product in such country;

"*Supernus Improvements*" means any and all improvements, enhancements and modifications, patentable or otherwise, which improvements, enhancements and modifications, patentable or otherwise, do not refer to, relate to, incorporate or claim United Therapeutics Intellectual Property, relating to Supernus Intellectual Property and Supernus Technology that has been, is or will be (i) identified or discovered by Supernus, or United Therapeutics, and their subcontractors or sublicensees, under any Development Plan or otherwise in accordance with this Agreement and which relate to the use of United Therapeutics Intellectual Property or Supernus Intellectual Property, or (ii) identified or discovered by United Therapeutics, and its subcontractors or sublicensees, with the use of Supernus Intellectual Property and which relate to Supernus Intellectual Property and Supernus Technology, or (iii) specific to the development and/or commercialization of Licensed Products and Licensed Combination Products within the Field;

"*Supernus Intellectual Property*" means the Licensed Patents and the Supernus Know-How existing as of the Effective Date and improved during the term of this Agreement as may be qualified by clause 25.16;

"*Supernus Know-How*" means all information, data and materials, including but not limited to the Supernus Technology, processes, formulae, data, inventions, analytical methods, know-how, trade secrets, Non-Clinical Development Data and Supernus Improvements, which are proprietary to or owned or controlled by Supernus and which are required for the development, use, manufacture or sale of Licensed Products or Licensed Combination Products, as may be qualified by clause 25.16, but which know how, trade secrets, results, inventions and any other intellectual property rights, whether patentable or otherwise, do not refer to, relate to, incorporate or claim United Therapeutics Intellectual Property;

"*Supernus Technology*" means Supernus' proprietary drug delivery technologies whether owned by Supernus, licensed to Supernus, or available to Supernus, existing as of the Effective Date including but not limited to ProPhile®, ProScreen®, OptiScreen®, Microtrol®, Solutrol®, EnSoTrol®, and any Supernus Improvements thereto that may be generated by Supernus during the term of this Agreement for use during the term of this Agreement as may be qualified by clause 25.16;

"*Specifications*" means the written methods, formulae, procedures, tests (and testing protocols) and standards and acceptance criteria relating to the testing and manufacture of Licensed Products and or Licensed Combination Products, as agreed upon in writing by the Parties;

"*Sub-Licensee*" means any Third Party sub-licensee of the rights granted to United Therapeutics to develop Licensed Products and Licensed Combination Products under this Agreement; provided, however, that entities purchasing Licensed Products and Licensed Combination Products from United Therapeutics, its Affiliates and Sub-Licensees in order to resell such Licensed Products and Licensed Combination Products to Third Parties shall not be deemed to be Sub-Licensees within the meaning of the foregoing sentence;

"*Sub-Licensee Agreement*" means any agreement entered into by United Therapeutics and a Sub-Licensee pursuant to which United Therapeutics sub-licenses any of the rights granted by Supernus under this Agreement provided such agreement contains the provisions set forth in clause 3;

"Territory" means the universe;

"Third Party" means any person or entity who or which are neither a Party nor an Affiliate of a Party;

"United Therapeutics Improvements" means any and all improvements, enhancements and modifications, patentable or otherwise, which improvements, enhancements and modifications, patentable or otherwise, do not refer to, relate to, incorporate or claim Supernus Intellectual Property relating to United Therapeutics Intellectual Property and United Therapeutics Technology that has been, is or will be (i) identified or discovered by United Therapeutics or Supernus, and their subcontractors or sublicensees, under a Development Plan or otherwise in accordance with this Agreement or with the use of United Therapeutics Intellectual Property or Supernus Intellectual Property, or (ii) identified or discovered by United Therapeutics or Supernus, and their subcontractors or sublicensees, with the use of United Therapeutics Intellectual Property or Supernus Intellectual Property and which relate solely to United Therapeutics Intellectual Property, or (iii) specific to the development and/or commercialization of Licensed Products and Licensed Combination Products within the Field;

"United Therapeutics Intellectual Property" means the Compound, United Therapeutics Patents, United Therapeutics Know How and United Therapeutics improvements;

"United Therapeutics Know How" means (i) all information, data and materials, including but not limited to reports, data, inventions, Clinical Development Data and all other data arising from the performance of *in silico* modeling of the Compound and all United Therapeutics Improvements, know how and trade secrets, patentable or otherwise, which are owned or controlled by United Therapeutics or its Affiliates and relate to the Compound or Licensed Products or Licensed Combination Products, and (ii) results, inventions and any other intellectual property rights, whether patentable or otherwise, created, developed, or arising from the performance of any Development Plan, but which know how, trade secrets, results, inventions and any other intellectual property rights, whether patentable or otherwise do not refer to, relate to, incorporate or claim Supernus Technology or Supernus Intellectual Property;

"United Therapeutics Patents" means all domestic and international Patents set out in Schedule 3; and

"Valid Patent Claim" means a claim of an issued Licensed Patent that has not (i) expired or been canceled, (ii) been declared invalid by an unreversed and unappealable decision of a court or other appropriate body of competent jurisdiction, (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, and/or (iv) been abandoned.

b. In this Agreement, unless the context requires otherwise:

3. the headings are included for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular clause;

4. references to "persons" includes individuals, bodies corporate (wherever incorporated), unincorporated associations, limited liability companies, partnerships and other entities;

5. words denoting the singular shall include the plural and vice versa;

6. words denoting one gender shall include each gender and all genders; and

7. any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.

c. The Schedules comprise part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Schedules and the terms of this Agreement, the terms of this Agreement shall prevail.

2. GRANT OF LICENSE

a. Subject to the terms of this Agreement, Supernus hereby grants United Therapeutics an exclusive license in the Field under the Supernus Intellectual Property to develop, make, have made, use, offer for sale, sell, have sold and import Licensed Products and Licensed Combination Products in the Territory for the Royalty Term.

b. The term "exclusive" for the purposes of clause 2.1 means to the exclusion of all others, including Supernus and its Affiliates, except to the extent necessary to enable Supernus to perform its obligations under this Agreement.

c. During the term of this Agreement, neither United Therapeutics nor its Affiliates shall have the right to use the Supernus Intellectual Property otherwise than as expressly set out and agreed to by the Parties in this Agreement, and without prejudice to the generality of the foregoing, United Therapeutics and its Affiliates shall not:

8. use or exploit the Supernus Intellectual Property for any purpose other than in respect of the use, development, manufacture, sale or supply of Licensed Products and Licensed Combination Products in the Field; or

9. utilize any part of the Supernus Intellectual Property in the making of any Patent application, except as otherwise agreed in writing by the Parties pursuant to the terms of this Agreement and shall be bound by, enforce and monitor its obligation set for in clause 25.16. herein

d. During the term of this Agreement, Supernus agrees that it shall not assert nor cause to be asserted against United Therapeutics, its Affiliates or its Sub-Licensees any existing information, data, materials, invention, Patent know-how, improvements or other Supernus Technology of any kind or nature not included in the Supernus Intellectual Property that is or might be infringed by reason of United Therapeutics', its Affiliates' or its Sub-Licensees' exercise of rights granted to United Therapeutics under clause 2.1.

e. During the term of this Agreement, United Therapeutics or its Affiliates, agree that it shall not assert nor cause to be asserted against Supernus, its Affiliates or its Sub-Licensees any claims relating to existing information, data, materials, invention, Patent know-how, improvements or other technology of any kind or nature that results from any development activity with parties other than Supernus or its Affiliates or its Sub-Licensees initiated by United Therapeutics that is infringed by Supernus, its Affiliates or its Sub-Licensees in connection with the development work done by Supernus, its Affiliates' or its Sub-Licensees on behalf of United Therapeutics resulting in this License Agreement to United Therapeutics.

f. United Therapeutics, at its expense, may register the exclusive license granted under this Agreement in any country, or community or association of countries within the Territory, where the use, sale or manufacture of a Licensed Product or Licensed Combination Product in such country would be covered by a Valid Patent Claim. Upon request of United Therapeutics, Supernus agrees after reviewing for accuracy to promptly execute any "short form" licenses in a form submitted to it by United Therapeutics from time to time in order to affect the foregoing registration in such country.

3. SUB-LICENSING

a. United Therapeutics shall have the right to grant sub-licenses of the rights granted to United Therapeutics by Supernus under clause 2.1 to its Affiliates or any Third Party provided that:

10. United Therapeutics shall, prior to execution of any Sub-Licensee Agreement or any sub-license agreement with an Affiliate, (i) ensure that all sub-license agreements and the obligations, covenants and agreements of sublicensee or Affiliate sublicense contained therein are consistent with and not contrary to the obligations, covenants and agreements of Licensee to Licensor in this Agreement, and (ii) provide Supernus with a copy of the agreement and give due consideration to any further comments offered in a timely manner in writing by Supernus;

11. any Sub-Licensee Agreement or any sub-license agreement with an Affiliate shall be in writing and shall give no greater rights to Sub-Licensee or Third Party than rights held by Licensor; and

12. the Sub-Licensee or Affiliate sub-licensee or Third Party shall not have the right to sub-license or assign any rights and any Sub-License Agreement or any sub-license agreement with an Affiliate shall terminate automatically on termination or expiration of this Agreement, subject to reasonable sell-off periods. In the event United Therapeutics licenses, sublicenses, transfers or in any way acts inconsistently with this Section 3, Supernus shall be entitled to immediate injunctive relief and incidental and consequential damages in addition to any other remedies available to Supernus.

b. In the event and to the extent that any such Sub-Licensee directly pays Supernus the Milestone Payments and royalty obligations under clauses 7 and 8, then in such event United Therapeutics shall not make such payments to Supernus.

4. COMMERCIALIZATION AND NEW DEVELOPMENT PLANS

a. Supernus has provided services under the Feasibility Agreement that United Therapeutics believes are sufficient for United Therapeutics to commercialize a Licensed Product or Licensed Combination Product for a first indication.

13. United Therapeutics may request in writing that Supernus perform additional services with respect to United Therapeutics' development of Licensed Products or Licensed Combination Products under this Agreement, including (i) additional work to be performed by Supernus with respect to a first indication, and (ii) work to be performed by Supernus with respect to indications beyond the first indication, together referred to as ***"Additional Services"***.

14. Upon receipt of a written request from United Therapeutics for Supernus to provide Additional Services, the Parties shall negotiate in good faith and enter into a Development Plan Agreement and with respect to each such request for Additional Services execute a work order which is bound by said Development Plan Agreement (***"Work Order"***) that will set forth the Development Costs for each such Development Plan. The Development Costs shall be Supernus' actual costs calculated at $[[1]*] plus [**]% on a mutually agreed invoicing schedule in connection with the activities carried out under each Development Plan and expansions thereof and billed accordingly. In addition, United Therapeutics shall reimburse Supernus for travel and other reasonable and customary out-of-pocket expenses incurred in the performance of a Development Plan as approved in advance in writing by United Therapeutics unless such expense satisfies previously agreed-upon written policies.

b. With respect to each such Development Plan Agreement or Work Order, Supernus shall:

15. perform such Additional Services in connection with each such Development Plan, and ensure that such services are performed with reasonable care and skill; and

16. ensure that personnel employed or engaged in the provision of services in connection with each such Development Plan are competent and have appropriate qualifications, training and experience.

c. United Therapeutics shall at its own cost provide Supernus with adequate supplies of the Compound in accordance with each such Development Plan. In the event that United Therapeutics fails to deliver or is late in delivering the Compound or any other active ingredient, the timetable for such Development Plan will be automatically extended accordingly.

d. If requested by United Therapeutics in writing, the Parties will negotiate the terms of a supply agreement with Supernus responsible for the manufacture and supply of Licensed Products or Licensed Combination Products to United Therapeutics for use in pre-clinical and clinical studies, in accordance with each such Development Plan.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Under such a supply agreement, Supernus shall manufacture Licensed Products and Licensed Combination Products:

17. in accordance with the Specifications; and

18. in compliance with cGMP, where applicable.

e. In the event that United Therapeutics wishes to amend or request additional services under a Development Plan, the Parties shall discuss the scope of any change in services under such Development Plan and the additional costs (if any). If mutually acceptable, the Parties shall, by written agreement, amend such Development Plan to incorporate the amended or additional services.

f. On reasonable written notice and no more than twice annually, Supernus shall give United Therapeutics or its preapproved nominee access to its offices and laboratories during normal business hours to review and discuss the progress of a Development Plan, approval of such nominee not to be unreasonably withheld or delayed. The Parties hereby acknowledge that since Supernus is in the partner-based drug delivery business, the Parties will be required to take certain reasonable precautions during facility visits, tours and audits to preserve the confidential nature of partner programs that may be in progress in the same facility at the appointed time.

g. The Parties shall establish a Development Team for each Development Plan consisting of not less than a representative from each Party who shall be the primary point of contact for all relevant aspects of the development and commercialization of Licensed Products and Licensed Combination Products.

h. The purpose of the Development Team is to provide a forum for the Parties to share information and knowledge in relation to the development, regulatory filing and commercialization of Licensed Products and Licensed Combination Products including, but not limited to, monitoring progress of each Development Plan, clinical studies, clinical trial programs and discussing relevant regulatory, technical, quality assurance or safety issues in relation to Licensed Products and Licensed Combination Products. The Development Team shall meet or hold telephone conferences as often as the Parties may reasonably determine.

i. The Development Plan Agreement shall set forth that Supernus shall:

19. from time to time during the course of each Development Plan and at United Therapeutics' expense, provide United Therapeutics with written updates on a mutually acceptable schedule detailing the work being performed, and will provide such other information or data reasonably requested by United Therapeutics; and

20. at the conclusion of each Development Plan, provide United Therapeutics with a written summary of the work performed in connection with each such Development Plan and the data generated.

j. After completion of any Development Plan and for as long as each such Licensed Product or Licensed Combination Product is manufactured or sold by United Therapeutics, its subcontractors, sublicensees, or assignees, United Therapeutics shall inform Supernus of any Improvements or proposed changes to such Licensed Product or Licensed Combination Product formulation, manufacturing process or United Therapeutics Know-How and shall consult with Supernus concerning the impact of any such Improvements or proposed changes.

k. United Therapeutics shall have complete control in its sole discretion over all aspects of the development and commercialization of Licensed Products or Licensed Combination Products under this Agreement, including without limitation to the development, use, manufacture and sale of Licensed Products or Licensed Combination Products in accordance with the Specifications. Pursuant to this clause, United Therapeutics will use commercially reasonable efforts to enforce confidentiality and limitations of use on its subcontractors, sublicensees and assignees as pertain to Supernus Intellectual Property and the Licensed Patents.

l. United Therapeutics shall, at its own cost, retain sole responsibility for the preparation, filing, prosecution and maintenance of all filings and applications for Product Approvals relating to Licensed Products or Licensed

Combination Products, and United Therapeutics shall solely in its direction manage all applications, requests for authorization, submissions of information and data and for all interactions with the FDA or applicable governing health authority for the purpose of attempting to obtain registration of Licensed Products and Licensed Combination Products within the Territory. United Therapeutics shall solely and exclusively own all regulatory applications, approvals, Clinical Development Data and Licensed Product and Licensed Combination Products registrations obtained by United Therapeutics or its Affiliates with respect to Licensed Products and Licensed Combination Products, including retaining control and ownership of each Drug Master File related to Licensed Products and Licensed Combination Products.

m. Supernus shall, at the request and reasonable expense of United Therapeutics, provide United Therapeutics with reasonable assistance in any IND, NDA or other regulatory filings and meetings worldwide relating to Compound or Licensed Products or Licensed Combination Products. United Therapeutics shall have the right to reference Non-Clinical Development Data, Supernus Technology and Supernus Intellectual Property to the extent necessary to support its worldwide regulatory filings and compliance program as may be pre-approved by Supernus, such approval not to be unreasonably withheld or delayed.

