Dear Supernus Stockholder,

2021 was another outstanding year for Supernus during which we continued to build on our long-term growth strategy and work towards minimizing the impact of the 2023 Trokendi XR transition.

During 2021, we launched Qelbree®, the first novel non-stimulant treatment for attention-deficit hyperactivity disorder (ADHD) to be launched in over a decade. We completed the acquisition of Adamas Pharmaceuticals, adding GOCOVRI® as another key growth asset. We also resubmitted the New Drug Application (NDA) for SPN-830, the apomorphine infusion device, which represents a third future growth driver for the Company. In addition, Supernus closed 2021 with record revenues of approximately $580 million, up 11% compared to 2020. Finally, we advanced SPN-820, our novel product candidate for treatment resistant depression, into Phase II clinical development, and nominated SPN-443 and SPN-446, two internally discovered novel central nervous system (CNS) drug candidates, for development in CNS indications.

Acquisition of Adamas Pharmaceuticals

The acquisition of Adamas Pharmaceuticals represents a significant step to further build a strong and diverse Parkinson's disease portfolio, and aligns with our focus of acquiring value-enhancing, clinically-differentiated medicines to treat CNS diseases. The acquisition strengthens our leading CNS and movement disorder portfolio, provides a new near-term growth catalyst, and further diversifies and increases our revenue base.

The Parkinson's disease market is expected to grow to $6.2 billion by the year 2026. It is the second most common chronic neurodegenerative disorder, affecting 1% to 2% of individuals 65 years and older, or about one million patients in the U.S. As patients with Parkinson's disease treated with levodopa therapy progress through the disease, their therapy may wear off, resulting in OFF episodes (stiffness, rigidity, and tremors occurring in between medication doses). Levodopa therapy may also cause dyskinesia, or sudden uncontrolled movements. It's been a major challenge for physicians and patients to address both of these issues at the same time. GOCOVRI is uniquely positioned in this market, as it is the first and only medication approved to treat both OFF episodes and dyskinesia in Parkinson's disease. In 2021 we made significant progress with the integration of Adamas into our Parkinson's sales force, which is now fully trained in the field promoting GOCOVRI.

Qelbree®—A Novel Non-Stimulant ADHD Product

In April 2021 we received approval from the U.S. Food and Drug Administration (FDA) for Qelbree for the treatment of ADHD in children and adolescents 6 to 17 years of age. Qelbree is the first novel non-controlled medication option in a decade to be added to the ADHD treatment paradigm and is our first foray into psychiatry. Qelbree is a well-differentiated product that is a non-controlled medication to treat ADHD, filling a gap for many of the nearly 6.1 million children and adolescents in the U.S. who are diagnosed with ADHD. It addresses a multi-billion-dollar market opportunity. We remain enthusiastic about its potential in offering patients an important new non-stimulant therapeutic option for ADHD.

The launch is progressing well as Qelbree continues its growth trajectory through an expanding base of prescribers and an increase in prescriptions. In addition, we continue to make good progress in our discussions with the managed care plans regarding the importance of Qelbree in the current treatment paradigm for ADHD. Preparations for the launch of Qelbree in the adult market in the second quarter of 2022 are well underway, assuming timely approval by the FDA of the supplemental NDA for the adult indication. Supernus will continue its investment in Qelbree's launch activities in 2022 as it is expected to enter the adult segment of the ADHD market, which represents about 50% to 60% of the total market.

Additional Highlights and Achievements in 2021

We were pleased with the overall performance of our products in 2021. Oxtellar XR finished another year with strong performance, reaching net sales of $111 million, up 12% compared to 2020. Also, Trokendi XR continues to hold up well despite the increased competition in the migraine prevention market, finishing the year with approximately $305 million in net sales. For full year 2021, the two products combined delivered net product sales of $416 million, essentially flat compared to $418 million in 2020. APOKYN closed out the year with sales close to $100 million given the competitive headwinds it faced during the year.

We are also excited about the nomination of two new molecules, SPN-443 and SPN-446, for development in CNS indications. These new chemical entities are the result of our internal R&D discovery program and have undergone several lead optimization and preclinical activities.

Our corporate development strategy continues to focus on the potential acquisition of commercial products in CNS, in-licensing novel pipeline product candidates, or entering into co-development or co-promotion partnerships. Our focus is to look for strategic opportunities that can strengthen our future growth and leadership position in CNS.

In summary, 2021 was a record year for Supernus with significant corporate achievements that will prepare us for the next phase in our history as a growth company.

2022 Key Milestones

In 2022 we are focused on the following key priorities:

- Driving growth behind Qelbree and GOCOVRI, continuing to manage our legacy products, and reducing our dependency on Trokendi XR;
- Obtaining FDA approval and launching Qelbree for the adult indication in the second quarter of 2022, assuming timely approval by the FDA;
- Obtaining FDA approval of the NDA for SPN-830 and preparing for potential commercial launch in the first quarter of 2023; and
- Initiating an open-label Phase II clinical study of SPN-817 for the treatment of treatment-resistant seizures in the second half of 2022.

I would like to thank our stockholders for their continued support and our employees for their continued dedication and commitment to the health of our patients.

Sincerely,

Jack A. Khattar,
President, Chief Executive Officer and Secretary of
Supernus Pharmaceuticals, Inc.

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, 2021

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 March 30, 2022	Trading Symbol	NAME OF EACH EXCHANGE ON WHICH REGISTERED:
Common Stock, $0.001 Par Value	53,386,305	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, 2021, 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 $1,634,702,733.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2022 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 2021 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, 2021

TABLE OF CONTENTS

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

We, including our subsidiaries 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®", "Qelbree®", "XADAGO®", "MYOBLOC®", "APOKYN®", "GOCOVRI®", "Osmolex ER®", "Namzaric®", 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-830 and supplemental NDA (sNDA) for SPN-812 (Qelbree) in adults, the outcome of any additional device testing associated with the SPN-830 NDA submission, the potential approval of the sNDA for SPN-812 (Qelbree) in adults, currently under review, and SPN-830 following resubmission, and the potential benefits and commercialization of SPN-812 (Qelbree) 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 Adamas Pharmaceuticals, Inc.; 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 other 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 30 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 February 18, 2022, we received a notice from the U.S. Food Drug Administration (FDA) that its New Drug Application (NDA) resubmission for SPN-830 (apomorphine infusion device) for the continuous treatment of motor fluctuations ("off" episodes) in PD is considered a Standard Review, thereby assigning a timeline of 10 months for review by the FDA and establishing a Prescription Drug User Fee Act (PDUFA) target action date of October 7, 2022.