5. NON-CLINICAL AND CLINICAL DEVELOPMENT DATA

a. As soon as practicable after the Effective Date, Supernus shall provide United Therapeutics in a timely manner with:

21. copies of all Non-Clinical Development Data and information generated in connection with any Development Plans, including without limitation all related Supernus Intellectual Property, that is necessary for United Therapeutics to develop and commercialize Licensed Products and Licensed Combination Products under this Agreement, including without limitation the development, use, manufacture and sale of Licensed Products and Licensed Combination Products;

22. any other information or data, that in Supernus' reasonable view is generally useful for United Therapeutics to develop and commercialize Licensed Products and Licensed Combination Products under this Agreement, including without limitation the development, use, manufacture and sale of Licensed Products and Licensed Combination Products; and

23. provide United Therapeutics at its expense as shall be mutually pre-agreed upon in writing, at its request with reasonable assistance and consultation regarding the Supernus Technology and Supernus Intellectual Property, as they relate to Licensed Products and Licensed Combination Products.

b. After the Effective Date and from time to time during the term of this Agreement United Therapeutics shall, and shall procure that its Affiliates and Sub-Licensees shall, supply any Clinical Development Data to Supernus, reasonably necessary for use in:

24. fulfilling Supernus' obligations under this Agreement or any Development Plan; or

25. preparing, filing, prosecuting or defending any Development Patents.

c. During the term of this Agreement, neither Supernus nor its Affiliates shall have the right to use the United Therapeutics Intellectual Property, Licensed Products and Licensed Combination Products otherwise than as expressly set out in this Agreement, and without prejudice to the generality of the foregoing, Supernus and its Affiliates shall not:

26. use, study, experiment with or otherwise exploit the United Therapeutics Intellectual Property, Licensed Products and Licensed Combination Products; and

27. utilize any part of the United Therapeutics Intellectual Property, Licensed Products and Licensed Combination Products (but excluding Supernus' Intellectual Property) in the making of any Patent application, except as otherwise agreed in writing by the Parties pursuant to the terms of this Agreement.

6. PAYMENT TERMS

a. Payments of Development Costs under this Agreement shall be made by United Therapeutics to Supernus within 30 days after United Therapeutics' receipt of Supernus' invoice. In the event that United Therapeutics disputes any Development Cost, it shall pay the undisputed amount of Supernus' invoice as provided above, and shall, within 15 Business Days of receipt of Supernus' invoice, provide written notice to Supernus identifying the disputed charge and providing a detailed explanation of the nature of its position with respect to disputed amount. If a notice of disagreement shall be duly delivered, Supernus and United Therapeutics shall, during the 30 days following such delivery, use their best efforts to reach agreement on the disputed charges or amounts. If during such period, Supernus and United Therapeutics are unable to reach such agreement, either Supernus or United Therapeutics by notice to the other party may initiate the process whereby they shall promptly jointly retain a nationally recognized accounting firm (the **"Accounting Referee"**) and cause it to promptly review this Agreement and the disputed charges or amounts and to resolve the disputed charges or amounts. The Accounting Referee shall deliver to Supernus, as promptly as practicable but no later than 45 days, a report setting forth its calculation of the disputed charges or amounts. Such report shall be final and binding upon Supernus and United Therapeutics and any amount due to be paid or reimbursed, as the case may be, shall promptly be paid or reimbursed by the appropriate party. The cost of such review and report shall be borne by Supernus if the Accountant Referee finds in United Therapeutics favor and Supernus is required to reimburse United Therapeutics, or shall be borne by United Therapeutics, if the Accountant Referee finds in Supernus' favor and United Therapeutics owes or has paid Supernus the disputed charges.

b. Unless otherwise agreed between the Parties, all sums due under this Agreement to Supernus shall be paid in United States dollars. Net Sales shall be determined in accordance with GAAP in the currency in which each Licensed Product or Licensed Combination Product was sold and shall be converted into United States dollars using the average buying rate as published in the Wall Street Journal for the [[2]*] for which such payment is being determined.

c. Other than as otherwise provided herein, all sums due under this Agreement shall be paid without deduction, set-off or counterclaim and shall be made in full without deduction of income, value added or other taxes, charges or duties that may be imposed, except (i) insofar as United Therapeutics is required to withhold or deduct the same to comply with Laws, and (ii) to the extent that the determination of Net Sales incorporates such deductions. In the event that United Therapeutics is required to make any such deduction, it shall promptly provide Supernus with a certificate or other documentary evidence sufficient to enable Supernus to support a claim for a tax credit in respect of any amount so withheld.

d. If Laws require withholding of income taxes or other taxes imposed upon any payments by United Therapeutics to Supernus under this Agreement, Supernus shall provide United Therapeutics with applicable forms or documentation required by any applicable taxation Laws, treaties or agreements to such withholding or as necessary to claim a benefit due to Supernus thereunder (including, but not limited to Form W-8BEN or any successor forms) and United Therapeutics shall make such withholding payments as required and subtract such withholding payments from the payments due Supernus as set forth in this Agreement. United Therapeutics will use commercially reasonable efforts consistent with its usual business practices and cooperate with Supernus to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future applicable taxation treaties or agreements between foreign countries.

e. Interest shall be payable by United Therapeutics on any amounts payable to Supernus under this Agreement which are not paid within 30 days of the due date for payment. All interest shall accrue and be calculated on a daily

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[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

basis (both before and after any judgment) at the rate of [**] as published in the Wall Street Journal on that due date, for the period from the due date for payment until the date of actual payment.

f. Notwithstanding any other provision of this Agreement, if at any time legal restrictions prevent the prompt remittance of part or all of the payments required hereunder in any country, payment shall be made through such lawful means or methods as United Therapeutics may determine. When in any country the Laws prohibit both the transmittal and deposit of royalties on sales in such a country, royalty payments shall be suspended for as long as such prohibition is in effect, and shall be paid within thirty (30) days after such prohibition ceases to be in effect all royalties that United Therapeutics would have been obligated to transmit or deposit, but for the prohibition, shall be deposited or transmitted, as the case may be, to the extent allowable, less any transactional costs. United Therapeutics shall use reasonable commercial efforts to resolve with any country any prohibitions or suspensions of royalty payments. If the royalty rate specified in this Agreement should exceed the permissible rate established in any country, the royalty rate for sales in such country shall be adjusted to the highest legally permissible or government approved rate.

7. MILESTONE PAYMENTS

a. Milestone Payments for the First Indication in the Field and Territory. Subject to the terms and conditions contained in this Agreement, and in consideration of the rights granted by Supernus hereunder, United Therapeutics shall pay Supernus, or an Affiliate of Supernus designated in writing, the following Milestone Payments as pertaining to the development of Licensed Products for a first indication, contingent upon the occurrence of the corresponding specified contingent Milestone Event detailed below. For the avoidance of doubt, each Milestone Payment shall be made no more than once with respect to the achievement of such Milestone Event, but shall be payable the first time such Milestone Event is achieved:

28. $[**] within 30 days of results of the [**] human pilot pharmacokinetic study and United Therapeutics' decision to continue development;

29. $[3*] within 30 days of release of the [**] batch of pivotal GMP supplies;

30. $[**] upon the earlier of (i) validation of technology transfer to commercial manufacturing site, or (ii) April 1, 2007. Validation of Technology transfer to Commercial Site shall mean the successful manufacture of the [**] of the [**] product strengths that are suitable for use in the clinic;

31. $[**] within 30 days of completion of the [**] pivotal efficacy study and United Therapeutics' decision to pursue filing for Product Approval; and

32. $[**] within 30 days of the [**] Product Launch for the first indication.

b. Milestone Payments for the Second Indication in the Field and Territory. Subject to the terms and conditions contained in this Agreement, and in consideration of the rights granted by Supernus hereunder, United Therapeutics shall pay Supernus, or an Affiliate of Supernus designated in writing, the following Milestone Payments as pertaining to the development of Licensed Products or Licensed Combination Products for a second indication, contingent upon the occurrence of the corresponding specified contingent Milestone Event detailed below. For the avoidance of doubt, each Milestone Payment shall be made no more than once with respect to the achievement of such Milestone Event, but shall be payable the first time such Milestone Event is achieved:

33. $[**] within 30 days of release of the [**] batch of pivotal GMP supplies in accordance with, or as a result of, a Development Plan for the second indication, if any;

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34. $[**] at the earlier of: (i) initiation of the [**] pivotal efficacy study for the second indication using any of the strengths developed for the first indication, or (ii) the successful manufacture of the [**] of the new product strength for the second indication that are suitable for use in the clinic;

35. $[**] within 30 days of completion of the [**] pivotal efficacy study for the second indication and United Therapeutics' decision to pursue regulatory filing for Product Approval; and

36. $[**] within 30 days of the [**] Product Launch for the second indication.

c. Milestone Payments for Each Combination Product in the Field and Territory. Subject to the terms and conditions contained in this Agreement, and in consideration of the rights granted by Supernus hereunder, United Therapeutics shall pay Supernus, or an Affiliate of Supernus designated in writing, the following Milestone Payments as pertaining to the development of each Licensed Combination Product, contingent upon the occurrence of the corresponding specified contingent Milestone Event detailed below. For the avoidance of doubt, each Milestone Payment shall be made no more than once for each Licensed Combination Product with respect to the achievement of such Milestone Event, but shall be payable the first time such Milestone Event is achieved:

37. $[**] within 30 days of results of the [**] human pilot pharmacokinetic study and a decision to continue development for each Licensed Combination Product;

38. $[**] within 30 days of release of the [**] of pivotal GMP supplies for each Licensed Combination Product in accordance with, or as a result of, a Development Plan, if any;

39. $[**] within 30 days of validation of technology transfer to commercial manufacturing site to include the successful manufacture of the [**] of the first product strength for each Licensed Combination Product that are suitable for use in the clinic;

40. $[**] within 30 days of both completion of the primary registration study using product manufactured at the commercial site for each Licensed Combination Product and United Therapeutics' decision to pursue registration filing for Licensed Combination Product approval; and

41. $[4*] within 30 days of the Product Launch for each Licensed Combination Product, or

42. as an alternative to Milestone Payments outlined in Articles 7.3.a through 7.3.e, a one-time payment of $[**] within sixty(60) days of signing of this Agreement to expand the Field from a single Compound to all Licensed Combination Products.

d. If any of the Milestone Events outlined for the Licensed Products or Licensed Combination Products are not met or not pursued by United Therapeutics (***"Missed Event"***) resulting in a non-payment of the Milestone amount(s) to Supernus, but United Therapeutics chooses to proceed with the development of the Licensed Products or Licensed Combination Products notwithstanding, the Milestone Payments, not previously paid to Supernus shall be paid at the moment that the next Milestone Event is pursued by United Therapeutics.

e. United Therapeutics shall notify Supernus immediately upon achievement of each Milestone Event and the corresponding Milestone Payment will be paid within (30) Business Days of United Therapeutics' receipt of an invoice from Supernus.

8. ROYALTIES

a. Subject to the terms and conditions contained in this Agreement, and in consideration of the rights granted by Supernus hereunder, United Therapeutics shall for the Royalty Term, pay each Quarter to Supernus, or an

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Affiliate of Supernus designated in writing, royalties based on Net Sales during the Royalty Term as set out in the following table:

Territory/Type of Product	Indication	Royalty rate as a percentage of Net Sales
Worldwide	First	[**] %
Worldwide	Second	[**] %
Worldwide	Third and beyond	[**] %
Each Licensed Combination Product, if existing Third Party royalty obligations	All	[**] %
Each Licensed Combination Product, if no existing Third Party royalty obligations	All	[**] %

b. Upon Product Approval of a Licensed Product for the second indication the royalty rate for the first indication will be reduced to [**]% and the royalty rate for the Second Indication will be [**]%. Upon Product Approval of a Licensed Product for the Third Indication, the royalty rate for the Second Indication will be reduced to [**]% and the royalty rate for the Third Indication will be [**]%.

c. In the event that [**] study for the second indication has not been initiated using Licensed Products or Licensed Combination Products at the time of first approval for a Licensed Product the royalty rate for the first indication will be increased to [**]%.

d. No royalties shall be payable on Licensed Products or Licensed Combination Products distributed to Third Parties without the receipt of compensation solely as a sample for testing or evaluation purposes. Only one payment of royalties shall be due with respect to the same unit of a Licensed Product or Licensed Combination Product, and no multiple royalties shall be payable because any Licensed Product or Licensed Combination Product, or its manufacture, sale or use, is covered by more than one Valid Claim or is subject to both Supernus Know-How and a Valid Patent Claim. Following First Commercial Sale in any country, United Therapeutics shall have the right to distribute (without receipt of compensation and without payment of a royalty to Supernus) in any calendar year for compassionate purposes to indigent patients, an aggregate of up to [**] ([**]%) of the total number of Licensed Products or Licensed Combination Products sold in units (with the receipt of compensation) in such country in such calendar year by United Therapeutics, its Affiliates and Sub-Licensees.

e. If United Therapeutics, its Affiliates or its Sub-Licensees are required to pay royalties to any Third Party because the manufacture, use or sale of Licensed Products or Licensed Combination Products infringes any Patent or other intellectual property rights of such Third Party in any country in the Territory in accordance with clause 14 and where such infringement is not otherwise caused by United Therapeutics, its Affiliates, its Sub-Licensees, subcontractors, or its suppliers, and where such Patent or other intellectual property rights cover Supernus Intellectual Property used in such Licensed Products or Licensed Combination Products, then United Therapeutics, its Affiliates or its Sub-Licensees may deduct from royalties thereafter due to Supernus with respect to Net Sales of any Licensed Product up to the lower of: (i) [5*] ([**]%) of the royalties or such other fees paid to acquire rights in such Patent or other intellectual property right, or (ii) [**] ([**]%) of the royalties due to Supernus with respect to Net Sales of any Licensed Product or Licensed Combination Products in a given quarter.

9. [DELIBERATELY OMITTED]

10. RECORDS AND REPORTS

a. During the term of this Agreement, and for a period of four years after its expiration or termination, United Therapeutics shall, and shall procure that its Affiliate and Sub-Licensees shall, keep at its normal place of business

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detailed, accurate and up to date records and books of account showing any regulatory filings made in relation to Licensed Products or Licensed Combination Products and price increases in each country in the Territory sufficient to ascertain the achievement, or progress towards achievement, of any Milestone Events.

b. Upon the written request of Supernus, and not more than once in each calendar year, United Therapeutics shall permit an independent certified public accounting firm of nationally recognized standing, selected by Supernus and reasonably acceptable to United Therapeutics, at Supernus' expense, to have access during normal business hours to such of the books of account and records of United Therapeutics as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any year ending not more than twenty-four (24) months (unless fraud has been determined by such certified public accounting firm of nationally recognized standing in writing) prior to the date of such request. The accounting firm shall disclose to Supernus only whether the records are correct or not and the specific details concerning any discrepancies. No other information shall be shared. The accounting firm shall be entitled to take copies or extracts from the records and books of account during any such review or audit.

c. Supernus shall be solely responsible for its costs in making such review and audit unless such accounting firm identifies a discrepancy in the amounts paid in any calendar year from those payable under this Agreement for that calendar year of greater than [**]%, in which event United Therapeutics shall pay the reasonable and direct fees and expenses charged by such accounting firm, and make good the deficit in any payments that are due to Supernus (including interest on the deficit at [**] as published in the Wall Street Journal on the due date on and from the date that the relevant payments became due).

d. All information disclosed by United Therapeutics, its Affiliates and its Sub-Licensees pursuant to this clause 10 shall be deemed Confidential Information, and Supernus shall cause its accounting firm and consultants to retain all such financial information in confidence.

11. LAUNCH AND MARKETING EFFORTS

a. United Therapeutics shall, and shall procure that its Affiliates and Sub-Licensees shall, use reasonable commercial efforts to develop and commercialize Licensed Products and Licensed Combination Products. For the purpose of this clause, reasonable commercial efforts means commercial efforts consistent with normal business practices and effort used by United Therapeutics in connection with other United Therapeutics products of similar market size or importance which United Therapeutics intends to launch or has launched and sold in the Territory or any part of it, or in the absence of any such similar products, then such effort as is consistent with good industry practice.

b. United Therapeutics shall use reasonable efforts to meet and comply with any timelines which are mutually agreed by the Parties in writing for the delivery of sufficient quantity of Compound, other related material, and information requested by Supernus as may be required for development, regulatory filing, launch and commercialization of Licensed Products and Licensed Combination Products.

12. OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS

a. Nothing in this Agreement shall affect the ownership of any Party's intellectual property rights existing at the date of this Agreement or generated outside of a Development Plan which one Party agrees to make available to the other in the course of a Development Plan.

b. Subject to clauses 12.1., 12.3 and 12.4, United Therapeutics shall retain and is the sole and exclusive owner of all existing and future right, title and interest in and to all Clinical Development Data, United Therapeutics Intellectual Property whether or not created, developed, or arising from the performance of any Development Plan hereunder and to the extent all such United Therapeutics Intellectual Property has not previously been assigned to United Therapeutics, Supernus hereby completely and irrevocably assigns and transfers to United Therapeutics any and all right, title and interest that it may have in and to such United Therapeutics Intellectual Property. At the request and expense of United Therapeutics, Supernus shall promptly execute such documents and do such acts as

may be reasonably necessary to completely and exclusively vest such rights in United Therapeutics. In the event that Supernus has any rights in and to the work which cannot be assigned, and which is not Non-Clinical Development Data, Supernus' Intellectual Property, Supernus' Improvements or subject to clause 25.16, Supernus agrees to waive enforcement worldwide of such rights against United Therapeutics, its successors, distributors, licensees and assigns and, if necessary, hereby grants a fully-paid up irrevocable worldwide exclusive license to United Therapeutics with the right to sublicense and assign. Subject to clause 5.3, and other than as may be required for the purposes of this Agreement, Supernus shall not use United Therapeutics Intellectual Property without the prior written consent of United Therapeutics. Notwithstanding the provisions of this clause 12.2, Supernus may use the Clinical Development Data only for purposes of preparing, prosecuting or maintaining Patents.

c. Subject to clauses 12.1., 12.2 and 12.4, Supernus shall retain and is the sole and exclusive owner of all existing and future right, title and interest in and to all Non-Clinical Development Data, Supernus Intellectual Property, Supernus Technology, and Supernus Improvements whether or not created, developed, or arising from the performance of any Development Plan hereunder, which intellectual property belonging to Supernus includes, but is not limited to, Supernus Technology, including ProPhile℠, ProScreen®, OptiScreen®, Microtrol®, Solutrol™, or EnSoTrol® technology platforms, but explicitly excludes the United Therapeutics Intellectual Property, and United Therapeutics hereby completely and irrevocably assigns and transfers to Supernus any and all right, title and interest that it may have in and to such Supernus Technology, Supernus Intellectual Property, and Supernus Improvements. At the request and expense of Supernus, United Therapeutics shall promptly execute such documents and do such acts as may be reasonably necessary to completely and exclusively vest such rights in Supernus. Subject to clause 5.3, and other than as may be required for the purposes of this Agreement, United Therapeutics shall not use Supernus Intellectual Property without the prior written consent of Supernus. Notwithstanding the provisions of this clause 12.3, United Therapeutics may use the Non-Clinical Development Data only for purposes of preparing, prosecuting or maintaining Patents that are not in conflict with Supernus' rights and obligations under this Agreement.

d. Each Party agrees (i) to disclose promptly to the other any and all Patent applications prepared or filed by that Party which applications are made directly or indirectly as a result of the collaboration under this Agreement or further collaboration between the Parties on the subject matter of this Agreement, and (ii) promptly upon request by the other Party to sign such documents and do such things, or procure the signing of such documents or the doing of such things, as is reasonably necessary to vest such relevant intellectual property rights in the other Party.

e. Subject to the terms of this Agreement, Supernus expressly acknowledges and agrees that it shall have no right, title or any other interest in the United Therapeutics Intellectual Property.

f. Subject to the terms of this Agreement, United Therapeutics expressly acknowledges and agrees that it shall have no right, title or any other interest in the Supernus Intellectual Property.

g. United Therapeutics shall only use the Supernus Intellectual Property and Non-Clinical Development data or any other Confidential Information provided by Supernus from the Agreement solely in connection with the development and commercialization of Licensed Products and Licensed Combination Products including, but not limited to, negotiating, implementing and operating Third Party development, use, manufacturing and other partnering agreements and relationships with respect to Licensed Products and Licensed Combination Products in accordance with the Specifications, provided that the relevant Third Party enters into a confidentiality agreement with United Therapeutics on terms no less onerous than those contained in clause 17 prior to such use and further agrees to be subject to the restrictions set forth herein in clause 25.16 herein.

h. United Therapeutics hereby grants Supernus a royalty-free, non-exclusive license to use United Therapeutics Intellectual Property only in relation to:

43. the performance of any services in connection with any Development Plan or the further development of a Licensed Product or Licensed Combination Product under this Agreement; or

44. the filing, prosecuting, maintaining or commercializing any Patent arising from and relating to the Supernus Intellectual Property and Development Patents.

i. The express provisions of this Agreement provide for all licenses granted by and to the Parties hereunder and no additional transfer, license or other grant of rights concerning a Party's intellectual property shall be implied from either such express provisions of this Agreement or from the performance under any Development Plan.

j. Each Party shall promptly disclose to the other Party, in such detail as is reasonably required, any Improvements developed in accordance with the terms of this Agreement.

k. Nothing in this Agreement gives either Party any right, title or interest in any trademarks owned or used by the other Party.

13. PATENTS

a. Subject to clause 13.3, Supernus shall at its sole option and expense prepare, file, prosecute and maintain the Licensed Patents that relate to the Licensed Products or Licensed Combination Products in the [**] and at the expense of United Therapeutics in any other countries requested in writing. At Supernus' option, all filings in additional countries will be prepared, filed, prosecuted and maintained by United Therapeutics on behalf of Supernus at United Therapeutics' sole cost and expense.

b. Supernus shall, at its sole option at its own cost, file, prosecute and maintain any Development Patents in the [6*] and at United Therapeutics' expense any other countries requested by United Therapeutics in writing. At Supernus' option, all filings of Development Patent applications in additional countries will be prepared, filed, prosecuted and maintained by United Therapeutics on behalf of Supernus at United Therapeutics' sole cost and expense.

c. In the event that Supernus elects to abandon any pending application or granted Patent for both Licensed Patents and Development Patents, it shall provide adequate written notice to United Therapeutics and give United Therapeutics the opportunity to file or maintain such application or Patent on behalf of Supernus, the cost and expense of which shall be deducted from payments to be made by United Therapeutics to Supernus under this Agreement. Without limiting the generality of the foregoing, in no event shall Supernus provide United Therapeutics with written notice of abandonment of any Licensed Patent or Development Patent less than 60 days prior to its date of lapse.

d. Each Party shall keep the other Party reasonably informed of all material matters in connection with the filing, prosecution and maintenance of Patents with respect to both Licensed Patents and Development Patents, including providing United Therapeutics with copies of substantive communications submitted to or received from patent offices throughout the Territory.

e. Each Party for a reasonable period of time shall make available to the other Party or its authorized attorneys, agents, consultants or representatives, if available, such information necessary or appropriate but subject to any restraints of confidentiality or contract to enable the appropriate Party to prepare, file, prosecute and maintain Patents with respect to both Licensed Patents and Development Patents as set forth in this clause 13 Where appropriate, each Party shall sign or cause to have signed all documents relating to said Patents at no charge to the other.

14. INFRINGEMENT OF THIRD PARTY RIGHTS

a. If either Party becomes aware that the exercise of such Party's rights and obligations under this Agreement are infringing, or may infringe, the intellectual property rights of a Third Party in any country in the Territory, it will

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promptly notify the other Party in writing and provide the other Party with such details of the Third Party's relevant intellectual property rights and the extent of any infringement as are known to it.

b. The Parties shall, after receipt of notice referred to in clause 14.1, discuss the infringement and, to the extent necessary, attempt to agree on a course of action. Such course of action may include:

45. obtaining an appropriate license from the Third Party; or

46. contesting any claim or proceedings brought by the Third Party.

c. If within 28 days of the date of the notice referred to in clause 14.1, the Parties have not agreed upon an appropriate course of action then:

47. Supernus may decide, at its own cost and expense, upon the course of action with respect to any claim which relates exclusively or predominantly to any of the Supernus Technology (***"Supernus Action"***); and

48. United Therapeutics may decide, at its own cost and expense, upon the course of action with respect to any claim which relates exclusively or predominantly to, such Licensed Product or Licensed Combination Product (so long as it does not fall within the definition of a Supernus Action), Clinical Development Data or other United Therapeutics Intellectual Property (***"United Therapeutics Action"***).

d. For the avoidance of doubt, United Therapeutics may negotiate a license for the use of Third Party intellectual property rights, in connection with any United Therapeutics Action, and Supernus may negotiate a license for the use of Third Party intellectual property rights, in connection with any Supernus Action. In such event, the Parties shall keep each other fully informed of any license negotiations.

e. If within 180 days from receiving notice from a Third Party relating to a Supernus Action, Supernus fails or refuses to respond to or defend any such claim or negotiate a license from such Third Party, United Therapeutics may defend such claim or (subject to the prior written consent of Supernus, not to be unreasonably withheld or delayed) negotiate a license with such Third Party. If within 180 days from receiving notice from a Third Party relating to a United Therapeutics Action, United Therapeutics fails or refuses to respond to or defend any such claim or negotiate a license from such Third Party, Supernus may defend such claim or (subject to the prior written consent of United Therapeutics, not to be unreasonably withheld or delayed) negotiate a license with such Third Party.

f. If at any time a Third Party files a lawsuit against United Therapeutics, its Affiliates, Sub-Licensees or distributors asserting that the alleged infringing process, method or composition is claimed under the Supernus Intellectual Property, Supernus shall have the right, in its sole discretion, to control the defense of such suit at its own expense, in which event United Therapeutics shall have the right to be represented by advisory counsel of its own selection, at its own expense, and shall cooperate fully in the defense of such suit and furnish to Supernus all evidence and assistance in its control. If Supernus does not elect within thirty (30) days after receiving written notice of such Third Party lawsuit to so control the defense of such suit, United Therapeutics may undertake such control at its own expense, and Supernus shall then have the right to be represented by advisory counsel of its own selection, at its own expense, and Supernus shall cooperate fully in the defense of such suit and furnish to United Therapeutics all evidence and assistance in United Therapeutics' control. The Party controlling the suit may not settle the suit or otherwise consent to an adverse judgment in such suit that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. Any judgments, settlements or damages payable with respect to legal proceedings covered by this clause 14.6 shall be paid by the Party which controls the litigation, subject to the other Party's indemnification obligations under clause 16, if any.

15. INFRINGEMENT OF LICENSED PATENTS BY THIRD PARTY

a. If either Party becomes aware of any Third Party infringement or suspected infringement of any Supernus Intellectual Property used in connection with a Licensed Product or Licensed Combination Product, it will promptly notify the other Party in writing and provide it with such details of the Third Party infringement as are known to it.

b. The Parties shall, after receipt of notice referred to in clause 15.1, discuss the infringement and, to the extent necessary, attempt to agree on the necessary steps to be taken to prevent or terminate such Third Party infringement, the proportions that any costs of proceedings or action shall be shared and the proportions that any damages or other sums awarded in their favor (or against them) shall be divided.

c. If within 90 days of the date of the notice referred to in clause 15.1, the Parties have not agreed upon an appropriate course of action then the following shall apply:

49. if the Licensed Patent or Development Patent contains one or more claims specifically directed to Compound or a Licensed Product or a Licensed Combination Product (including but not limited to compositions containing the Compound), then United Therapeutics shall have the right, but not the obligation, to commence, at its sole expense, any action or proceedings, negotiate a license or take such other steps as are necessary to terminate or prevent the Third Party infringement. United Therapeutics shall provide Supernus with prior written notice of the initiation of any such action or proceedings and shall keep Supernus informed of any significant developments. In the event that United Therapeutics has not commenced any action or proceedings to terminate or prevent such infringement within 120 days after having become aware of such potential infringement, then Supernus may at its reasonable discretion take such action as is reasonably necessary and appropriate to terminate or prevent such infringement; and

50. if the Licensed Patent or Development Patent does not contain one or more claims specifically directed to formulations of Compound or a Licensed Product or a Licensed Combination Product (including but not limited to compositions containing the Compound), then Supernus shall have the right, but not the obligation, to commence, at Supernus' expense, any action or proceedings, negotiate a license or take such other steps as are necessary to terminate or prevent the Third Party infringement. Supernus shall provide United Therapeutics with prior written notice of the initiation of any such action or proceedings and shall keep United Therapeutics informed of any significant developments. In the event that Supernus has not commenced any action or proceedings to terminate or prevent such infringement within 120 days after having become aware of such potential infringement, then United Therapeutics may at its reasonable discretion take such action as is reasonably necessary and appropriate to terminate or prevent such infringement.

d. The Party controlling the action or proceedings shall not settle the action or proceedings or otherwise consent to an adverse judgment that diminishes the rights or interests of the other Party without the prior written consent of that Party, such consent not to be unreasonably withheld or delayed.

e. Each Party shall use reasonable efforts to cooperate with the other Party's requests and, to the extent possible, shall keep the other Party reasonably informed of all material matters in connection with the commencement and prosecution of any such action or proceeding.

f. Each Party shall make available to the other Party or its authorized attorneys, agents, consultants or representatives, if available, such information necessary or appropriate to enable the appropriate Party to commence and prosecute any such action or proceeding for a period of time reasonably sufficient for such Party to obtain the assistance it needs from such personnel.

g. Any award of damages or other amount received by either Party as a result of a successful action, proceedings or settlement negotiations under clauses 14 or 15 shall be divided between the Parties as follows:

51. the Party that initiated, prosecuted or maintained the defense of the action or proceedings shall recoup all of its costs and expenses (including reasonable attorneys' and expert fees) incurred in connection with the action or proceedings;

52. after deducting the costs and expenses identified in clause 15.7(a), the other Party shall, to the extent possible, recover its costs and expenses (including reasonable attorneys' and expert fees) incurred in connection with the action or proceedings;

53. if Supernus initiated, prosecuted or maintained the defense of, the action or proceedings, any amount remaining after the deduction of both Parties' costs and expenses outlined in clauses 15.7 (a) and (b) shall be retained by Supernus; and

54. if United Therapeutics initiated, prosecuted or maintained the defense of the action or proceedings, any amount remaining after the deduction of both Parties' the costs and expenses outlined in clauses 15.7 (a) and (b) shall be retained by United Therapeutics, except that Supernus shall receive a portion equivalent to the royalties it would have received under this Agreement if such remaining recovery amount were deemed to be Net Sales.

16. INDEMNIFICATION AND LIABILITY

a. Subject to Supernus' compliance with clause 16.3, United Therapeutics will indemnify and hold Supernus, and its Affiliates and its and their directors, officers, employees and agents (each an "***Supernus Party***") harmless from and against any Third Party costs, claims, damages and expenses (including reasonable attorneys' fees, expenses to defend and amounts paid in settlement of any action paid in accordance with clause 16.3. herein) suffered or incurred by any Supernus Party, and arising out of any development activity initiated by United Therapeutics with Third Parties, or in connection with the clinical trials to be conducted by or on behalf of United Therapeutics under this Agreement or under any Development Plan, or in connection with any aspect of bringing Licensed Products or Licensed Combination Products to market including but not limited to any development, scale-up, transfer, manufacturing, marketing, sale and distribution of Licensed Products or Licensed Combination Products, except to the extent that such costs, claims, damages or expenses arise from the gross negligence, breach of the terms of this Agreement or willful misconduct by a Supernus Party.

b. Subject to United Therapeutics' compliance with clause 16.3, Supernus will indemnify and hold United Therapeutics, its Affiliates, Sub-Licensees and its and their directors, officers, employees and agents (each a "***United Therapeutics Party***") harmless from and against any Third Party costs, claims, damages and expenses (including reasonable attorneys' fees, expenses to defend and amounts paid in settlement of any action paid in accordance with clause 16.3. herein) suffered or incurred by any United Therapeutics Party, and arising out of or in connection with the activities conducted by Supernus or by Third Parties under its control in its facility in connection with any Development Plan under this Agreement, except to the extent that such costs, claims, damages or expenses arise from the gross negligence, breach of the terms of this Agreement or willful misconduct by a United Therapeutics Party.

c. In all cases where a Party seeks indemnification by the other under this clause 16, the Party seeking indemnification shall promptly notify the indemnifying Party in writing, in the manner set forth in clause 23, of receipt of any claim or lawsuit covered by such indemnification obligation and shall cooperate fully with the indemnifying Party in connection with the investigation and defense of such claim or lawsuit. The indemnifying Party shall have the right to control the defense, with counsel of its choice, provided that the non-indemnifying Party shall have the right to be represented by advisory counsel at its own expense. The indemnifying Party shall not settle or dispose of the matter in any manner, which could negatively and materially affect the rights or liability of the non-indemnifying Party without the non-indemnifying Party's prior written consent, which shall not be unreasonably withheld or delayed.

d. EXCEPT AS MAY BE OTHERWISE SET FORTH HEREIN, UNDER NO CIRCUMSTANCES WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, COLLATERAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OR FOR ANY LOST PROFITS OF THE OTHER

PARTY, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING OUT OF THE PERFORMANCE OR FAILURE TO PERFORM ANY OBLIGATIONS SET FORTH HEREIN, EXCEPT FOR THOSE DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR WILLFUL MALFEASANCE.