On October 10, 2021, we entered into an Agreement and Plan of Merger (Merger Agreement) by and among the Company, Adamas Pharmaceuticals, Inc. (Adamas) and Supernus Reef, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (Purchaser). On November 24, 2021, the Purchaser was merged with and into Adamas (Merger), with Adamas continuing as the surviving corporation in the Merger as a wholly owned subsidiary of the Company (Adamas Acquisition). At the time of the Adamas Acquisition, Adamas held and markets two established commercial products in its portfolio, GOCOVRI® and Osmolex ER®, and had royalty rights to Namzaric®. Allergan plc markets and sells Namzaric in the United States.

Following the Adamas Acquisition, during the fourth quarter of 2021 and continuing into the first quarter of 2022, Adamas was reorganized with the interests of Adamas Pharmaceuticals, LLC, formerly Adamas Pharmaceuticals, Inc, in GOCOVRI and Osmolex ER were effectively transferred to Adamas Operations, LLC (Adamas Operations). Adamas Operations, and Adamas Pharmaceuticals, LLC are wholly-owned subsidiaries of Adamas Holdings, LLC (collectively, the "Adamas Subsidiaries"). Adamas Holdings, LLC is a wholly-owned subsidiary of Supernus Pharmaceuticals, Inc. During the first quarter of 2022, Supernus Pharmaceuticals, Inc. was granted a license by Adamas Operations to market and sell GOCOVRI and Osmolex ER (such reorganization and licensing arrangement, the "Adamas Reorganization"). Each of the Adamas Subsidiaries are distinct legal entities that contract with Supernus Pharmaceuticals, Inc. for the provision of certain corporate and other support services.

On April 2, 2021, the FDA approved Qelbree (viloxazine extended-release capsule) for the treatment of ADHD in pediatric patients 6 to 17 years of age. In May 2021, we launched Qelbree in the U.S. On September 2, 2021, the FDA has acknowledged receipt of the supplemental new drug application (sNDA) for Qelbree for adult patients with ADHD and assigned a PDUFA target action date of April 29, 2022.

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, the Company added three established commercial products and a product candidate in late-stage development to its portfolio, through its subsidiaries. These commercial products, APOKYN, XADAGO, and MYOBLOC, are primarily for the treatment of PD. In the second quarter of 2021 and within one year from the Closing Date, the Company finalized its accounting for the business combination, including the purchase price allocation.

On April 21, 2020, we entered into a Development and Option Agreement (Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor Inc.) and also acquired an ownership position in Navitor Inc. Under

the terms of the Development Agreement, the Company and Navitor Inc. will jointly conduct a Phase II clinical program for NV-5138 (SPN-820) in treatment resistant depression (TRD). In March 2021, Navitor Inc. underwent a legal restructuring whereby Navitor Inc. became a wholly owned subsidiary of a newly formed limited liability company, Navitor Pharmaceuticals, LLC (Navitor LLC) (Navitor Restructuring) and our ownership position in Navitor Inc. was exchanged for an equivalent ownership position in Navitor LLC. In December 2021, we received a $12.9 million cash distribution pursuant to our ownership position in Navitor LLC following its sale of its subsidiary.

Our Strategy

Our mission is to improve the lives of patients suffering from CNS diseases. Our vision is to be a leader in the CNS industry by 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.* Using dedicated sales and marketing resources in the U.S., we will continue to drive the revenue growth of our market products.
- *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 candidate, Qelbree (viloxazine hydrochloride) for treatment of ADHD in adults and SPN-830 (apomorphine infusion device) for treatment of hypomobility in PD, to regulatory approval and commercialization.
- *Continue to grow our pipeline.* We will continue to evaluate and develop additional CNS product candidates that we believe have significant commercial potential through our internal research and development efforts.
- *Target strategic business development opportunities.* We are actively exploring a broad range of strategic opportunities. This includes in-licensing products and entering into co-promotion and co-development partnerships for our commercial products and product candidates.

Commercial Products

Our commercial products, including those sold by or through our subsidiaries, include:

Trokendi XR®

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

Trokendi XR is indicated for: initial monotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic (PGTC) seizures; as add-on therapy in patients 6 years of age and older with partial onset or PGTC seizures or with seizures associated with Lennox-Gastaut Syndrome; and for prophylaxis of migraine headache in adults and adolescents 12 years of age and older. Trokendi XR's once-daily dosing is designed to improve patient adherence over the current immediate release products, which must be taken multiple times per day. We believe a once-daily dosing regimen improves 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 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.

Qelbree®

Qelbree (viloxazine extended-release capsules) is a selective norepinephrine reuptake inhibitor indicated for the treatment of ADHD in pediatric patients 6 to 17 years of age. The FDA approved Qelbree in April 2021 for the treatment of ADHD in pediatric patients of 6 to 17 years of age, and in May 2021, we launched Qelbree in the U.S. Given its new chemical entity (NCE) status in the U.S., Qelbree has been granted market exclusivity through April 2026.

We received approval for Qelbree from the FDA based on certain post-marketing commitments, including the requirement to conduct a clinical efficacy and six month open label safety extension study for ADHD in pediatric patients 4 to 5 years of age, a lactation study and a descriptive study related to the use of Qelbree during pregnancy, and to assess the risks of adverse events and potential complications. We will conduct post-marketing commitment studies, including a new study of Qelbree in preschool aged children 4 to 5 years of age with ADHD. The completion of these studies responds to a written request from the FDA, which we expect would result in the FDA granting an additional 6 months of market exclusivity.

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 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 marketed rimabotulinumtoxinB in select European countries under the trade name NeuroBloc. In April 2021, we notified the European Medicines Agency that we will cease the marketing of rimabotulinumtoxinB. In addition, our collaboration partner Eisai has been marketing rimabotulinumtoxinB in Japan since 2013 under the trade name NerBloc.

GOCOVRI

GOCOVRI (amantadine) extended release capsules is the first and only FDA-approved medicine indicated for the treatment of dyskinesia in patients with PD receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as an adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes.

GOCOVRI was approved by the FDA in August 2017 for treatment of dyskinesia and in February 2021 as an adjunctive treatment for "off" episodes. The February 2021 update to the label indication makes GOCOVRI the only medicine clinically proven and approved to reduce both "off" episodes and dyskinesia in PD patients taking a levodopa-based medication, resulting in a clinically meaningful increase in good "on" time without the need for a "trade-off' when managing motor complications.

GOCOVRI has been granted orphan drug exclusivity until August 24, 2024 for the treatment of dyskinesia in patients with PD receiving levodopa-based therapy with or without concomitant dopaminergic medications.