17. CONFIDENTIALITY AND PUBLICATIONS

a. The Parties, their Affiliates and their respective employees, directors, officers, consultants and contractors shall keep and maintain as confidential and shall not publish or otherwise disclose any Confidential Information supplied by the other Party during the term of this Agreement. The confidentiality and non-disclosure obligations contained in this Agreement shall not apply to the extent that a Party can demonstrate by competent written evidence that such Confidential Information is:

55. information that at the time of disclosure by one Party to the other is in the public domain or otherwise generally available to the public;

56. information which after disclosure by one Party to the other becomes part of the public domain or otherwise becomes generally available to the public, other than by breach of this Agreement by the receiving Party;

57. information which the receiving Party can establish was already in its possession at the time of receipt or was independently developed by the receiving Party; or

58. information received from a Third Party who was lawfully entitled to disclose such information and the disclosure of which will not violate clause 25.16 herein.

b. Notwithstanding the limitations in this clause 17.1, but so long as it does not violate the provisions of clause 25.16, each Party may disclose Confidential Information to the extent such disclosure is reasonably necessary in the following instances, but solely for the limited purpose of such necessity:

59. prosecuting or defending litigation;

60. complying with applicable governmental Laws, including without limitation, NASDAQ and SEC disclosure requirements, or court orders;

61. to file Patent applications or prosecute such applications to grant or to gain approval to conduct clinical trials in relation to Licensed Products or Licensed Combination Products;

62. disclosure to employees, consultants or agents, solely in furtherance of this Agreement, provided that such individuals have agreed in writing to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in clause 17.1; or

63. general information of a non-material nature regarding the general status of the development and commercialization of Licensed Products or Licensed Combination Products.

Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the Confidential Information of the other Party pursuant to clauses 17.2(a) and (b), it will give prompt advance written notice to the other Party of such disclosure and shall use its best efforts to assist the other Party in securing confidential treatment of such information.

c. The Parties shall consult with each other, in advance, with regard to the terms of all proposed press releases, public announcements and other public statements relating to any Confidential Information or the transactions contemplated under this Agreement. The obligations contained in this clause 17 shall continue for the duration of the Agreement and for a period of [7*] after the termination or expiration of this Agreement.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

d. From time to time it may be to the mutual interest of the Parties to publish articles relating to data generated or analyzed as a part of this Agreement. Neither Party shall submit for written or oral publication or presentation any manuscript, abstract, writing, printed material or the like which includes data or any other information generated and provided solely by the other Party without first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, provided however, that (i) valid commercial reasons may exist for withholding such consent, (ii) such prior consent shall not be required for publications and presentations that do not disclose details of the Supernus Technology (e.g., clinical articles), and (iii) if a party does not object within ten days of its receipt of a proposed publication or presentation from the other party, then it will be deemed to have consented to such publication or presentation. Nothing contained herein shall be construed as precluding either Party from its own intellectual property, making, in its discretion, any disclosures of information of any type which relate to the safety, efficacy, toxicology, or pharmacokinetic characteristics of the Licensed Products and Licensed Combination Products to the extent that either Party may be required by law to make disclosures of such information.

e. The terms of this Agreement are deemed to be Confidential Information, subject to clause 17.1; provided however, each Party shall be free to disclose the terms of the Agreement to potential investors, financial institutions, licensors, licensees and consultants provided such disclosures are subject to no less restrictive terms of confidentiality than as are set forth in this Agreement.

18. COVENANTS, REPRESENTATIONS AND WARRANTIES

a. Covenants by Both Parties throughout the Term of this Agreement:

64. Each Party covenants that it will use its reasonable best efforts to obtain and maintain in full force and effect all necessary licenses, permits and other authorizations required by Law to carry out its duties and obligations under this Agreement. Each Party shall cooperate with the other to provide such letters, documentation and other information on a timely basis as the other Party may reasonably require to fulfill its reporting and other obligations under Laws to applicable regulatory authorities. Except for such amounts as are expressly required to be paid by a Party to the other under this Agreement, each Party shall be solely responsible for any costs incurred by it to comply with its obligations under Laws. Each Party shall conduct its activities hereunder in an ethical and professional manner.

65. Each Party hereby covenants that each of its employees and other Third Parties performing any work under the any Development Plan and otherwise in accordance with this Agreement shall have entered into a written invention assignment agreement requiring that each such Third Party assign to such Party all right, title and interest in and to any intellectual property conceived of and/or reduced to practice by such Third Party or its employees, consultants or agents in connection with any activities under any Development Plans and otherwise in accordance with this Agreement.

66. Each Party hereby covenants that it has not and shall not knowingly misappropriate or otherwise misuse, nor shall it knowingly permit any of its employees, consultants or agents to misappropriate or otherwise misuse, any intellectual property of any Third Party in its conduct in accordance with any Development Plan and this Agreement.

67. Each Party covenants that it shall cooperate with the other and provide such assistance and resources as the other Party may reasonably request in connection with performance of the obligations under this Agreement.

68. Each Party covenants that it shall not, without the prior written consent of the other Party, acquire, directly or indirectly, any securities of the other Party or any right or options to acquire any such securities, or issue any public announcements naming the other Party without the prior written consent of such Party.

69. Each Party covenants that it will immediately notify the other in writing if any debarment proceedings have commenced against a Party or any employees of consultants of a Party, or if an employee or consultant of a Party is debarred by the FDA.

b. By Supernus. Supernus represents and warrants to United Therapeutics as of the Effective Date that:

70. It has the full right, power and authority to enter into this Agreement, perform this Agreement and to grant all of the rights, property and authorizations granted in this Agreement; that this Agreement has been duly executed and delivered by Supernus and is a legal, valid and binding obligation enforceable against Supernus in accordance with its terms; that, to the best of its knowledge, there are no agreements, commitments or obstacles, technical or legal, including intellectual property rights of others, which could prevent it from carrying out all of its obligations hereunder; and that the execution, delivery and performance of this Agreement does not and will not violate any law, statute, local ordinance, state or federal regulation, court order, or administrative order ruling, its corporate charter or bylaws, nor any agreement by which it is bound;

71. It is the sole owner or exclusive licensee of the Supernus Intellectual Property in the Territory with the power and right to license or sublicense the Supernus Intellectual Property in accordance with this Agreement and, to the best of Supernus' knowledge as of the Effective Date, the use of the Supernus Intellectual Property under the terms and conditions contemplated by this Agreement will not infringe upon any Third Party's know-how, Patent or other intellectual property rights or constitute misuse of confidential information by United Therapeutics;

72. To the best of its knowledge, there is no (i) action, suit, proceeding or investigation pending or threatened against Supernus that challenges the validity of this Agreement or the right of Supernus to enter into this Agreement, or to consummate the transactions contemplated hereby, or which might result, either individually or in the aggregate, in any material adverse change in the development of the Supernus Intellectual Property or commercial sales of a Licensed Product or Licensed Combination Product hereunder. The foregoing includes, without limitation, actions pending or threatened involving the prior employment of any of Supernus' employees, their use in connection with Supernus' business or any confidential information or techniques allegedly proprietary to any of their former employers, or their obligations under any agreements with prior employers; (ii) any pending or threatened claims or litigation brought by a Third Party under any Third Party Patent, trade secret or other Third Party proprietary right in respect of Supernus' exploitation of the Supernus Intellectual Property; (iii) any basis upon which practice of the inventions described in the Licensed Patents or Supernus Intellectual Property would infringe on the rights of Third Parties; (iv) any licenses or other restrictions on the ability to develop, make, have made, use, import, market, promote, sell, have sold or otherwise practice the Supernus Intellectual Property; or (v) any scientific information, published or unpublished, relating to studies or experiments with the Supernus Intellectual Property, whether conducted by Supernus or by Third Parties, that would suggest development and commercialization of the Supernus Intellectual Property is not feasible;

73. To the best of its knowledge, Supernus is not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any court or government agency or instrumentality that would have a material adverse effect on the license granted pursuant to clause 2.1;

74. To the best of its knowledge, Supernus is not in violation of any applicable Laws or restriction of any domestic or foreign government or any instrumentality or agency thereof in respect of the conduct of its business or the ownership of its properties which violation would have a material adverse effect on the development and commercialization of Licensed Products and Licensed Combination Products hereunder;

75. To the best of its knowledge, Supernus nor any of its employees or consultants engaged in any Development Plan have been "debarred" by the United States Food and Drug Administration (the "***FDA***"), nor have any such debarment proceedings against it or any such employees or consultants been commenced;

76. A complete list of (i) all Patents included in the Licensed Patents as of the Effective Date and (ii) all Patents owned by Third Parties and validly and exclusively licensed to Supernus, with the unrestricted right except as may be qualified herein to exclusively sublicense to United Therapeutics, is provided at Schedule 2 attached to this Agreement. Supernus owns or controls under valid licenses and has the right to license or sublicense, except as may be qualified herein all right, title and interest in and to any Third Party Patents listed on Schedule 2; and

77. It has made available to United Therapeutics all material Supernus Know-How, Non-Clinical Development Data and Supernus Confidential Information in its possession or control that is required for the development and commercialization of the Supernus Intellectual Property as permitted in clause 2.1, including without limitation the development, use, manufacture and sale of Licensed Products.

c. By United Therapeutics. United Therapeutics represents and warrants to Supernus as of the Effective Date that:

78. It has the full right, power and authority to enter into this Agreement, perform this Agreement and to grant all of the rights, property and authorizations granted in this Agreement; that this Agreement has been duly executed and delivered by United Therapeutics and is a legal, valid and binding obligation enforceable against United Therapeutics in accordance with its terms; that, to the best of its knowledge, there are no agreements, commitments or obstacles, technical or legal, including intellectual property rights of others, which could prevent it from carrying out all of its obligations hereunder; and that the execution, delivery and performance of this Agreement does not and will not violate any law, statute, local ordinance, state or federal regulation, court order, or administrative order ruling, its corporate charter or bylaws, nor any agreement by which it is bound;

79. It has the power and right to commercialize Licensed Products and Licensed Combination Products in accordance with this Agreement and, to the best of United Therapeutics' knowledge as of the Effective Date, the use of the United Therapeutics Intellectual Property and Confidential Information under the terms and conditions contemplated by this Agreement will not infringe upon any Third Party's know-how, Patent or other intellectual property rights or constitute misuse of confidential information by either Party hereto;

80. To the best of its knowledge, there is no (i) action, suit, proceeding or investigation pending or threatened against United Therapeutics that challenges the validity of this Agreement or the right of United Therapeutics to enter into this Agreement, or to consummate the transactions contemplated hereby, or which might result, either individually or in the aggregate, in any material adverse change in the development of a Licensed Product or Licensed Combination Product hereunder. The foregoing includes, without limitation, actions pending or threatened involving the prior employment of any of United Therapeutics' employees, their use in connection with United Therapeutics' business or any confidential information or techniques allegedly proprietary to any of their former employers, or their obligations under any agreements with prior employers; or (ii) any pending or threatened claims or litigation brought by a Third Party under any Third Party Patent, trade secret or other Third Party proprietary right in respect of United Therapeutics exploitation of the United Therapeutics Intellectual Property;

81. To the best of its knowledge, United Therapeutics is not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any court or government agency or instrumentality that would have a material adverse effect on the development and commercialization of Licensed Products and Licensed Combination Products hereunder; and

82. To the best of its knowledge, United Therapeutics is not in violation of any applicable Laws or restriction of any domestic or foreign government or any instrumentality or agency thereof in respect of the conduct of its business or the ownership of its properties which violation would have a material adverse effect on the development and commercialization of Licensed Products and Licensed Combination Products hereunder; and

83. To the best of its knowledge, United Therapeutics' nor any of its employees or consultants engaged in any Development Plan have been "debarred" by the United States Food and Drug Administration (the "***FDA***"), nor have any such debarment proceedings against it or any such employees or consultants been commenced.

d. EXCEPT AS EXPRESSLY PROVIDED HEREIN EACH PARTY DISCLAIMS ALL WARRANTIES AND MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED. THE PARTIES EACH ACKNOWLEDGES AND AGREE THAT THE DEVELOPMENT ACTIVITIES HEREUNDER ARE EXPERIMENTAL IN NATURE AND THAT NEITHER PARTY MAKES A GUARANTEE AS TO THE RESULTS OR PERFORMANCE THEREOF THROUGH THE DEVELOPMENT STAGE. HOWEVER, THIS

PROVISION IS NOT INTENDED TO MITIGATE OR REDUCE THE EFFECT OF THE INDEMNITY PROVISIONS SET FORTH HEREIN.

19. TERM

This Agreement commences on the Effective Date and, subject to earlier termination in accordance with clause 20, shall expire on a country-by-country and Licensed Product-by-Licensed Product or Licensed Combination Product-by-Licensed Combination Product basis upon the date of the last to expire payment obligation pursuant to the Royalty Term.

20. TERMINATION

a. Either Party may terminate this Agreement by giving written notice to the other if the other Party commits any material breach of this Agreement, which, in the case of a breach capable of remedy, is not remedied by the Party in default within 60 days of receipt of a detailed notice requiring it to do so.

b. In the event of the institution by or against either Party of insolvency, receivership, bankruptcy proceedings, or any other proceedings for the settlement of a Party's debts which are not dismissed within sixty (60) days, or upon a Party's making an assignment for the benefit of creditors, or upon a Party's dissolution or ceasing to do business, the other Party may terminate this Agreement upon written notice. All rights and licenses granted to United Therapeutics under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that United Therapeutics, as a licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code; provided however, nothing herein shall be deemed to constitute a present exercise of such rights and elections and such rights shall be no greater than provided pursuant to this Agreement. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Supernus under the U.S. Bankruptcy Code, and so long as United Therapeutics is not in material breach of this Agreement, United Therapeutics shall be entitled to reasonable access to appropriate Supernus Intellectual Property, unless Supernus elects to continue to perform all of its obligations under this Agreement

c. This Agreement may be terminated by United Therapeutics by notice in writing to Supernus at any time after Supernus has a reasonable opportunity to cure after receiving written notice (if a cure is possible) from United Therapeutics for a technical, strategic or market-related cause (including, without limitation, technical, safety, efficacy, regulatory, competition, patient-related issues, emergence of new technologies, etc. rendering further development unjustified in United Therapeutics' opinion) in its sole discretion upon written notice to Supernus. Termination by United Therapeutics shall immediately terminate all licenses granted hereunder.

d. If United Therapeutics or any Sub-Licensee, after having launched a Licensed Product or Licensed Combination Product in any country in the Territory, discontinues sale of such Licensed Product or Licensed Combination Product in such country for a period of [8*] or more for reasons unrelated to Force Majeure (as defined in clause 22), regulatory or safety issues and subsequently fails to resume sales of any Licensed Product or Licensed Combination Product in such country within 120 days of having been notified in writing of such failure by Supernus, then Supernus may in its discretion terminate the license granted to United Therapeutics under this Agreement with respect to such discontinued Licensed Product or Licensed Combination Product in such country. For the purposes of this clause 20.5, sales of minimal or commercially insignificant quantities of a Licensed Product or Licensed Combination Product in a country shall be deemed to constitute a discontinuation of sales in such country.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

21. CONSEQUENCES OF TERMINATION

a. On termination or expiration of this Agreement for any reason other than a material breach by Supernus, the license granted under clause 2.1 shall immediately cease and United Therapeutics shall, and shall procure that its Affiliates and Sub-Licensees shall, immediately:

84. subject to clause 21.3, cease to carry out any of the activities permitted by this Agreement (or any relevant Sub-License Agreement or Third Party Agreement) and cease to use or exploit in any way the Supernus Intellectual Property;

85. within 30 days of the effective date of the termination, make all outstanding undisputed payments, including any Milestone Payments and royalty payments due to Supernus at the date of termination; and

86. return, or at Supernus' option, destroy all Supernus Know-How and Supernus Confidential Information and any materials containing the Supernus Know-How and Supernus Confidential Information in its possession, custody or power except for such records as may be required by any Laws; provided however, that United Therapeutics may retain one copy of each document of Supernus' Confidential Information to enable United Therapeutics to determine its surviving obligations of confidentiality and non-use with respect to Supernus' Confidential Information, provided, however, that the copy (i) is kept in a secure place with access limited to the General Counsel only, and (ii) is returned to Supernus at the expiration of the last of any surviving obligations.

b. On termination or expiration of this Agreement for any reason, Supernus shall promptly return, or at United Therapeutics' option, destroy all United Therapeutics Know-How and United Therapeutics Confidential Information and any materials containing the United Therapeutics Know-How and United Therapeutics Confidential Information in its possession, custody or power except for such records as may be required by any Laws; provided however, that Supernus may retain one copy of each document of United Therapeutics Confidential Information to enable Supernus to determine its surviving obligations of confidentiality and non-use with respect to United Therapeutics Confidential Information, provided, however, that the copy (i) is kept in a secure place with access limited to the General Counsel only, and (ii) returned to United Therapeutics at the expiration of the last of any surviving obligations.

c. Subject to payment of royalty and related obligations, United Therapeutics, its Affiliates and its Sub-Licensees shall be entitled to continue to sell existing stocks of the Licensed Products and Licensed Combination Products in the Territory for a period of not longer than [9*] following the date of termination in accordance with the terms and conditions of this Agreement.

d. Upon the termination or expiration of this Agreement, United Therapeutics shall, and shall procure that its Affiliates and Sub-Licensees shall, execute such documents as Supernus may reasonably require to record at all appropriate patent offices throughout the Territory that United Therapeutics or the relevant Sub-Licensee has ceased to be entitled to use and exploit the Licensed Patents.

e. Clauses 6, 8, 10, 12, 13, 14, 15, 16, 17 (for [**]), 18.2 and 18.3 (for three years), 19, 21, 25, and applicable definitions herein shall survive the termination or expiration of this Agreement.

f. Termination or expiration of this Agreement shall not relieve either Party of any liability that accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

g. Termination of this Agreement will be without prejudice to Supernus' right to receive payment of (i) all undisputed Development Costs, Milestone Payments or Royalties, incurred or committed to as of the effective date

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[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

of the termination, and (ii) all Royalties for as long as the Licensed Products and Licensed Combination Products are sold by United Therapeutics, its Affiliates or Sub-Licensees.

h. In the event of termination of this Agreement, the Parties shall meet in good faith to discuss and endeavor to agree on the steps required to affect an orderly closure of any ongoing Development Plan. In the event that the termination of this Agreement occurred for a reason other than as a result of a material breach by Supernus, Supernus shall be entitled to reasonable payment for work carried out or for noncancellable or unavoidable work committed to by Supernus under a Development Plan and any reasonable and direct out-of-pocket expenses incurred or noncancellable or unavoidable reasonable and direct out-of-pocket expenses committed to by Supernus under a Development Plan as of the date of termination.

22. FORCE MAJEURE

a. Neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any act of God, earthquake, flood, labor strike or lockout, war, revolution, civil commotion, epidemic, blockage or embargo, failure or default of public utilities or common carriers, destruction of production facilities or materials, or similar catastrophic event (*"**Force Majeure**"*), provided the Party affected shall give prompt written notice thereof to the other Party. Subject to clause 21.2, the Party giving such notice shall be excused from such of its obligations hereunder for so long as it continues to be affected by Force Majeure and the non-performing Party takes commercially reasonable efforts to remove the condition.

b. Notwithstanding the foregoing, if any such Force Majeure continues unabated for a period of at least [10*], the Parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected Party. If resolution has not been reached within [**] of good faith discussion, either Party shall have the right to terminate the Agreement on a country by country basis.

23. NOTICES

a. Any notice, consent or other document given under this Agreement shall be in writing in the English language, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given if (i) personally delivered or sent by prepaid first class certified or registered mail, express delivery service, or (ii) sent by fax transmission or e-mail and confirmed through one of the methods described in (i) above, to the address of the receiving Party as set out in clause 23.3, unless a different address or fax number has been notified to the other in writing for this purpose.

b. Each such notice or document shall:

87. if personally delivered or if sent by express delivery service, be deemed to have been given when delivered at the relevant address;

88. if sent by sent by prepaid first class certified or registered mail, be deemed to have been given seven days after posting; or

89. if sent by fax transmission be deemed to have been given when transmitted provided that a confirmatory copy of such facsimile transmission shall have been sent by prepaid airmail within 24 hours of such transmission.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

c. The address for services of notices and other documents on the Parties shall be:

To Supernus:		**To United Therapeutics:**	
Address:	1550 East Gude Drive, Rockville, Maryland 20850 United States of America	**Address:**	One Park Drive Research Triangle Park, NC 27709 United States of America
Fax:	+301-424-1364	**Fax:**	919-485-8352
Attention:	Jack Khattar Chief Executive Officer	**Attention:**	Roger Jeffs, Ph.D. President & COO
Copy To:	Supernus Legal Department and Mark I. Gruhin, Esq. Schmeltzer, Aptaker & Shepard, P.C. 2600 Virginia Avenue, N.W. Suite 1000 Washington, D.C. 20037	**Copy To:**	Paul A. Mahon, Esq. General Counsel United Therapeutics Corporation 1735 Connecticut Ave, NW Washington, DC 20009
Fax:	202-342-3434	**Fax:**	202-483-4006

24. ASSIGNMENT

a. Subject to clauses 24.2 and 24.3, neither Party shall assign or transfer this Agreement or any of its rights or obligations under this Agreement without the prior written consent of the other.

b. Notwithstanding the prohibition in clause 24.1, either Party may assign or transfer this Agreement to a wholly owned subsidiary or to a successor to the Party's business by merger, sale of stock, or sale of substantially all assets, provided that, in the case of any assignment or transfer of this Agreement to a wholly-owned subsidiary, the assigning or transferring Party shall remain fully liable for all of its obligations hereunder. Any permitted successor or assignee of rights and/or obligations hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. This Agreement shall be binding upon and shall inure to the benefit of each Party's permitted successors-in-interest and permitted assigns. Any assignment or attempted assignment by either Party in violation of the terms of this clause 24.2 shall be null and void and of no legal effect

c. Notwithstanding the prohibition in clause 24.1, United Therapeutics may sub-license all or any of its rights or obligations under this Agreement provided that United Therapeutics and its Sub-Licensees comply with the obligations set out in clauses 3.1 and 25.16 of this Agreement.

25. GENERAL PROVISIONS

a. Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any person that it has any such right or authority. Nothing in this Agreement shall be construed as establishing a partnership or joint venture relationship between the Parties.

b. Dispute Resolution. Any disagreement between Supernus and United Therapeutics on the interpretation of this Agreement or any aspect of the performance by either Party of its obligations under this Agreement shall be resolved in accordance with the dispute resolution procedure set out in Schedule 4.

c. Further Actions. Each of the Parties shall do, execute and perform and shall procure to be done, executed and performed, all such further acts, deeds, declarations, documents and things as the other Party may reasonably

require from time to time to give full effect to the terms of this Agreement and carry out the purposes and intent of this Agreement.

d. Costs. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

e. Entire Agreement. Except as otherwise set forth herein, this Agreement sets out the complete, final and exclusive agreement and understanding between the Parties in respect of the subject matter hereof, and all of the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to such subject matter, and supersedes and terminates any prior agreements and understandings, either oral or written, with respect to such subject matter. It is further agreed that:

90. there are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth herein;

91. no Party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other Party which is not expressly set out in this Agreement;

92. no Party shall have any remedy in respect of misrepresentation or untrue statement made by the other Party or for any breach of warranty which is not contained in this Agreement;

93. this clause shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation: and

94. this Agreement supersedes any inconsistent language contained in any Feasibility Agreement.

f. Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event of an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement. Nothing in this Agreement shall operate to:

95. exclude any provision implied into this Agreement by law and which may not be excluded by law; or

96. limit or exclude any liability, right or remedy to a greater extent than is permissible under law.

g. Amendment. No extension, termination, alteration, amendment, modification, change, addition to or other variation of this Agreement shall be binding upon the Parties unless it is in writing and signed by an authorized officer of each Party. Unless expressly agreed, no such amendment or variation shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the Parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so varied.

h. Severability. If and to the extent that any provision of this Agreement is held to be illegal, void, invalid or unenforceable, such provision shall be given no effect and shall he deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

i. No Waiver. No failure or delay by either Party in enforcing a Party’s rights under this Agreement or exercising any right or remedy provided by law under or pursuant to this Agreement, or any waiver as to a particular default or other matter, shall be construed as a waiver of such Party’s rights to the future enforcement of its rights

under this Agreement or impair such right or remedy or operate or preclude its exercise at any subsequent time, and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

j. Remedies Cumulative. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.

k. No Prejudice to Licensed Patents. If in any jurisdiction the effect of any provision of this Agreement or the absence from this Agreement of any provision would be to prejudice the Licensed Patents or any remedy under the Licensed Patents, the Parties will make such amendments to this Agreement and execute such further agreements and documents limited to that part of the Territory which falls under such jurisdiction as may be necessary to remove such prejudicial effects.

l. Counterparts. This Agreement may be executed in any number of counterparts and by the Parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.

m. Governing Law; Jurisdiction and Venue. Except as maybe otherwise set forth herein, this Agreement will be governed and construed in accordance with the Laws of the State of Maryland. No lawsuit pertaining to any matter arising under or growing out of this Agreement shall be instituted in any jurisdiction other than in the courts located in the State of Maryland, and the Parties consent to exclusive jurisdiction before the federal or state courts of the State of Maryland without reference to the choice of law provisions of any other jurisdiction.

n. Legal Fees. If any dispute arises between the Parties with respect to the matters covered by this Agreement which leads to a proceeding to resolve such dispute, the prevailing Party in such proceeding shall be entitled to receive its reasonable attorneys' fees, expert witness fees and out-of-pocket costs incurred in connection with such proceeding, in addition to any other relief it may be awarded.

o. Maintenance of Records. Each Party shall keep and maintain all records required by law or regulation with respect to development of a Licensed Product or Licensed Combination Product and shall make copies of such records available to the other Party upon request.

p. Certain Arrangements of Supernus with Shire; Third Party Beneficiary Rights.

97. United Therapeutics acknowledges that Supernus represents that it has certain contractual agreements with subsidiaries of Shire plc ("**Shire**") pursuant to which (i) Supernus has granted to Shire and its subsidiaries an irrevocable, exclusive license, including the right to sue, in intellectual property rights (including without limitation patents, patent applications and know-how) owned by Supernus to research, develop, formulate, test, design, have manufactured, manufacture, use, offer to sell, sell, distribute, import and export any pharmaceutical product containing at least one of the Restricted Compounds (as defined below) as an active ingredient anywhere in the world and (ii) Supernus has agreed not to engage, directly or indirectly, including as a principal or for its own account or solely or jointly with others or in cooperation with a third party, or as a licensor of intellectual property, in any research, formulation development, testing, manufacture, offer for sale, sale, distribution, importation, exportation, design, technology assessment or oral bioavailability screening or enhancement that relates, in whole or in part, to any of the Restricted Compounds in any field of use, or otherwise aid or assist any third party in connection with any of the foregoing. For purposes hereof, "**Restricted Compounds**" means any and all of: (A)(I) (+)-alpha-Methylbenzeneethanamine, also known as "amphetamine", (II) carbamazepine (5H-Dibenz{b,f}azepine-5-carboxyamide), (III) guanfacine (N-(Aminoiminomethyl)-2,6-dichlorobenzeneacetamide), (IV) lanthanum, and (V) mesalamine (5-Amino-2-hydroxybenzoic acid), (B) any isomers, salts, solvates, hydrates, polymorphs, esters, prodrugs, or metabolites of clause (A), and (C) any compound involving forming or breaking a bond or bonds with any of clause (A) or (B) where at least one prophylactic, therapeutic or diagnostic indication of such compound and/or its metabolite is substantially the same as that of any of clause (A) or (B), but excluding 10,11-Dihydro-10-oxo-5H-debenz[b,f]azepine-5-carboxamide, also known as "oxcarbazepine".

98. United Therapeutics hereby agrees that it shall not use any of the services or Confidential Information provided to it, or work performed on its behalf, by Supernus pursuant to this Agreement, or the results therefrom, or any intellectual property rights licensed to it by Supernus in any activity that is outside the purpose of this Agreement and, in particular, in any activity that, directly or indirectly, relates, in whole or in part, to any of the Restricted Compounds in any field of use. The provisions of this clause 25.16 (i) are intended to benefit, and shall be enforceable by, Shire and its subsidiaries, (ii) shall survive any termination or expiration of this Agreement and (iii) shall not be amended or waived, in whole or in part, without the prior written consent of Shire. Supernus has agreed to provide Shire with a list of its customer names from time to time for monitoring purposes and United Therapeutics hereby agrees to its name being provided to Shire. Shire has agreed to keep the list and the terms of this Agreement confidential in accordance with the terms of a confidentiality agreement with Supernus, except to the extent reasonably necessary for Shire to investigate any alleged violation of, or to enforce its rights under, the provisions of this clause 25.16. United Therapeutics acknowledges that Supernus has agreed with Shire that if Shire or any of its subsidiaries in its sole discretion believes that there may be, or may have been, a breach or threatened breach of the provisions of this clause 25.16, at the written request of Shire, Supernus shall provide Shire and its subsidiaries with an executed copy of this Agreement, and United Therapeutics hereby consents to Supernus providing such copy to Shire or any of its subsidiaries.

99. In the event United Therapeutics breaches or threatens to breach the provisions of this clause 25.16, should the breach or threatened breach relate directly or indirectly to any activities relating to any of the Restricted Compounds then, in addition to any rights that Supernus may have against United Therapeutics, United Therapeutics acknowledges and agrees that Shire or any of its subsidiaries shall have the right to bring a suit, action or proceeding against United Therapeutics for any and all damages suffered or incurred by Shire and its subsidiaries as a result of United Therapeutics' breach or threatened breach, whether or not Supernus is a party to the suit, action or proceeding. If any legal action or other proceeding is brought by Shire for the enforcement of this clause 25.16, and such action is successful, Shire shall be entitled to recover its reasonable attorney's fees, court costs and reasonable expenses, even if not taxable or assessable as court costs (including, without limitation, all such fees, costs and expenses incident to appeal) incurred in that action or proceeding in addition to any other relief to which Shire may be entitled. If any legal action or other proceeding is brought by Shire for the enforcement of this clause 25.16, and such action is unsuccessful, United Therapeutics shall be entitled to recover its reasonable attorney's fees, court costs and reasonable expenses, even if not taxable or assessable as court costs (including, without limitation, all such fees, costs and expenses incident to appeal) incurred in that action or proceeding in addition to any other relief to which United Therapeutics may be entitled. United Therapeutics further acknowledges that a breach or threatened breach of these provisions may cause irreparable harm to Shire and its subsidiaries and that the remedy or remedies at law for any such breach or threatened breach may be inadequate. United Therapeutics agrees that, in the event of any such breach or threatened breach, in addition to all other available remedies they may have available to them, Shire and its subsidiaries shall have the right to obtain equitable relief.

100. United Therapeutics agrees that Shire and its subsidiaries shall not be liable for any claim or counterclaim (equitable, statutory, contractual or otherwise) that could he asserted by United Therapeutics against Supernus and that no such claims or counterclaims shall be asserted against Shire or any of its subsidiaries. United Therapeutics further agrees to waive against Shire and its subsidiaries any such claims or counterclaims (equitable, statutory, contractual or otherwise) and also agrees that in any action by Shire or any of its subsidiaries it will not assert and will waive any defense, bar or other similar matter (equitable, statutory, contractual or otherwise) based on or relating to the actions, inactions or status of Supernus. To the extent that the assertion of any such claims, counterclaims, defenses, bars or similar matters is compulsory, Supernus may be joined in the action and such claims, counterclaims, defenses, bars or other matters asserted against Supernus (but only against Supernus) and Supernus hereby agrees to such joinder.

101. The provisions of this clause 25.16 shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law rules of such state. Each of the Parties hereto acknowledges and agrees that this provision of this Agreement has been entered into in express reliance upon 6 Del. C. § 2708 and hereby waives, to the fullest extent permitted by law, any and all objections to the laws of the State of Delaware governing this provision of this Agreement.

102. Each of the Parties hereto irrevocably and unconditionally submits to the jurisdiction of the courts of the State of Delaware and of the Federal courts sitting in the State of Delaware any Delaware State or Federal court sitting in New Castle County, Delaware and any appropriate appellate courts therefrom in any suit, action or proceeding arising out of or relating to this provision of this Agreement and irrevocably consents to the jurisdiction of such courts and any appropriate appellate courts therefrom in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in ay such court or that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. Each of the Parties hereto irrevocably and unconditionally agrees that (i) to the extent such party is not otherwise subject to service of process in the State of Delaware, to appoint and maintain an agent in the State of Delaware as such party's agent for acceptance of legal process and to notify the other party of the name and address of such agent and (ii) to the fullest extent permitted by law, service of process may also be made on such party by prepaid certified mail with a validated proof of mailing receipt constituting evidence of valid service, and that service made pursuant to (i) or (ii) above shall, to the fullest extent permitted by law, have the same legal force and effect as if served upon such party personally within the State of Delaware. For purposes of implementing the Parties' agreement to appoint and maintain an agent for service of process in the State of Delaware, each party that has not as of the date hereof already duly appointed such an agent does hereby appoint [name to be inserted], as such agent.

103. EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THE PROVISIONS OF THIS CLAUSE 25.16.

AS WITNESS WHEREOF this Agreement has been signed by the duly authorized representatives of the Parties on the day and year first above written.

SIGNED for and by behalf of	)	/s/ Jack Khattar
SUPERNUS PHARMACEUTICALS, INC.		
	)	Jack Khattar, CEO
		Print Name and Title
SIGNED for and by behalf of	)	/s/ David Mottola
UNITED THERAPEUTICS CORPORATION	)	David Mottola, VP-Product Dev.
	)	**Print Name and Title**

SCHEDULE 1

Feasibility Agreements and Expansions

[[11]*]

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

SCHEDULE 2

Licensed Patents -Issued Patents and Patent Applications

G = Granted; **I** = Inactive; **F** = Filed

[[12]*]

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

SCHEDULE 3

United Therapeutics Patents

[13*]

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

SCHEDULE 4

Dispute Resolution Procedure

The Parties agree to consult and negotiate in good faith to try to resolve any dispute, controversy or claim that arises out of or relates to this Agreement.