Osmolex ER

Osmolex ER (amantadine) extended release tablets is for the treatment of PD and drug-induced extrapyramidal reactions in adult patients.

Osmolex ER was approved by the FDA in February 2018.

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 in clinical development.

Product Candidate	Indication	Development	NDA
Qelbree (SPN-812)	Adult ADHD		Under Review[(1)]
SPN-830	Continuous prevention of "off" episodes in PD patients		Under Review[(2)]
SPN-820	Depression	Phase II	
SPN-817	Severe Epilepsy	Phase I	
SPN-443	CNS	Preclinical	
SPN-446	CNS	Preclinical	

(1) PDUFA target action date in April 2022.

(2) PDUFA target action date in October 2022.

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.

Qelbree (viloxazine extended-release capsules)

In September 2021, the FDA acknowledged it received the sNDA for Qelbree for the treatment of ADHD in adult patients with a PDUFA target action date of April 29, 2022.

SPN-830 (apomorphine infusion device)

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.

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 December 2021, we resubmitted the NDA to the FDA. In February 2022, we received a notice from the FDA that the resubmission of the NDA for SPN-830 is considered as a Standard Review, thereby was assigned a timeline for review of 10 months by the FDA. The PDUFA target action date is October 7, 2022. The Company is preparing for the commercial launch of SPN-830 in the first quarter of 2023 assuming timely approval by the FDA.

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 MOA 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.

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 randomized Phase II clinical study for the treatment of focal seizures in adult patients is expected to start in the second half of 2022.

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.

An Investigational New Drug (IND) application was submitted to the FDA in September 2021. We initiated a Phase II multicenter, randomized double-blind placebo-controlled parallel design study of SPN-820 in adults with treatment resistant depression. The study will examine the efficacy and safety of SPN-820 over a course of five weeks of treatment in approximately 400 patients. The primary outcome measure is the change from baseline to end of treatment period on the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score, a standard depression rating scale.

SPN-443 and SPN-446—Two novel CNS drug candidates nominated for development

Our internal research and development discovery program generated several new chemical entities including SPN-443 and SPN-446 that were nominated for development across various CNS indications.

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 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 device (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.

GOCOVRI (amantadine) extended-release capsules is the first and only FDA-approved medicine indicated for the treatment of dyskinesia in patients with PD receiving levodopa-based therapy, with or without concomitant dopaminergic medications. It is also the only medicine clinically proven to reduce both dyskinesia and "off" periods. GOCOVRI, taken once daily at bedtime, provides an initial lag and a slow rise in amantadine concentration during the night, resulting in a high concentration from the morning and throughout the waking day. Additionally, in the clinical trials, the adjunctive use of GOCOVRI did not require changes to dopaminergic therapies.

In well-controlled clinical studies, GOCOVRI demonstrated a durable reduction in dyskinesia and "off" time in people with PD. In addition, the open label safety study of GOCOVRI, EASE LID 2, demonstrated a sustained improvement in levodopa-induced dyskinesia (LID) among patients using GOCOVRI. Results showed the treatment effect of GOCOVRI on motor complications (dyskinesia and "off") was maintained for at least two years, providing long-term durability and safety data for GOCOVRI. This effect was seen in all patients in the study, including those who were switched from amantadine immediate release treatment

to GOCOVRI and patients who had received deep brain stimulation treatment. Data from the open label study were accepted for publication in the Journal of Parkinson's Disease and published online in January 2020.

Osmolex ER is an extended release tablet formulation that contains both immediate-release and extended-release amantadine, that is dosed once daily in the morning. We believe Osmolex ER's once-daily morning dose offers a more convenient option by reducing the number of pills a patient must take each day, which may improve patient compliance with treatment regimens. While Osmolex ER is bioequivalent to immediate-release amantadine, the product provides a consistent delivery of amantadine throughout the day. Peak serum drug concentration conveniently occurs in the middle portion of a patient's day when the drug is administered in the morning.

According to their Prescribing Information, neither GOCOVRI nor Osmolex ER are interchangeable with other amantadine immediate- or extended-release products for their respective approved indications.

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 first 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. In February 2022, the FDA approved the first generic of Apokyn (apomorphine hydrochloride injection) to treat hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease. This approval is for an application of the drug cartridges only, which are compatible for use with the APOKYN pen, the brand-name pen injector. Patients treated with generic apomorphine hydrochloride will need to separately obtain the APOKYN pen. Refer to Part I, Item 1A—Risk Factors—If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the sales of our products or the commercial success of our product candidates would be adversely affected. Also refer to risk factor—Any impairment in the value of our intangible assets, including goodwill, would negatively affect our operating results and total capitalization.

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.

GOCOVRI is the first and only FDA-approved medicine for the treatment of dyskinesia in patients with PD receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as an adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes. GOCOVRI has been granted orphan drug exclusivity until August 24, 2024 for the treatment of dyskinesia in patients with PD receiving levodopa-based therapy with or without concomitant dopaminergic medications. GOCOVRI is marketed and sold by our subsidiary, Adamas Operations. Adamas Operations faces competition from various branded and generic drugs approved for the treatment of PD that physicians either have historically used or may use in an attempt to manage dyskinesia. Competition may arise from all versions of levodopa including, SINEMET, PARCOPA, RYTARY, DUOPA, INBRIJA; dopamine agonists, including REQUIP XL, MIRAPEX and MIRAPEX ER, NEUPRO Patch, KYNMOBI; MAO-B inhibitors including, selegiline, AZILECT; adenosine receptor antagonist NOURIANZ; COMT inhibitors (ONGENTYS, COMTAN, TASMAR); and other versions of amantadine such as Symmetrel—amantadine immediate release.

GOCOVRI will also face competition from investigational drugs in late stage development for the treatment of PD, if approved, and from drugs currently in development for dyskinesia in PD or for PD, from a number of pharmaceutical companies, some of which have significantly greater resources than us.

Osmolex (amantadine) extended-release tablets is FDA-approved for the treatment of PD and drug-induced extrapyramidal reactions in adult patients. According to the products' Prescribing Information, neither GOCOVRI nor OSMOLEX ER are interchangeable with other amantadine immediate-release or extended-release products for their respective approved indications. Osmolex ER tablet contains an outer layer that immediately releases the medication upon the patient taking the tablet and an inner core that slowly releases the medication over long periods of time. This allows Osmolex ER to be taken just once a day, easing complicated medication routines.