1.1 In the event of any controversy or claim arising out of, relating to or in connection with an ongoing Development Program, the Parties shall try to settle their differences amicably between themselves by referring the disputed matter to the Development Team. Within 10 Business Days of receipt of a written request from either Party to the other, the Development Team shall meet to discuss and in good faith try to resolve any claim, dispute, controversy, or disagreement (a "***Dispute***") between the Parties arising out of or in connection with such Development Program without recourse to legal proceedings.

1.2 In the event of a Dispute in connection with this Agreement, or the rights or obligations of the Parties hereunder, that is not related to an ongoing Development Program, the Parties shall try to settle their differences amicably between themselves by referring the disputed matter to Group Legal Counsel of the Parties (the "***Legal Counsel***") for discussion and resolution. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within fifteen Business Days of receipt of such notice, the Legal Counsel shall meet to discuss and in good faith try to resolve such Dispute arising out of or in connection with the terms (or interpretation of the terms) of this Agreement without recourse to legal proceedings.

1.3 If resolution of the Dispute does not occur within 20 Business Days after the Development Team meeting or the meeting of the Legal Counsel, as the case may be, the matter shall be escalated for determination by the respective Presidents of the Parties ***(the "Officers")*** who may resolve the matter themselves or jointly appoint a mediator or an independent expert. The Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within 20 Business Days after such notice is received. If the Officers are unable to settle the Dispute between themselves within 20 Business Days, and the Officers are unable to agree on the appointment of an independent expert, they shall report to the Parties on the progress of the negotiations in writing and the Dispute shall then be referred to mediation as set forth in the following subsection 1.3.

Mediation

1.4 Upon the Parties receiving the Officers' report that the Dispute referred to them pursuant to subsection 1.3 has not been resolved, the Dispute shall be referred to mediation by written notice from either Party to the other. The mediation shall be conducted pursuant to the rules of the American Arbitration Association ("***AAA***"). The place of the mediation shall be Washington, D.C., United States and the language of the mediation shall be English.

1.5 If after the procedures set forth in subsections 1.2 to 1.4, the Dispute has not been resolved, a Party shall have the right to pursue its action in a court of law or equity having jurisdiction over the matter.

Exhibit 10.12

CERTAIN CONFIDENTIAL INFORMATION IDENTIFIED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

PURCHASE AND SALE AGREEMENT

THIS PURCHASE AND SALE AGREEMENT is made as of June 9, 2006 (the "Effective Date") by and between Supernus Pharmaceuticals Inc, a Delaware corporation with principal offices located at 1550 East Gude Drive, Rockville, Maryland 20850 ("Supernus") and Rune Healthcare Limited, an English corporation, with principal offices located at 9a Magdala Road, Nottingham NG3 5DE, United Kingdom ("RH").

RECITALS:

WHEREAS, RH has developed and owns the RH Concept (as hereinafter defined);

WHEREAS, RH has agreed to sell to Supernus and Supernus has agreed to buy from RH the RH Concept on the terms and conditions set forth herein; and

WHEREAS, RH has agreed not to compete, recreate or sell the RH Concept to any other party on the terms and conditions set forth herein; and

NOW THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement, the parties agree as follows:

ARTICLE 1.

DEFINITIONS

a. **"RH Concept"** shall mean RH pharmaceutical Product concepts, RH Market Analysis, any supportive data, information, reports, intelligence, or other data that may be in the possession of RH prior to the Effective Date (attached herein as Schedule 1) or may be obtained by RH at any time during the term of this Agreement that may be applicable or supportive to any Product, or Supernus Product.

b. **"Supernus Product"** shall mean any Product that is developed by or on behalf of Supernus and is based on the RH Concept.

c. **"RH Market Analysis"** shall mean those items set forth on Schedule I including but not limited to (i) Market Review with comparison of Product Profile vs. competitive products, (ii) RH Concept Analysis - publication search, (iii) Patent Search - Worldwide search dated, albeit minimal analysis done by patent experts, (iv) Primary Research - 50 structured experts' interviews at an international conference held in Europe and (v) Preliminary Forecasting Analysis based on said Primary Research, all such documents having been provided by RH to Supernus in writing prior to the Effective Date.

d. **"Affiliate"** shall mean a corporation or other business entity controlled by, controlling, or under common control with a Party. For this purpose, control shall mean the direct or indirect ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of such corporation or other business.

e. **"Agreement"** shall mean this Agreement.

f. **"Confidential Information"** shall mean any information of either Party, which, if written, is marked confidential by the disclosing Party or, if oral, is reduced to writing, marked confidential by the disclosing Party, and

provided to the non-disclosing Party within thirty (30) days of the oral disclosure, (b) all information relating to RH Concept and Supernus Product.

g. **"Due Diligence"** shall mean all necessary activities to be conducted by Supernus in its sole discretion and at its own cost following the Effective Date through the Due Diligence Period.

h. **"Due Diligence Period"** shall mean [[1]*] from the Effective Date.

i. **"Default"** shall mean, with respect to either Party, such Party shall have failed to perform any material obligation set forth herein; provided however, that such Party shall have not brought, or not commenced substantial remedial action to bring, the facts underlying such representation or warranty into conformance with such representation or warranty or shall not have performed, or commenced substantial remedial action to perform, such material obligation, within sixty (60) days after receipt of written notice from the other Party specifying in detail the material obligation which has not been performed and requesting that the failure to perform be remedied within sixty (60) days.

j. **"Effective Date"** shall mean the date of this Agreement.

k. **"First Commercial Sale"** shall mean the initial sale of a Supernus Product by Supernus to a Third Party in exchange for cash or some equivalent to which value can be assigned for purposes of determining Net Sales.

l. **"Field"** shall mean the treatment, diagnosis or prevention of diseases in humans or animals.

m. **"Force Majeure"** shall mean any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by the Party of any of its obligations hereunder, if such occurs by reason of any act of God, flood, fire, explosion, breakdown of plant, earthquake, strike, lockout, labor dispute (other than strike, lockout or labor dispute of a Party's own employees), casualty or accident, or war, revolution, civil commotion, acts of public enemies, blockage or embargo, or any reasonably unforeseen delays associated with clinical trials of the Supernus Product, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision including but not limited to the requirements and conditions of the Food and Drug Administration of the United States, authority or representative or any such government, inability to procure or use materials, including but not limited to any material needed to manufacture any Supernus Product, equipment, transportation, or energy sufficient to meet manufacturing needs without the necessity of allocation, or any other cause whatsoever, whether similar or dissimilar to those above enumerated, beyond the reasonable control of such Party, if and only if the Party affected shall have used reasonable efforts to avoid such occurrence and to remedy it promptly if it shall have occurred and shall have notified the other Party in writing of the reasons for the delay or default.

n. **"Net Sales"** means the gross amount invoiced by Supernus, its Affiliates or its Licensees for the sale of the Supernus Products in the Territory commencing upon the date of First Commercial Sale, after deducting the following:

a. trade quantity or ordinary discounts including prompt payment and volume discounts; chargebacks from wholesalers and other allowances granted to customers (whether in cash or trade);

b. allowances for Product returns;

c. sales or excise taxes, VAT or other taxes charged or levied on sales (but excluding taxes on the income of Supernus, its Affiliates or its Licensees);

d. rebates or similar payments made in connection with sales of Supernus Product to any governmental or regulatory authority in respect of any State or Federal Medicare, Medicaid or

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[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

similar programs in any country of the Territory. Sales or other transfers between Supernus and its Affiliates or Licensees shall be excluded from the computation of Net Sales, and

e. freight, packing, freight insurance and rebates.

o. **"Party"** shall mean Supernus or RH, as the case may be, and "**Parties**" shall mean Supernus and RH collectively.

p. **"Person"** shall mean an individual, a partnership, a joint venture, a corporation, a trust, an estate, an unincorporated organization, or any other entity, or a government or any department or agency thereof.

q. **"Product"** shall mean [[2]*] or formulations thereof for the [**].

r. **"Territory"** shall mean the World.

s. **"Third Party"** shall mean any Person other than RH and Supernus or an Affiliate.

t. **"Licensee"** shall mean a person or entity appointed by Supernus as a licensee under this Agreement and shall include any sub-licensee appointed by such Licensee.

ARTICLE 2.

PURCHASE AND SALE OF RH CONCEPT

a. **RH Concept Purchase.** On the terms and subject to the conditions and exceptions contained herein, RH agrees to sell to Supernus and Supernus agrees to purchase from RH on the Closing Date, free and clear of all liens, claims, liabilities, obligations and encumbrances (except those liens, encumbrances and security interests set forth on Schedule 2.1 (the "Permitted Encumbrances")) all of Seller's right, title and interest in and to the RH Concept including but not limited to all of RH's right, title and interest in any copyrights or other intellectual property or ownership rights in and to the RH Concept.

b. **Due Diligence Period.** Supernus shall have the Due Diligence Period to determine whether or not it desires to close on the purchase of the RH Concept. RH hereby agrees to cooperate on a timely basis, with Supernus and provide Supernus with such information it has in its possession or readily available to it that Supernus may reasonably require for it to conduct its Due Diligence process. In the event Supernus desires not to purchase the RH Concept for any reason, it shall notify RH of same prior to the expiration of the Due Diligence Period by executing and delivering written notice attached hereto as Exhibit 2.2. and made a part hereof by this reference. If no notice is sent by Supernus to RH prior to the expiration of the Due Diligence Period, the parties shall close the purchase and sale of the RH Concept on the Closing Date.

c. **Closing.** The transactions contemplated herein shall be consummated (the "Closing") within thirty (30) calendar days following the expiration of the due diligence period or at such other time mutually acceptable by the parties hereto at the offices of Schmeltzer, Aptaker & Shepard, P.C., 2600 Virginia Avenue, N.W., Suite 1000, Washington, D.C. 20037.

d. **Non-Competition and Related Matters.** At the Closing, RH shall enter into a non-competition, non-solicitation, non-disclosure and non-circumvention agreement **(the "Noncompetition Agreement")** with Supernus in the form attached as Exhibit 2.4.

ARTICLE 3.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

REPRESENTATIONS, WARRANTIES AND COVENANTS

Whenever the terms “knowledge” or “Supernus’ knowledge” are used in this Agreement, including this Article 3, such terms shall mean the knowledge, after reasonably diligent inquiry, of Supernus. In order to induce RH to enter into this Agreement and to consummate the transactions contemplated herein, and with the knowledge that the RH is relying on the representations, warranties and covenants herein contained, Supernus represents and warrants to RH on the date hereof, to be ratified in all respects as of the Closing Date.

a. Representations and Warranties of Supernus. Supernus offers as warranties the statements set forth herein. Supernus makes no other warranties.

i..Corporate Power. Supernus is duly organized and validly existing under the laws of the State of Delaware and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

ii..Due Authorization. Supernus is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder. The Person executing this Agreement on Supernus’ behalf has been duly authorized to do so by all requisite corporate action.

iii..Binding Agreement. This Agreement is a legal and valid obligation binding upon Supernus, and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by Supernus does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

iv..No Other Warranties. SUPERNUS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED REGARDING THE SUCCESS OF THE DEVELOPMENT, MANUFACTURING OR MARKETING OF THE RH CONCEPT OR SUPERNUS PRODUCTS.

b. Representations and Warranties of RH. RH offers as warranties the statements set forth herein. RH makes no other warranties.

Whenever the terms “knowledge” or “RH’s knowledge” are used in this Agreement, including this Article 3, such terms shall mean the knowledge, after reasonably diligent inquiry of RH. In order to induce Supernus to enter into this Agreement and to consummate the transactions contemplated herein, and with the knowledge that the Supernus is relying on the representations, warranties and covenants herein contained, RH represents and warrants to Supernus on the date hereof, to be ratified in all respects as of the Closing Date.

i..Corporate Power. RH is duly organized and validly existing under the laws of England and has full corporate power and authority to enter into this Agreement and carry out the provisions hereof.

ii..Due Authorization. RH is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder. The Person executing this Agreement on RH’s behalf has been duly authorized to do so by all requisite corporate action. Licensor represents and warrants that it has the full and lawful right and authority to grant the exclusive option and exclusive licensing rights described hereunder.

iii..Binding Agreement. This Agreement is a legal and valid obligation binding upon RH, and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by RH does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

iv..No Undisclosed Liabilities. There are no liabilities or obligations (whether absolute, accrued, contingent or otherwise) in connection with the RH Concept.

v..Good Title. RH has and, upon consummation of the transactions contemplated hereby Supernus will have, good and marketable title to the RH Concept, free and clear of any lien, pledge, mortgage, security interest or encumbrance of any kind.

vi..No Notice. RH has not received any notice from any government agency or any other third party which is applicable to the RH Concept and which would have a Material Adverse Effect on Supernus' full rights to develop the RH Concept or the Supernus Product as contemplated herein after the Closing Date.

vii..No Other Contracts. Other than this Agreement, Seller is not a party to any oral or written contract, or understanding with any other party in connection with the RH Concept. RH is not in default under any contract, agreement or other understanding relating to the RH Concept to which it is or was a party.

viii..No Litigation. RH is not party to any litigation and to the best of RH's knowledge no litigation is pending or threatened and no ground or basis exists which, either absolute or contingently would give rise to any litigation in connection with the RH Concept.

ix..No Warranties Regarding Intellectual Property or Fitness. RH does not warrant that it has any intellectual property rights in the RH Concept except as described in this Agreement and makes no representations whatsoever with regard to the scope of the RH Concept or that the Supernus Product may he exploited without infringing other patents or other intellectual property rights of Third Parties. RH MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR INFRINGEMENT OF ANY SUBJECT MATTER DEFINED BY THE RH MARKET ANALYSIS. RH MAKES NO WARRANTIES, EXPRESSED OR IMPLIED REGARDING THE SUCCESS OF THE DEVELOPMENT, MANUFACTURING OR MARKETING OF THE RH CONCEPT OR ANY SUPERNUS PRODUCT.

x..True Information. The information including but not limited to the RH Concept furnished by or on behalf of RH to Supernus in connection with this Agreement does not contain any untrue statement of a material fact and does not omit to state any material fact necessary to make the statements made, in the context in which made, not false or misleading. Notwithstanding any knowledge or facts determined or which might have been determined by Supernus pursuant to any rights hereunder to investigate, Supernus shall be entitled to rely fully upon all representations, warranties, covenants and agreements and other undertakings contained in this Agreement or in any schedule, document or instrument delivered pursuant hereto or otherwise made pursuant to this Agreement, in Supernus' determination to consummate the transactions contemplated by this Agreement.

ARTICLE 4.

DEVELOPMENT AND COMMERCIALIZATION

a. Development and Commercialization. Supernus, in its sole discretion and at its sole cost and risk, shall have the right to make all decisions relating to the development and commercialization of the Supernus Products under the RH Concept including, but not limited to, all decisions relating to the research, pre-clinical, and clinical development of the RH Concept, and the promotion, advertising, marketing and pricing of the Supernus Products. Supernus shall use its commercially reasonable efforts and judgment to actively develop and market the Supernus Product(s) throughout the Territory.

b. Reports. Supernus shall deliver to RH, on a semi-annual basis, project updates on Supernus development activities for the Supernus Product (including project timelines and the identities of actual partners).

ARTICLE 5.

CONSIDERATION

a. **Consideration.** In consideration for the sale of the RH Concept and the execution of the Non-Competition Agreement, in addition to the other payments set forth in this Article 5, Supernus shall pay to RH the U.S. equivalent of £25,000 at Closing.

b. Royalties.

i..Net Sales. In consideration for the sale of the RH Concept and the execution of the Non-Competition Agreement in addition to the other payments set forth in this Article 5, Supernus shall pay to RH in immediately available funds royalties of [3*]% of Net Sales of the Supernus Product.

ii.. No Multiple Royalties. Royalties under this Section 5.2 shall be payable on a Supernus Product-by-Supernus Product basis, and shall be imposed only once with respect to any sale of the same unit of Supernus Product by Supernus and no multiple royalties shall be payable by Supernus.

iii..Expiration of Royalty Payments. Supernus' obligation to pay royalties to RH on a country by country basis shall expire upon the earlier of:

1... Ten (10) years from the date of First Commercial Sale of an Supernus Product or

2... The market entry in a country of the Territory of a Product by any entity other than Supernus, an Affiliate of Supernus, or its Licensees.