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

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

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

We are also aware of clinical development efforts by Otsuka, to develop additional treatment options for ADHD. Otsuka Pharmaceutical Co., Ltd. announced an agreement with Neurovance, Inc. to acquire Neurovance, a privately held, venture-funded, clinical stage pharmaceutical company, focused on ADHD and related disorders. Otsuka is currently conducting Phase III clinical trials to evaluate the efficacy, safety, and tolerability of non-stimulant Centanafadine sustained-release tablets in adults with ADHD.

Sales and Marketing

We, including our subsidiaries, market our products through our own sales forces in the U.S. and seek strategic collaborations with other pharmaceutical companies to commercialize our products, and those of our subsidiaries, outside of the U.S. We have a commercial sales and marketing organization in the U.S. to support sales of our commercial products, and those of our subsidiaries. We believe our current sales forces are effectively targeting healthcare providers to support and grow our current commercial products, which include the commercial products of our subsidiaries.

As a result of the USWM and Adamas Acquisitions, we established our commercial capabilities in the Parkinson's area with focus on serving movement disorder specialists and other specialized health care providers in the U.S.

With the launch of Qelbree for pediatric patients, we expanded our sales efforts to market the commercial product to the relevant physician audience of psychiatrists, pediatricians, and primary care physicians. Our sales representatives who supported Trokendi XR and Oxtellar XR now devote their full efforts to the launch of Qelbree. A smaller contract field force now supports Trokendi XR and Oxtellar XR.

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, Qelbree, and XADAGO are made to wholesalers and distributors. In addition, MYOBLOC is available for direct purchase by physicians and hospitals. The majority of sales of APOKYN and GOCOVRI 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 2021 and collectively accounted for more than 85% of our total product revenue in 2021.

Manufacturing

We, including our subsidiaries, 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 to support Phase III clinical trials or support commercial production. We currently employ internal resources to manage our manufacturing contractors.

For our commercial products, including Oxtellar XR, Trokendi XR and Qelbree, 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. 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 Trokendi XR, Oxtellar XR, Qelbree, as well as for our pipeline product candidates. With respect to GOCOVRI, Adamas Operations has recently qualified an additional manufacturer of bulk drug substance. These CMOs offer a comprehensive range of contract manufacturing and packaging services. The majority of our commercial products, in each case including those of our subsidiaries, 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 €3.9 million. XADAGO is provided to us as a finished product by Zambon S.p.A. (Zambon). Osmolex ER is manufactured and packaged by Osmotica Pharmaceutical US LLC (Osmotica), which is the sole manufacturer of Osmolex ER and a subsidiary of Osmotica Pharmaceuticals plc.

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: Qelbree, Trokendi XR and Oxtellar XR; Adderall XR (developed for Shire); Intuniv (developed for Shire); Mydayis (developed for Shire); Orenitram (developed for United Therapeutics Corporation); and Namzaric (developed for Allergan plc).

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 towards Investigational New Drug application (IND), enabling toxicology studies to support potential future clinical investigation.

Intellectual Property and Exclusivity

Overview

We, including our subsidiaries, continue to build our intellectual property portfolio to provide protection for our technologies, products, and product candidates. We, including our subsidiaries, 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, and that of our subsidiaries, by, among other things, filing patent applications in the U.S. and abroad, including Europe, Canada, and other countries when appropriate. We, including our subsidiaries, also rely on trade secrets, know-how, proprietary knowledge, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position. Neither we, nor our subsidiaries can be sure that patents will be granted with respect to our pending patent applications or with respect to any patent applications filed by us, or any of our subsidiaries in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us, or any of our subsidiaries in the future will be commercially useful in protecting our technology, our products, or those of our subsidiaries. Neither we, nor any of our subsidiaries can be sure that any patents, if granted, will sustain a legal challenge.

Patent Portfolio

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

The Company has ongoing litigations concerning Trokendi XR, Oxtellar XR and XADAGO. For more information, refer to Part I, Item 3—*Legal Proceedings* in this annual Report on Form 10-K.

Trokendi XR

We currently have 10 U.S. patents that cover Trokendi XR. We own all of the issued patents. We also own additional foreign patents for extended release topiramate. 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 on or after January 1, 2023, or earlier under certain circumstances.

Oxtellar XR

Our extended release oxcarbazepine patent portfolio currently includes 12 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 also own additional foreign patents for extended release oxcarbazepine.

XADAGO

As an NCE, XADAGO is under the 5 year FDA exclusivity period that expired on March 21, 2022. The patent portfolio covering XADAGO has three U.S. patents licensed from Zambon. These patents will expire from 2027 and 2031.

Qelbree

We have three families of pending U.S. non-provisional and foreign counterpart patent applications for Qelbree. Patents, if issued, could expire from 2029 to 2033. We have patents issued in Canada, and certain countries in Europe covering a method of treating ADHD using viloxazine hydrochloride. In a second family, covering the novel synthesis process of the active ingredient, we have patents issued in the U.S. as well as in certain foreign countries. In a third family, we have four patents issued in the U.S. covering modified release formulations of viloxazine hydrochloride, three of which cover Qelbree. We also have patents issued in certain foreign countries. We own all of the issued patents and the pending patent applications.

GOCOVRI

GOCOVRI is currently covered for its FDA-approved indication by a total of 18 issued U.S. patents. We have additional pending applications containing method and composition claims relating to the pharmacokinetic profile and dosing of amantadine as well as the GOCOVRI formulation. These issued patents expire through 2038. These patents and patent applications are wholly owned by Adamas Operations and, as of the first quarter of 2022 are licensed to Supernus Pharmaceuticals, Inc. We, through our subsidiary Adamas Operations, own additional foreign patents and patent applications covering GOCOVRI.

Prior to our acquisition of Adamas, Adamas entered into settlement agreements with third parties, permitting the sale of a generic version of GOCOVRI (amantadine) extended release capsules (including for any new indications approved under the GOCOVRI NDA) on or after March 4, 2030, or earlier under certain circumstances.

Osmolex ER

Osmolex ER is currently covered for its FDA-approved indications by a total of 18 issued U.S. patents and additional applications containing method and composition claims relating to the pharmacokinetic profile and dosing of amantadine as well as Osmolex ER formulation. These issued patents expire through 2038. These patents and patent applications are wholly owned by Adamas Operations and, as of the first quarter of 2022 are licensed to Supernus Pharmaceuticals, Inc. Adamas Operations also owns additional foreign patents covering Osmolex ER.

Namzaric

Namzaric is covered by a total of 19 of Adamas's issued U.S. patents containing method and compositions claims relating to the pharmacokinetic profile and dosing of memantine. These patents expire as late as 2029. Namzaric is currently marketed by Allergan plc under an exclusive license agreement between Adamas and Forest Laboratories Holdings Limited ("Forest"), an indirect, wholly-owned subsidiary of Allergan plc (collectively, "Allergan") in the United States. Adamas also owns additional foreign patents and patent applications covering Namzaric.

SPN-830 (apomorphine infusion device)

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.

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. and certain foreign countries 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.

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, including our subsidiaries, seek trademark protection in the U.S. and internationally, where available and when appropriate. We, including our subsidiaries, have filed for trademark protection for several marks, which are use in connection with our pharmaceutical research and development collaborations as well as with our products and those of our subsidiaries. We or our subsidiaries 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®", "Qelbree®", "XADAGO®", "MYOBLOC®", "APOKYN®", "GOCOVRI®", "Osmolex ER®", "Namzaric®", and the registered Supernus Pharmaceuticals logo.

From time to time, we, including our subsidiaries 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 or our subsidiaries 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 and our subsidiaries 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 and that of our subsidiaries, 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 or those of our subsidiaries is subject to uncertainties that cannot be quantified in advance. In the event of an adverse outcome in litigation, we or our subsidiaries 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 or that of our subsidiaries. In addition, litigation involving our patents or those of our subsidiaries carries the risk that one or more of our patents or those of our subsidiaries 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 or our subsidiaries. In addition, third parties could allege that our products or those of our subsidiaries infringe their intellectual property rights and pursue legal action against the Company or any of its subsidiaries. See Part I, Item 1A—*Risk Factors* for risk factors related to intellectual property.

Collaborations and Licensing Arrangements

We, including our subsidiaries, obtained exclusive licenses from third parties for proprietary rights to support our commercial products and product candidates. Under these license agreements, we or our subsidiaries may be required to pay certain amounts upon the achievement of defined milestones. If these products are ultimately commercialized, we or the applicable subsidiary 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.

We, including our subsidiaries, also have entered into in-licensing agreements to license our intellectual property and technology or that of our subsidiaries to third parties. Under these in-license agreements, we or our subsidiaries may be entitled to receive certain amounts upon the achievement of defined milestones and royalties from third parties, generally computed as a percentage of net product sales, for each respective product under a license agreement.

APOKYN and SPN-830 (apomorphine infusion device)

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 $30.0 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 milestone 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.

Osmolex ER

Our subsidiary Adamas Operations has the global rights to Osmolex ER. Pursuant to the Asset Purchase Agreement with Osmotica Pharmaceutical US LLC and Vertical Pharmaceuticals LLC (Osmotica) entered into on December 1, 2020 (transaction closed on January 4, 2021) both parties gave each other mutual releases and agreed to dismiss their respective claims relating to certain patent litigation; Adamas Operations acquired the global rights to Osmolex ER and existing inventory and the assumption of certain liabilities; and Osmotica agreed not to engage in the development, manufacture, or sale of any product in the U.S. that is a generic version of any dosage strength of Osmolex ER for a period of five years from the closing of the Asset Purchase Agreement.

SPN-817 (huperzine A)

In September 2018, we 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 and up to an additional $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. In December 2021, we received a $12.9 million cash distribution pursuant to our ownership position in Navitor LLC following the sale of one of its subsidiaries. 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 based 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 8, Financial Statements and Supplementary Data, Note 5, *Investments*, in the Notes to the Consolidated Financial Statements.

United Therapeutics

We have a license agreement with United Therapeutics Corporation for it 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 $2.0 million milestone payment to the Company. In the third quarter of 2014, we received a cash payment of $30.0 million from HealthCare Royalty Partners III, L.P.'s (HC Royalty), for the purchase of certain of our rights under our license agreement with United Therapeutics Corporation related to the commercialization of Orenitram. 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. Microtrol, one of our key proprietary technology platforms, was utilized to develop Mydayis. The Company is eligible to receive royalties under this agreement based on net product sales of Takeda's product, Mydayis.

GOCOVRI and Osmolex ER

Adamas Operations, one of our subsidiaries, entered into a licensing agreement with Supernus Pharmaceuticals, Inc. during the first quarter of 2022 under which Supernus received the right to market and sell GOCOVRI and Osmolex ER.

Namzaric

Namzaric (memantine hydrochloride extended release and donepezil hydrochloride) capsules for the treatment of moderate to severe dementia of an Alzheimer's type is currently marketed by Allergan plc under an exclusive license agreement between Adamas Pharmaceuticals, LLC (Adamas Pharmaceuticals) and Forest Laboratories Holdings Limited ("Forest"), an indirect, wholly-owned subsidiary of Allergan plc (collectively, "Allergan") in the United States. Adamas Pharmaceuticals receives royalties on net sales of Namzaric from May 2020. Allergan is responsible for all manufacturing related to Namzaric.

In November 2012, Allergan was granted an exclusive license, with right to sublicense, certain of Adamas Pharmaceuticals' intellectual property rights relating to human therapeutics containing memantine in the United States. In connection with these rights, Allergan markets and sells Namzaric (memantine and donepezil hydrochlorides) extended-release capsules and NAMENDA XR (memantine hydrochloride) extended release capsules for the treatment of moderate to severe dementia related to Alzheimer's disease.

Adamas Pharmaceuticals is entitled to receive royalties on net sales in the United States by Allergan, its affiliates, or any of its sublicensees of controlled-release versions of memantine products covered by the terms of the license agreement. Allergan's obligation to pay royalties with respect to fixed-dose memantine-donepezil products, including Namzaric, continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Allergan in the United States or (ii) the expiration of the Orange Book listed patents for which Allergan obtained rights from Adamas covering such product. However, Allergan's obligation to pay royalties for any product covered by the license is eliminated in any quarter where there is significant competition from generics.

Royalties recognized from Allergan are in the low double digits to mid-teens, as a percent of net sales of Namzaric in the United States. Based on recent trends of Namzaric sales, the tiered royalty is expected to be in the low double digits through the term of the agreement. Based on the current settlement agreements with the Namzaric Abbreviated New Drug Application (ANDA) filers to date, the earliest date on which any of these agreements grant a license to market a Namzaric ANDA filer's generic version of Namzaric is January 1, 2025 (or earlier in certain circumstances). Alternatively, the Namzaric ANDA filers with the earliest license date have the option to launch an authorized generic version of Namzaric beginning on January 1, 2026 instead of launching their own generic version of Namzaric on January 1, 2025.

Adamas expects that it will not receive royalties on sales of NAMENDA XR because of the entry of multiple generic versions of NAMENDA XR.