3... Reduction of Royalty Payments. Supernus' obligation to pay royalties to RH shall at Supernus' sole discretion be reduced by the full amount of any damages or expenses resulting from RH's inability to fulfill any of its obligations under this Agreement including but not limited to Article 10 herein.

c. **Payment of Royalties; Reports**.

i..First Commercial Sale. Supernus shall report to RH the date of First Commercial Sale of a Supernus Product within thirty (30) days of such occurrence in each country of the Territory.

ii..Royalty Statements. Supernus shall deliver to RH, within sixty (60) days after the end of each calendar quarter, a statement setting forth the Net Sales of the Supernus Product during such calendar quarter (including the country of sale and an itemized calculation of the amount of Net Sales) and the royalties due hereunder. Each such statement shall be accompanied by a remittance of the royalties in United States Dollars due for such calendar quarter.

iii..Manner of Payment. All payments hereunder shall be in United States dollars and shall be made by wire transfer to such bank account as may be designated in writing from time to time by RH.

iv..Currency. If Net Sales are in a currency other than United States Dollars, the Net Sales, for the purpose of calculating payments hereunder shall be determined in the applicable foreign currency and then converted into United States Dollars at the end of each calendar quarter using an exchange rate equal to [**] by the Federal Reserve Bank of New York (available on Bloomberg L.P. and Reuters).

v..Taxes. All taxes levied on account of royalties payable to Supernus hereunder shall be paid by Supernus. In the event laws or regulations require withholding of taxes from any payment of royalties, the taxes will be deducted by Supernus from the royalty payment and will be paid by Supernus to the proper taxing authority. Supernus will furnish RH with the copies of all official receipts for such taxes. In the event of any such withholding, the Parties agree to confer regarding other measures to minimize such withholding.

[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

vi..Overdue Payments. Any overdue payments under this Agreement, including without limitation, royalty payments made hereunder after the date such payment is due, shall bear interest at [**] as of the date such payment was due (the "Interest Rate"). The Interest Rate shall be calculated based on a 360-day year from the date payment was due until received by RH as cleared funds.

ARTICLE 6.

AUDIT

a. Audit. Once per twelve-month period from the Effective Date, Supernus agrees to make its records for payment of royalties and the calculation of Net Sales due available for examination by RH during normal business hours. RH shall have the option to engage, at its own expense, an independent certified public accountant reasonably acceptable to Supernus to examine, in confidence, Supernus' records as may be necessary to determine the correctness of any payment of royalties or calculation of Net Sales hereunder made by Supernus. The report of such accountant shall be limited to a certificate verifying any report made or payment submitted by Supernus during such period but may include, in the event the accountant shall be unable to verify the correctness of any such payment, information relating to why such payment is unverifiable. All information contained in any such certificate shall be deemed to be the Confidential Information of Supernus hereunder. If any audit performed under this Section 6.1 shall indicate that any payment due hereunder was underpaid, incorrect or unverifiable, Supernus shall promptly pay the amount of any underpayment, correct the figures or provide verification (as appropriate). If any audit performed under this Section 6.1 shall indicate that any payment hereunder was in error to RH's detriment by more than 8 percent for any annual period, Supernus shall pay the cost of the audit. Supernus undertakes to maintain true and accurate records of all transactions concerning the payment of royalties and the calculations of Net Sales.

ARTICLE 7.

CLOSING

a. Conditions to Supernus' Obligations. Each and every obligation on the part of Supernus to be performed hereunder, including the payment of the Consideration, shall be subject to the prior satisfaction (in accordance with the terms of this Agreement) of each and every one of the following conditions precedent, provided that all transfers contemplated by this Agreement shall be deemed to take place simultaneously at Closing and to be interdependent, so that Supernus shall not be obligated to consummate any transfer unless all of the conditions precedent relating to all transfers shall have been satisfied in full:

i..Delivery of Documents By RH. Prior to or at the Closing, RH shall have executed and/or delivered to Supernus:

(i) Such instruments of sale, transfer, assignment, conveyance and delivery in the form set out in Exhibit 7.1.1;

(ii) The Noncompetition Agreement;

(iii) The RH Concept including but not limited to all items scheduled on Schedule 1.1;

(iv) A copy, certified by the secretary of RH, of resolutions of the board of directors of RH authorizing the execution, delivery and consummation of this Agreement and the transactions contemplated hereby together with evidence of Seller's qualification and good standing in England and any required approval by the Shareholders; and

(v) Such other, further and different certificates, assurances and documents as Supernus may reasonably request (i) in order to evidence the accuracy of RH's representations and warranties, the performance of its covenants and agreements to be performed at or prior to the Closing Date, and the fulfillment of the conditions to Supernus' obligations; or (ii)

which are otherwise necessary to consummate the transactions contemplated in this Agreement.

ii..Closing Certificate. Supernus shall have received at Closing a closing certificate in the form attached hereto as Exhibit 7.1.2. signed by RH.

iii..Consents; Regulatory Approvals. RH shall have obtained all contractual and governmental consents, approvals, and authorizations which are necessary or reasonably required to effectuate the consummation of the transactions contemplated hereby and the satisfaction of the conditions precedent to the obligations of Supernus under terms acceptable to Supernus in the exercise of its business judgment. RH agrees to cooperate with Supernus in effectuating the timely transfer of any and all permits and licenses, if any, which may require governmental consent and/or approval.

iv..No Pending Litigation. As of the Closing Date, no litigation, order, enforcement action, or claim exists and to the best of RH's knowledge no litigation shall be pending or threatened against RH or any person holding an equity interest therein, seeking to enjoin, or to procure damages or fines as a result of, the consummation or the proposed consummation of the transactions contemplated herein.

v..Unrestricted Control. As of the Closing Date, the Seller shall have unrestricted control, possession of and title to the RH Concept.

vi..Conditions to Seller's Obligations. The obligation of RH to consummate the transactions contemplated hereby is subject to Supernus executing and/or delivering to RH at or prior to the Closing the following:

(a) Payment of the Consideration due at Closing;

(b) The Noncompetition Agreement; and

(c) A copy, certified by the secretary of Supernus, of resolutions of Supernus' governing body authorizing the execution, delivery and consummation of this Agreement and the transactions contemplated hereby.

ARTICLE 8.

PATENTS AND INTELLECTUAL PROPERTY RIGHTS

a. Infringement of Third Party Rights.

i..Notice of Infringement. In the event that RH becomes aware that the rights and title acquired by Supernus under this Agreement are infringing, or may infringe, the intellectual property rights of a Third Party in any country in the Territory, it will promptly notify Supernus in writing and provide it with such details of the Third Party's relevant intellectual property rights and the extent of any infringement as are known to it. Any defense of potential lawsuits brought on by a Third Party will be carried out as described in Sections 8.2.2 and 8.2.3 below.

ii..Supernus Product. Subject to Section 8.2.3, if the Third Party claim is specifically related to the RH Concept or the Supernus Product, Supernus will defend any suit resulting directly from such claim. RH hereby agrees to be joined in such suit, should RH be found to be an indispensable party to the proper defense of such suit provided that Supernus reimburses RH's costs unless the claim is directly linked to a RH breach of warranty as set forth in Article 3. RH may choose to obtain its own counsel for such litigation in which event it shall be liable for its own costs.

iii..Change to Royalty Payments. Royalty Payments in respect of the Product due to RH under Article 5 with respect to RH Product Concept Product sold in such country will be reduced to the extent that (i) Supernus is required, by a final court order from which no appeal can be taken, to obtain license from a Third Party under any

patent, which would be infringed by the manufacture, use, offer for sale, sale or import of the Product by Supernus, its Affiliates, contractors, or licensees, or (ii) Supernus in the exercise of its reasonable judgment, believes that a license from such Third Party, is necessary. To the extent that the Royalty Payments required to be made under Article 5 for any country are reduced as provided hereunder, they will be reduced, in such country, by an amount equal to all considerations actually paid by Supernus to such Third Party under such license with respect to such country. Supernus will use reasonable efforts to minimize any such required payments to Third Parties.

iv..Cooperation. Each Party shall use reasonable efforts to cooperate, at its own expense, with the other Party's reasonable requests and, to the extent reasonably possible, provide or procure the provision of such reasonable assistance in defending any such action or any proceedings.

b. Supernus' Ownership in Intellectual Property. Supernus shall retain all right, title and interest in and to shall become the owner of all Intellectual Property Rights in the RH Concept and all Supernus Products developed thereunder. At Supernus' request, RH will sign any documents and do all such things as Supernus may deem reasonably necessary to vest such rights in Supernus.

ARTICLE 9.

CONFIDENTIALITY AND NON-COMPETITION

a. This Agreement. The Parties agree that the material terms of the Agreement, the documents, information and data comprising the RH Concept and RH Market Analysis and such other trade secrets or intellectual property sold by RH to Supernus, all financial statements, financial information, projections, forecasts, business plans, development plans, formulations, product profiles, methods, ideas, concepts, materials, documents, records, computer programs, customer lists, referral sources, work, models, processes, designs, drawings, plans, inventions, devices, parts, improvements, other physical and intellectual property or other information in any form whatsoever relating directly or indirectly to the RH Concept and the documents generated pursuant to the obligations hereunder shall be considered Confidential Information of the Party providing or disclosing the same to the other.

b. Notwithstanding the foregoing, (i) the Parties shall be permitted to disclose in filings with the Securities Exchange Commission ("SEC") or the London Stock Exchange or to any applicable government authority including but not limited to the applicable taxing authorities, those terms of this Agreement required to be disclosed under law or regulation; provided that the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any such filings, and provided however, that in the event of a filing each party shall seek confidential treatment in its filings for the financial terms of this Agreement (ii) each Party shall have the right to disclose in confidence the terms of the Agreement to parties retained by such Party to perform legal, accounting or similar services and who have a need to know such terms in order to provide such services and (iii) at the request of either Party, the Parties shall mutually agree on a press release to be issued upon execution of this Agreement or reasonably soon thereafter.

ARTICLE 10.

INDEMNIFICATION

a. Indemnification by Supernus.

i..Scope. Supernus shall indemnify, defend and hold harmless RH, its officers, directors, employees, stockholders, shareholders, agents and representatives (collectively, "RH Indemnitees") from any and all third party losses, demands, damages, liabilities, costs and expenses, including reasonable attorneys' fees (collectively, "Losses"), arising out of or relating to any breach of this Agreement (including any the warranties and representations made by Supernus in the Agreement) by Supernus, its affiliates or Licensees or arising out of or relating to the research, development, marketing, design, manufacture, promotion, marketing, distribution, use and/or sale of Supernus Product by, on behalf of, or under authority of, Supernus, its Affiliates or its Licensees.

ii..Notification of Claim. Each RH Indemnitee shall notify Supernus in writing promptly upon becoming aware of any pending or threatened claim, suit, proceeding or other action ("Claim") to which such indemnification may apply. Failure to provide such notice shall constitute a waiver of Supernus' indemnity obligations hereunder if and to the extent that Supernus is materially damaged thereby. Supernus shall have the right to assume and control the defense of the Claim at its own expense. If the right to assume and control the defense is exercised, the RH Indemnitee shall have the right to participate in, but not control, such defense at its own expense, and Supernus' indemnity obligations shall be deemed not to include attorneys' fees and litigation expenses incurred by the RH Indemnitee after the assumption of the defense by Supernus. If Supernus does not assume the defense of the Claim, the RH Indemnitee may defend the Claim, at Supernus' expense; provided that the RH Indemnitee shall not settle or compromise the Claim without the consent of Supernus, which consent shall not be unreasonably withheld. The RH Indemnitee shall cooperate with Supernus and will make available to Supernus all pertinent information under the RH Indemnitee's control.

b. Indemnification by RH.

i..Scope. RH shall indemnify, defend and hold harmless Supernus, its officers, directors, employees, stockholders, shareholders, agents and representatives (collectively, "Supernus Indemnitees") from any and all third party losses, demands, damages, liabilities, costs and expenses, including reasonable attorneys' fees (collectively, "Losses") arising out of or relating any breach of this Agreement (including the warranties and representations made by RH in the Agreement) by RH. Notwithstanding the foregoing, no Supernus Indemnitee shall be entitled to indemnification under this Section 10.2 against any Losses arising out of such Supernus Indemnitee's negligence or willful misconduct or breach of warranties and representations made by Supernus in the Agreement.

ii..Notification of Claim. Each Supernus Indemnitee shall notify RH in writing promptly upon becoming aware of any pending or threatened claim, suit, proceeding or other action ("Claim") to which such indemnification may apply. Failure to provide such notice shall constitute a waiver of RH's indemnity obligations hereunder if and to the extent that Supernus is materially damaged thereby. RH shall have the right to assume and control the defense of the Claim at its own expense. If the right to assume and control the defense is exercised, the Supernus Indemnitee shall have the right to participate in, but not control, such defense at its own expense, and RH's indemnity obligations shall be deemed not to include attorneys' fees and litigation expenses incurred by the Supernus Indemnitee after the assumption of the defense by RH. If RH does not assume the defense of the Claim, the Supernus Indemnitee may defend the Claim, at RH's expense; provided that the Supernus Indemnitee shall not settle or compromise the Claim without the consent of RH, which consent shall not be unreasonably withheld. The Supernus Indemnitee shall cooperate with RH and will make available to RH all pertinent information under the Supernus Indemnitee's control.

c. Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED WARRANTY PROVIDED HEREIN.

d. Insurance.

i.. Supernus shall maintain, through self-insurance or commercially-placed insurance, adequate coverage for the indemnification obligations set forth herein, consistent with pharmaceutical industry practices and mutually acceptable to both parties.

ii.. Subject to Article 5.2.3.3 herein Rune shall purchase and maintain general liability, casualty product liability or such other insurance necessary to secure its obligations to Supernus hereunder including but not limited to its indemnity obligations. The insurance policies shall be with companies authorized to do business in the state of Maryland, satisfactory to Supernus. Copies of the policies shall be delivered to Supernus together with proof of payment no later than fifteen days from Closing. Supernus shall be listed as a named insured under all such policies.

Such insurance policies shall not be cancelable without the permission of Supernus provided Rune may cancel same, provided it replaces the insurance with the same or better insurance coverage with another company meeting the obligations above. Further, the insurance companies shall be obligated to provide reasonable notice to Supernus in the event Rune cancels or defaults on its payment obligations in connection with said insurance. Notwithstanding anything to the contrary herein, Rune's maximum obligation for total insurance coverage shall be [[4]*] annual coverage for a period of [**] commencing from the date of Closing.

ARTICLE 11.

TERMINATION

a. **Termination by Supernus.** Supernus may terminate this Agreement prior to the expiration of the Due Diligence Period. In the event of termination by Supernus, Supernus shall not compete with the RH Concept.

b. **Termination for Discontinuation of Development.** In the event that Supernus and/or its Licensees discontinue all development or commercialization activities relating to a specific Supernus Product for a period of [[5]*], RH shall have a right of first refusal to continue such development or commercialization activities relating to said specific Supernus Product provided RH agrees to a license from Supernus on terms and conditions mutually acceptable by the parties. Said right of first refusal shall expire if the parties are unable to reach a negotiated agreement within [**].

c. **Termination for Default.** In the event of a Default by Supernus in its payment of Royalties or breach of its representations or warranties as set forth under this Agreement, RH's sole recourse is to sue Supernus for damages. RH shall have no recourse to reacquire or obtain any right title or interest or have a security interest in the RH Concept or any Supernus Product. In the event of a Default by RH in a breach of its representations or warranties as set forth under this Agreement, in addition to all of its other rights under law or equity, Supernus shall have the right to offset its damages and expenses in connection therewith against future Royalty payments.

d. **Surviving Obligations.** The provisions of this Article and Articles 3, 5, 6, 8, 9, 10, 11 and Articles 12.1, 12.4, 12.8, 12.9, 12.11, 12.12 and 12.13 shall survive any termination or expiration of this Agreement. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration.

ARTICLE 12.

a. **Assignment.** This Agreement shall not be assignable by either Party without the prior written consent of the other Party; provided that either Party may assign this Agreement and all of its rights and obligations hereunder, without such consent, to an entity which acquires all or substantially all of the product rights to which this Agreement pertains, whether by merger, consolidation, reorganization, acquisition, sale, license or otherwise. This Agreement shall be binding upon the successors and permitted assigns of the Parties, and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 12.1 shall be void. Nothing herein shall preclude Supernus from licensing its rights purchased herein.

b. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

c. **Force Majeure.** Neither Party shall be liable to the other for loss or damages, nor shall have any right to terminate this Agreement for any default or delay attributable to any Force Majeure, if the Party affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from

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[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
[**] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled, provided however, that such affected Party commences and continues to take reasonable and diligent actions to cure such cause.

d. **Notices.** All notices and other communications required by this Agreement shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the parties at the following addresses (or at such other address for a Party as shall be specified by like notice, provided however, that notices of a change of address shall be effective only upon receipt thereof):

If to Supernus, addressed to:

Supernus Pharmaceuticals, Inc.
1550 East Gude Drive
Rockville, Maryland 20850
Attention: Chief Executive Officer
Facsimile: (301) 424-1364

With a copy to:

Schmeltzer, Aptaker & Shepard, P.C.
The Watergate
2600 Virginia Avenue, N.W.
Suite 1000
Washington, D.C. 20037
Attention: Mark I. Gruhin, Esq.