Confidential Information and Inventions Assignment Agreements

We, including our subsidiaries, require our employees, temporary employees, and consultants to execute confidentiality agreements upon the commencement of employment, consulting, or collaborative relationships with us or our subsidiaries. These agreements provide that all confidential information developed by or made known during the course of the relationship with us or our subsidiaries 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 or the exclusive property of the applicable subsidiary, in each case, to the extent permitted by applicable law.

We and our subsidiaries seek to protect our respective 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 (15 to 30 individuals), to assess safety, tolerability, potential dosing, and if possible, early evidence on effectiveness.
- Phase II—Involves trials in a relatively small group of patients (fewer than 100) 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. Phase III trials include both a control group that receives the standard treatment and a study group that receives the new treatment that is being tested.

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 under various conditions and for commercially viable lengths of time.

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

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. 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 health care professionals, and elements to assure safe use, such as 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" or "stand-alone" 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 a product's primary mode of

action as well as 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 intent of the PREA is to compel sponsors whose drugs have pediatric applicability to study those drugs in pediatric populations, rather than ignoring pediatric indications for adult indications that could be more economically desirable. 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., but there is no reasonable expectation that the cost of developing and making the product available in the U.S. for the disease or condition will be recovered from sales of the product. 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. However, a competitor obtaining orphan product exclusivity for a therapeutic agent before we do, could block the approval of one of our products for seven years for the same indication, unless we are able to demonstrate that our product is clinically superior or the competitor cannot supply sufficient quantities of the product.

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 for 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 and contract 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 a type of non-patent marketing exclusivity granted in the U.S. If granted, pediatric exclusivity, 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 are 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 the MDD Subsidiaries 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. The False Claims Act provides that any Person who knowingly submits false claims to the government is liable for treble damages as well as additional penalties.

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 participation in federally funded healthcare programs for a material breach of the CIA, which would result in substantial losses to the Company.

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; civil monetary penalties statute; and security and transparency statutes and regulations.

The Federal Open Payments program requires certain manufacturers, including those that engage in the production, preparation, propagation, compounding, or conversion of drugs, devices, biological, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to the federal government information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, we are also required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives.

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, we are subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that negatively affects our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH). HIPAA and its implementing regulations impose certain requirements on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates (including us) that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, which

are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we must comply with the Veterans Health Care Act of 1992 (VHCA). The VHCA requires manufacturers to offer their covered drugs (biologics and single source and innovator multiple source drugs) for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs (VA), on a Federal Supply Schedule contract, at a price no higher than the statutory Federal Ceiling Price (FCP). The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we will have to calculate and report to the VA on a quarterly and annual basis. In addition, the Federal Supply Schedule contract requires compliance with applicable federal procurement laws.

Depending on the circumstances, failure to comply with these laws can result in penalties, including significant criminal, civil, and/or administrative criminal penalties, damages, fines, disgorgement, exclusion of products from reimbursement under government programs, "qui tam" actions brought by individual whistleblowers in the name of the government, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits, and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business.

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 third-party payor 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 entities. 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 prices 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 by such third-party payors. A third-party 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.

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. Federal, state, and local governments in the U.S. continue to consider legislation to limit the growth of health care costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals, such as the product candidates that we are developing.

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 and each of our subsidiaries believe that our operations, including those of our subsidiaries, 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, 2021, we employed 575 full-time employees in the U.S. None of our employees are 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 packages, 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.

Any investment in our business 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. If a material, adverse event were to occur, 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.

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 generating, 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®, Qelbree®, GOCOVRI®, or 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, amantadine, or viloxazine 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 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 two generic companies to launch a generic to Qudexy XR in 2020. In February 2021, one of the generic companies, 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. The Company has entered into settlement agreements with third parties permitting the sale of a generic version of Trokendi XR on January 1, 2023, or earlier under certain circumstances. These circumstances include specific thresholds of volume declines for extended unit prescriptions as reported by IQVIA. We have the right to defend our products against third parties who may infringe or are infringing our patents.

Third parties in the future may receive approval to manufacture and market their own versions of extended release oxcarbazepine in the U.S. 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 hydrochloride, in 2020. In February 2022, the FDA approved the first generic of Apokyn (apomorphine hydrochloride injection) to treat hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease. This approval is for an application of the drug cartridges only, which are compatible for use with the APOKYN pen, the brand-name pen injector. Patients treated with generic apomorphine hydrochloride will need to separately obtain the APOKYN pen. The success of these products and the entry of new products could adversely impact the sales of prescriptions for APOKYN.

Third parties in the future may receive approval to manufacture and market their own versions of viloxazine hydrochloride. Accordingly, if any third party is successful in obtaining approval to manufacture and market its own version of viloxazine hydrochloride, such competing products may limit the potential success of Qelbree in the U.S. Our business and growth prospects could be materially impaired.

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 increased, 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 for adult ADHD patients 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, Qelbree, GOCOVRI, 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, Qelbree, GOCOVRI, 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 2022 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 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, GOCOVRI, and Osmolex ER 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 2021 and collectively accounted for more than 85% of our total product revenue in 2021.

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. With the approval of Qelbree, our sales representatives who supported Trokendi XR and Oxtellar XR now devote their full efforts to the launch of Qelbree. A smaller contract field force now supports Trokendi XR and Oxtellar XR, which could have a detrimental impact on the future sales performance of Trokendi XR and Oxtellar XR.

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;

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(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.

- 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.

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.

Following FDA approval of Qelbree in April 2021 for the treatment of ADHD in pediatric patients, additional indications may be submitted using the Section 505(b)(2) regulatory pathway. We submitted a sNDA application, filing under Section 505(b)(2), to the FDA for Qelbree in adults in the third quarter of 2021. In September 2021, the FDA acknowledged it received the sNDA for Qelbree for the treatment of ADHD in adult patients and assigned a PDUFA target action date in late April 2022.The FDA may not approve our filing under Section 505(b)(2) for this 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). We have previously submitted the NDA for SPN-830 to the FDA in September 2020 and received a refusal to file letter from the FDA. We met with the FDA in March 2021 to clarify the steps required for the resubmission of the NDA for SPN-830. We resubmitted the NDA for SPN-830 in December 2021 and we received FDA acceptance for review of NDA for SPN-830 on February 18, 2022. The regulatory and developmental contingent consideration payments include a $25 million milestone due upon the FDA acceptance of the SPN-830 NDA for review, which was paid in first quarter of 2022.