If to RH addressed to:

Rune Healthcare Limited
9a Magdala Road
Nottingham, NG3 5DE
United Kingdom
Facsimile: +44 (0) 115 969 2017

e. **Amendment.** No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

f. **Waiver.** No provision of the Agreement shall be waived by any act, omission or knowledge of any Party or its agents or employees, except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

g. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one Party, but all such counterparts taken together shall constitute one and the same agreement.

h. **Descriptive Headings.** The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

i. **Governing Law.** Each of the parties hereto irrevocably and unconditionally submits to the jurisdiction of any Delaware State or Federal court sitting in New Castle County, Delaware and any appropriate appellate courts therefrom in any suit, action or proceeding arising out of or relating to the provisions of this Agreement, and irrevocably consents to the jurisdiction of such courts and any appropriate appellate courts therefrom in any such suit, action or proceeding, and irrevocably waives, to the fullest extent permitted by law, any objection that it may

now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. Each of the parties hereto irrevocably and unconditionally agrees that (i) to the extent such party is not otherwise subject to service of process in the State of Delaware, to appoint and maintain an agent in the State of Delaware as such party's agent for acceptance of legal process and to notify the other party of the name and address of such agent, and that the annual cost of maintaining such agent shall be paid for by Supernus on RH's behalf, and (ii) to the fullest extent permitted by law, service of process may also be made on such party by prepaid certified mail with a validated proof of mailing receipt constituting evidence of valid service, and that service made pursuant to (i) or (ii) above shall, to the fullest extent permitted by law, have the same legal force and effect as if served upon such party personally within the State of Delaware. For purposes of implementing the parties' agreement to appoint and maintain an agent for service of process in the State of Delaware, each party that has not as of the date hereof already duly appointed such an agent does hereby appoint Capitol Services, Inc. as such agent.

j. **Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. Invalidity, non-enforceability or expiration of any of the provisions herein as it relates to an RH Concept Product shall not affect Supernus' ownership rights in and to the RH Concept or any other Supernus Products.

k. **Entire Agreement of the Parties.** This Agreement (including all Exhibits and Schedules attached hereto and documents referred to, which are incorporated herein by reference) constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, representations, promises, understandings and agreements, whether oral or written, between the Parties respecting the subject matter thereof.

l. **Dispute Resolution.** The Parties agree that in the event of a dispute between them arising from, concerning or in any way relating to this Agreement, the Parties shall undertake good faith efforts to resolve any such dispute in good faith. In the event the Parties shall be unable to resolve any such dispute, the matter shall be first referred to the general counsel for each Party for further review and resolution and, if necessary, then to the chief executive officer of each Party. If after such efforts the Parties are unable to resolve such dispute, a Party may seek any remedy available under applicable law.

m. **Use of Name.** No right, express or implied, is granted to either Party by this Agreement to use in any manner any trademark or trade name of the other Party, including the names "Supernus" and "Rune," without the prior written consent of the owning Party.

n. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

o. **No Brokers.** Neither Supernus nor RH nor any Shareholder has engaged, or caused to be incurred any liability to, any finder, broker, or sales agent in connection with the origin, negotiation, execution, delivery, or performance of this Agreement or the transactions contemplated hereby.

p. **Public Announcements.** Except as required by law, prior to the Closing, RH shall make no public announcement of the transactions contemplated hereby without the prior written consent of Supernus. After the Closing, Supernus and RH may make public announcements regarding the transactions contemplated hereby with respective mutual consent.

q. **Interpretation.** The parties hereby agree that each party has reviewed and had the opportunity to review this Agreement, and each party has had the opportunity, whether exercised or not, to have each respective party's attorney review this Agreement. Accordingly, the normal rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in duplicate by their respective duly authorized officers.

SUPERNUS PHARMACEUTICALS, INC.

BY: /s/ Jack Khattar

TITLE: President & CEO

DATE: 6/9/06

RUNE HEALTHCARE LIMITED

BY: /s/ Russ Pendleton

TITLE: CEO

DATE: 12/6/06

EXHIBIT 2.4

NON-COMPETITION, NON-SOLICITATION, NON-DISCLOSURE AND NON-CIRCUMVENTION AGREEMENT

THIS NON-COMPETITION, NON-SOLICITATION, NON-DISCLOSURE AND NON-CIRCUMVENTION AGREEMENT ("Agreement") is made and entered into as of the 9th day of June, 2006 (the "Effective Date"), by and between Supernus Pharmaceuticals Inc., a Delaware corporation with principal offices located at 1550 East Gude Drive, Rockville, Maryland 20850 (the "Company" or "Supernus"), and Rune Healthcare Limited, an English corporation with principal offices located at 9a Magdala Road, Nottingham NG3 5DE, United Kingdom and any of its affiliates or any of their respective officers, directors, shareholders, partners, members, employees or agents (collectively, "RH" or "Seller").

All initially capitalized terms used, but not defined herein, shall have the meanings ascribed thereto in the Purchase Agreement, as defined below.

RECITALS:

WHEREAS, on the Effective Date, the Company has consummated the purchase of the RH Concept of Seller, as defined in and pursuant to the terms of that certain Purchase and Sale Agreement dated as of June 9, 2006 (the "Purchase Agreement"), between the Company and Seller; and

WHEREAS, the Company is willing to consummate the purchase and sale contemplated in the Purchase Agreement upon the Seller's execution and delivery of this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises and covenants hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, including, without limitation, the consideration provided pursuant to the Purchase Agreement, the parties hereto hereby agree as follows:

1. Non-Competition.

(a) The Seller covenants and agrees that until the expiration of the Royalty Term in the Purchase Agreement (the "Applicable Period"), they shall not, directly or indirectly, as a principal, shareholder, partner, member, representative, agent contemplated in the RH Concept" shall mean and refer to any business, directly or indirectly researching, promoting, developing, manufacturing, marketing, selling, distributing, or licensing the RH Concept or any Products in the Field.

(b) The Seller shall not be treated as engaging in an activity that competes with the business of the Company solely by reason of: (i) owning an equity interest of less than 1% of the capital and profits of a corporation, partnership, limited liability company or other entity whose securities are publicly traded on national exchange; or (ii) owning a debt obligation of any entity, provided that such debt obligation entitles Seller to receive only interest that is fixed, or varies by reference to an index or formula that is not based on the value or results of operations of such entity.

(c) If for any reason a court of competent jurisdiction shall determine that the foregoing covenant is unenforceable by reason of the scope of the term [or the territory] involved, the parties agree that the term [or territory] shall be reduced to the maximum amount or amounts enforceable under applicable law.

2. Non-Solicitation. During the Applicable Period, the Seller covenants and agrees (a) not to, directly or indirectly, interfere with, attempt to disrupt any account, customer, client, supplier or other person or entity with whom the Seller is aware or the Company notifies the Seller that the Company has a material business relationship and which would have a materially negative impact on the development or commercialization of the Supernus

Product (b) not to, directly or indirectly, induce or attempt to induce any of the employees of the Company or any of its subsidiaries or affiliates to leave the employment of the Company or any of its subsidiaries or affiliates.

3. Non-Disclosure

(a) The Seller covenants and agree not to disclose the Confidential Information (hereinafter defined) to any person; provided, however, the Seller may disclose the Confidential Information only (i) in response to a valid order or subpoena issued by a court or administrative agency of competent jurisdiction (provided, however, the Seller shall immediately notify the Company of any such order or subpoena in order to provide the Company the opportunity to protect its interest in such Confidential Information); or (ii) to such other persons as are expressly approved by the written consent of the Company prior to the disclosure of the Confidential Information.

(b) In no event shall the Seller utilize the Confidential Information to promote or otherwise enhance the business of the Seller in competition with the Company or for any other commercial purpose whatsoever.

(c) The term "Confidential Information" means and includes any and all non-public and proprietary information regarding the RH Concept or the Supernus Product in the Field in any therapeutic dose, and such other trade secrets or intellectual property sold by RH to Supernus pursuant to the Purchase Agreement. The term "Confidential Information" shall include, without limitation, all financial statements, financial information, projections, forecasts, business plans, development plans, formulations, product profiles, methods, ideas, concepts, materials, documents, records, computer programs, customer lists, referral sources, work, models, processes, designs, drawings, plans, inventions, devices, parts, improvements, other physical and intellectual property or other information in any form whatsoever relating directly or indirectly to the RH Concept.

4. Non-Circumvention.

(a) The Seller agrees not to contact or initiate contact at any time for any purpose, either directly or indirectly, in connection with the RH Concept or Supernus Products, or any other property or properties whose identity was revealed through the efforts of the Company (or its subsidiaries or affiliates), unless such approval is specifically granted in written form by Company on a case-by-case basis. The Seller further agrees not to undertake any transaction or a series of transactions of any kind in connection with any Company Opportunity (hereinafter defined) or to collect any fees in connection with a Company Opportunity without the express prior written consent of Company, which consent may be withheld in Company's sole discretion.

(b) The term "Company Opportunity" means and includes each and every business opportunity that is within the scope and purpose of the RH Concept or Supernus Products.

5. Equitable Relief. The Seller acknowledges, stipulates and agrees that irreparable harm will result to the Company if the Seller violates any provision of Sections 1 through 4 hereof, and that monetary damages will not adequately compensate the Company for such violation. Accordingly, the Seller agrees that the Company shall be entitled to enjoin and restrain the Seller from continuing any act that violates the provisions of Sections 1 through 4 hereof; provided, however, nothing contained in this Section 5 shall be construed as a waiver or election by the Company to forego any other remedy or remedies that may be available to it hereunder or at law or in equity and, if the Seller violates any provision of Sections 1 through 4 hereof, it shall be liable to the Company for any and all loss, cost or damage suffered by the Company, including, without limitation, profits received by the Seller or any other person and attorneys' fees.

6. Miscellaneous.

(a) *Notice.* All notices and other communications required by this Agreement shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the parties at the following addresses (or at such other address for a Party as shall be specified by like notice, provided however, that notices of a change of address shall be effective only upon receipt thereof):

If to Supernus, addressed to:

Supernus Pharmaceuticals, Inc.
1550 East Gude Drive
Rockville, Maryland 20850
Attention: Chief Executive Officer
Facsimile: (301) 424-1364

With a copy to:
Schmeltzer, Aptaker & Shepard, P.C.
The Watergate
2600 Virginia Avenue, N.W.
Suite 1000
Washington, D.C. 20037
Attention: Mark I. Gruhin, Esq.

If to RH addressed to:

Rune Healthcare Limited
9a Magdala Road
Nottingham, NG3 5DE
United Kingdom
Facsimile: +44 (0) 115 969 2017

(b) *Interpretation.* The parties hereby agree that each party has reviewed and had the opportunity to review this Agreement, and each party has had the opportunity, whether exercised or not, to have each respective party's attorney review this Agreement. Accordingly, the normal rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement.

(c) *Incorporation.* All agreements and instruments referred to herein are hereby incorporated by reference into this Agreement as fully as if copied herein verbatim.

(d) *No Waiver.* No provision of the Agreement shall be waived by any act, omission or knowledge of any Party or its agents or employees, except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

(e) *Attorneys' Fees.* If any legal action or other proceeding is brought for the enforcement of this Agreement, or because of any alleged dispute, breach, default or misrepresentation in connection with any provisions of this Agreement and such action is successful, the prevailing parties shall be entitled to recover reasonable attorney's fees, court costs and all reasonable expenses, even if not taxable or assessable as court costs (including, without limitation, all such fees, costs and expenses incident to appeal) incurred in that action or proceeding in addition to any other relief to which such party may be entitled.

(f) *Section Headings.* The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

(g) *Governing Law.* This Agreement shall be governed in all respects, including validity, interpretation and effect by, and shall he enforceable in accordance with the internal laws of the State of Delaware without regard to conflicts of laws principles.

(h) *Severability.* Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such

prohibition or invalidity, without invalidating the remainder of this Agreement. Invalidity, non-enforceability or expiration of any of the provisions herein as it relates to an RH Concept Product shall not affect Supernus' ownership rights in and to the RH Concept or any other Supernus Products.

(i) *Counterpart Execution.* This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one Party, but all such counterparts taken together shall constitute one and the same agreement.

(j) *Successors and Assigns.* This Agreement is binding on the successors and assigns of all parties hereto.

(k) *Amendments.* No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

(l) *Entire Agreement.* This Agreement contains the entire agreement between the parties regarding the subject matter hereof. Any prior agreements, discussions or representations not expressly contained herein shall be deemed to be replaced by the provisions hereof, and no party has relied on any such prior agreements, discussions or representations as an inducement to the execution hereof.

(m) *Rules of Construction.* As used in this Agreement:

(i) All defined terms in the singular and plural shall have comparable meanings when used in the plural and vice-versa, unless otherwise specified.

(ii) Any reference to a "person" shall mean and refer to any individual, partnership, firm, corporation, limited liability company, association, joint venture, trust or other entity, or any governmental or political subdivision or agency department or instrumentality thereof.

(iii) Any reference to a "business day" shall mean and refer to any day that is not a Saturday, Sunday or any other day on which national banks located in Montgomery County, Maryland, arc required or permitted to close their regular banking business.

(iv) All pronouns and any variations thereof shall be deemed to refer to masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

(v) The words "hereof," "herein," "hereunder" and words of similar import shall refer to this Agreement as a whole and not any particular provision of this Agreement.

(vi) The word "party" or "Parties" when used in this Agreement means only those persons or entities who are signatories to this Agreement.

(vii) References to all documents, contracts, agreements or instruments shall include any and all supplements and amendments thereto.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement or caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

COMPANY:

SUPERNUS PHARMACEUTICALS, INC.

By: /s/ Jack Khattar

Name: Jack Khattar

Title: President & CEO

Address: 1550 E. Gude Drive
Rockville, MD 20850

Attn: J.W. Bryan
Telephone: 301-838-2681
Facsimile: 301-424-1364

SELLER:

RUNE HEALTHCARE LIMITED, an English corporation

By: /s/ Russ Pendleton

CEO

Address: 9A Magdala Road
Nottingham, UK, NG3 5DE
Telephone: +44 115 969 2016
Facsimile: +44 115 969 2017

EXHIBIT 21

SUBSIDIARIES OF SUPERNUS PHARMACEUTICALS, INC.

Name of Subsidiaries	Jurisdiction of Organization
MDD US Enterprises, LLC	Delaware
MDD US Operations, LLC	Delaware
Supernus Europe Ltd.	United Kingdom
Biscayne Neurotherapeutics, Inc.	Delaware

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 statement Nos. 333-181479, 333-201049, 333-216135, 333-239459 on Form S-8 of Supernus Pharmaceuticals, Inc. of our report dated March 8, 2021, with respect to the consolidated balance sheets of Supernus Pharmaceuticals, Inc. as of December 31, 2020 and 2019, 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, 2020, and the related notes (collectively, the "consolidated financial statements"), and the effectiveness of internal control over financial reporting as of December 31, 2020, which reports appear in the December 31, 2020 annual report on Form 10-K of Supernus Pharmaceuticals, Inc.

Our report dated March 8, 2021, on the effectiveness of internal control over financial reporting as of December 31, 2020, contains an explanatory paragraph that states The Company acquired USWM Enterprises during 2020, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2020, USWM Enterprises' internal control over financial reporting associated with total assets of 8.8% (excluding the goodwill and other intangible assets, which are included within the scope of the assessment) and total revenues of 17.5% included in the consolidated financial statements of the Company as of and for the year ended December 31, 2020. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of USWM Enterprises.

/s/ KPMG LLP

Baltimore, Maryland
March 8, 2021

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 8, 2021

By: /s/ JACK A. KHATTAR

Jack A. Khattar
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, James P. Kelly, 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 8, 2021

By: /s/ JAMES P. KELLY

James P. Kelly
Executive Vice-President and Chief Financial Officer

EXHIBIT 32.1

SUPERNUS PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. sec. 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Supernus Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 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 8, 2021

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

EXHIBIT 32.2

SUPERNUS PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. sec. 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Supernus Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James P. Kelly, Executive 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 8, 2021

By: /s/ JAMES P. KELLY

James P. Kelly
Executive Vice-President and Chief Financial Officer