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 clinical manufacturing

organizations (CMOs), who offer a comprehensive range of contract manufacturing and packaging services, in various countries for the supply of API for our products and product candidates, including drug substances for our preclinical research and clinical trials. We currently rely on single source suppliers to produce and package final dosage forms for our products. For Trokendi XR, Oxtellar XR, Qelbree, MYOBLOC, XADAGO, APOKYN, and Osmolex ER, we currently rely on single source suppliers for raw materials, including API. With respect to GOCOVRI, Adamas Operations has recently qualified an additional manufacturer of bulk drug substance.

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, supply chain or business-related issues affecting our suppliers. At this time while we do not know of any circumstances where our European supply chain is impacted by the war in Ukraine, it is unknown to us whether the war in Ukraine will ultimately have an impact on our European supply chains or whether it will create other unforeseen consequences affecting us or 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. 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, APOKYN, XADAGO, and MYOBLOC where various suppliers are based 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 and a five-year marketing exclusivity period for Oxtellar XR and Qelbree, respectively, 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 our products or the commercial success of our 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 Serina Therapeutics and AbbVie 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, demand for our product may significantly decline or 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 Requirements*, 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 Requirements*, for more information.

We have post-marketing clinical and manufacturing studies and data commitments for MYOBLOC. We have initiated work on some of these commitments. We are currently conducting the required post-marketing study of MYOBLOC for treatment of spasticity.

We received approval for Qelbree from the FDA based on certain post-marketing commitments, including the requirement to conduct a clinical efficacy and six month open label safety extension study for ADHD in pediatric patients 4 to 5 years of age, a lactation study and a descriptive study related to the use of Qelbree during pregnancy, and to assess the risks of adverse events and potential complications. We are working towards these post-marketing commitments for Qelbree in a timely manner.

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.

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.

We also have agreements with leading CMOs to manufacture our commercial products, Trokendi XR, Oxtellar and Qelbree. We have entered into agreements with Catalent Pharma Solutions for the manufacture of these commercial products. We have also entered agreement with Bachem for the production of API of Qelbree. These CMOs offer a comprehensive range of contract manufacturing services.

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.

Namzaric (memantine hydrochloride extended release and donepezil hydrochloride) capsules for the treatment of moderate to severe dementia of an Alzheimer's type is currently marketed by Allergan plc under an exclusive license agreement between Adamas Pharmaceuticals, LLC (Adamas Pharmaceuticals) and Forest Laboratories Holdings Limited ("Forest"), an indirect, wholly-owned subsidiary of Allergan plc (collectively, "Allergan") in the United States. Adamas Pharmaceuticals receives royalties on net sales of Namzaric from May 2020. Adamas Operations, one of our subsidiaries, entered into a licensing agreement with Supernus Pharmaceuticals, Inc. during the first quarter of 2022 under which Supernus received the right to market and sell GOCOVRI and Osmolex ER.

Refer to Part I, Item 1, *Business, Collaborations and Licensing Agreements*, of our Annual Report on Form 10-K 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.

An existing team of experienced Supernus sales representatives who supported Trokendi XR and Oxtellar XR are focused on supporting Qelbree, which was launched in May 2021. By removing these resources from the field promotion of Trokendi XR and Oxtellar XR and replacing them with a contract field force of smaller size there could be a detrimental impact on the performance of Trokendi XR and Oxtellar XR.

In September 2020, we submitted the NDA for SPN-830 to the FDA. In November 2020, 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. In March 2021, we met with the FDA to discuss the path forward for resubmission of the SPN-830 NDA. The FDA provided additional clarity related to the contents of the RTF letter and the requirements for resubmission and in December 2021, the Company resubmitted the SPN-830 NDA to the FDA. In February 2022, the Company received notice from the FDA that the company's New Drug Application (NDA) resubmission for its apomorphine infusion device (SPN-830) for the continuous treatment of motor fluctuations ("off"episodes) in Parkinson's disease is considered a Standard Review thereby assigning a timeline of 10 months for review by the FDA and establishing a Prescription Drug User Fee Act (PDUFA) target action date in early October, 2022. The Company will work closely with the FDA as it reviews the SPN-830 NDA. The Company is preparing for the commercial launch of SPN-830 in the first quarter of 2023 assuming timely approval by the FDA.

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. We currently rely on single source suppliers to produce and package final dosage forms for our commercial products. For Trokendi XR, Oxtellar XR, Qelbree, MYOBLOC, XADAGO, APOKYN, and Osmolex ER, we currently rely on single source suppliers for raw materials, including API. In addition, we rely on a single source supplier of API and infusion delivery device 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. 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.

For example, 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/ postural hypotention; 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.

Viloxazine products, which use the same API as Qelbree, are known to cause various side effects, including but not limited to; increased suicidal thoughts and behavior. Higher rates of insomnia and irritability may occur; these side effects, along with other side effects such as depressed mood, anxiety, agitation, akathisia, mania, hypomania, panic attacks, impulsive behavior, and aggression may represent precursors to emerging suicidal ideation or behavior; observation for the emergence of these symptoms, especially within the first few months of treatment or when the dose is changed should be addressed. Qelbree is not indicated in pediatric patients that also take monoamine oxidase inhibitors, or MAOIs, or those patients who take medicines metabolized by CYP1A2, such as theophylline.

Amantadine products, which use the same API as GOCOVRI and Osmolex ER, are known to cause various side effects, including but not limited to: hallucinations, dry mouth, dizziness, peripheral edema, fall, constipation, orthostatic hypotension, urinary tract infections, nausea, anxiety, insomnia, somnolence, confusion, withdrawal-emergent hyperpyrexia, benign prostatic hyperplasia, contusion, decreased appetite, suicidality, depression or depressed mood, headache, livedo reticularis, lightheadedness, depression, anxiety, irritability, psychotic behavior, confusion, anorexia, ataxia, livedo reticularis, peripheral edema,

nervousness, dream abnormality, agitation, dry nose, diarrhea, and fatigue. The use of GOCOVRI or Osmolex ER may cause similar side effects compared to these reference products or may cause additional or different side effects.

Products that are currently on the market and use the same API as our product candidates, including SPN-817 (and over the counter 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: 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-817 may cause similar side effects as compared to these reference products or may cause additional or different side effects.

Apomorphine products, which use the same API as contained in SPN-830 (apomorphine infusion device) has side effects related to the administered apomorphine medication. These side effects may include but are not limited to infusion site erythema; nodule; pruritus; pain; inflammation; also the apomorphine medication may cause but are not limited to nausea; vomiting; somnolence; headache; dizziness; fatigue; insomnia; confusional state; dyskinesia; hallucination; visual hallucination; stereotypy; orthostatic hypotension; hypotension; fall; peripheral edema; eosinophilia.

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, among others:

- regulatory authorities may withdraw approval of the product 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; or
- 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.

GOCOVRI has been granted orphan drug exclusivity until August 24, 2024 for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy with or without concomitant dopaminergic medications.

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 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 new administration.

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 took 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 are 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") and RiconPharma ("Ricon") directed to the Oxtellar XR Orange Book patents, which generally cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. We have filed lawsuits against Apotex and Ricon alleging infringement of these Orange Book patents. The Company intends to vigorously enforce its intellectual property rights relating to Oxtellar XR.

Similarly, we have received Paragraph IV Notice Letters from our generic drug makers directed to the Trokendi XR Orange Book patents, which generally cover once-a-day topiramate formulations and methods of treating seizure using those formulations. We have filed lawsuits against all four generic companies alleging infringement of these Orange Book patents. The Company intends to vigorously enforce its intellectual property rights relating to Trokendi XR.

We have also received Paragraph IV Notice Letters from six generic drug makers directed to the Xadago Orange Book patents. The Company, jointly with Zambon S.p.A. ("Zambon") and Newron Pharmaceuticals S.p.A. ("Newron"), filed lawsuits against the six companies alleging infringement of these Orange Book patents.

For more information, refer to Part I, Item 3—*Legal Proceedings* contained in this Annual Report 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. We increased employee headcount from 563 employees in 2020 to 575 employees in 2021. Revenues in 2021 were $579.8 million, compared to $520.4 million in 2020. 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, similar to the 2021 ransomware attack, could compromise confidential client information, confidential employee information or other sensitive data, cause a disruption or delay in our

operations, harm our reputation, result in improper use of our systems and networks, the manipulation and destruction of data, or the release of defective products and may otherwise expose us to liability, including as a result of the release of third party information improperly obtained from our systems, any of which in turn could negatively impact our business, financial results, reputation and the value of our common shares. We have and continue to implement measures to safeguard our systems and information and mitigate potential 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 additional 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. Any future attacks or other security breaches could also cause us to incur remediation costs with respect to our information technology systems, as occurred following the 2021 ransomware attack. Refer to Item 7—Management Discussion and Analysis—Overview—Ransomware Attack for additional information regarding the 2021 ransomware attack. Additionally, a cyberattack or security breach may remain undetected for an extended period of time, potentially escalating the adverse effects of any such incident.

In response to a cyberattack or security breach, as was the case following the 2021 ransomware attack, we may accelerate previously planned information technology investments in ways designed to improve our information security and technology infrastructure. As a result, we have incurred costs in 2021 and expect to continue to incur costs in the future, which may be significant, in connection with efforts designed to enhance our data security and take further steps designed to protect against unauthorized access to, or manipulation of, our systems and data. In response to any future cyberattack or security breach we may further increase our information technology investments. Despite these efforts, we may not have identified and remediated all of the potential causes of the 2021 ransomware attack and similar incidents may occur in the future.

While integrating acquired businesses and operations, including those of Adamas, undertaking a transition to a more modern ERP system for financial reporting, and upgrading the Company's information technology systems, we may face an elevated cybersecurity risk. We also face the possibility of having a material weakness of internal control.

At the time of the 2021 ransomware attack we self-insured by assuming the full risk of costs related to cybersecurity incidents. Following the attack and re-assessment of our likelihood of being the target of a cybersecurity attack, we are in the process of obtaining cyber insurance in addition to our business insurance coverage, however, it will not cover the 2021 ransomware attack. Our insurance coverage may be insufficient to cover the full impact of a cyberattack.

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 the NDA of SPN-812 in adults with ADHD. 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

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%. In addition, our acquired tax attributes are subject to Section 382 limitations. As of December 31, 2021, we had U.S. Federal and state net operating loss carryforwards of approximately $449.3 million and $431.9 million, respectively. As of December 31, 2021, we had research and development tax credit carryforwards of approximately $1.6 million. Future changes in stock ownership may also trigger an additional ownership change and, consequently, another Section 382 or 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 identified material weaknesses in our internal controls which might cause stockholders to lose confidence in our financial and other public reporting, particularly if not remediated appropriately and timely, which in turn would harm our business and the trading price of our common stock.

Maintaining effective internal control 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.

Our 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 are required to 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.

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2021. Refer to Part II, Item 9A for additional information regarding the material weaknesses. We have been implementing and will continue to implement measures designed to ensure that the control deficiencies contributing to the material weaknesses are remediated; however, we cannot provide assurances that these measures will be successful. If we are unable to remediate the material weaknesses or are unable to otherwise maintain effective internal control over financial reporting, our ability to report financial information timely and accurately could be adversely affected. As a result, we could lose investor confidence and become subject to litigation or investigations, which could adversely affect our business, operations, and financial condition and trading price of our Common Stock.

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 additional deficiencies in our internal control 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 continue to be unable to maintain effective internal control 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.

We devote significant resources and time in an effort 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.

The integration of acquired businesses, including the acquisition of Adamas in November 2021, may result in our systems and controls becoming increasingly complex and more difficult to manage, regardless of whether such acquired business was previously privately or publicly held. The integration of acquired businesses may also result in material challenges to the Company's control environment, 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; and 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. The integration of the internal controls relating to the business acquired through the Adamas Acquisition into ours is currently ongoing. We have excluded the acquisition of Adamas Pharmaceuticals, Inc. from our evaluation of internal control over financial reporting for the year ended December 31, 2021. 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.

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 financial reporting and 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 are properly recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. However, we have identified material weaknesses in our internal control over financial reporting as of December 31, 2021. We have expended and anticipate that we will continue to expend significant resources in order to improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, including to remediate the material weaknesses that have been identified. Refer to Part II, Item 9A for additional information regarding the material weaknesses that have been identified and our remediation plans.

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. We completed the Adamas Acquisition in November 2021 and the USWM Acquisition in June 2020.

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 and Adamas 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

In regards to the USWM Acquisition, the Company acquired the right to further develop and commercialize APOKYN, XADAGO, and the Apomorphine Infusion Device (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.

As regards the Adamas Acquisition, the Company acquired Adamas through a tender offer for $8.10 per share in cash (or an aggregate of approximately $400 million), payable at closing plus two non-tradable contingent value rights (CVR) collectively worth up to $1.00 per share in cash (or an aggregate of approximately $50 million), for a total consideration of $9.10 per share in cash (or an aggregate of approximately $450 million). The first CVR, worth $0.50 per share, is payable upon achieving net sales of GOCOVRI of $150 million in any four consecutive quarters between closing and the end of 2024. The second CVR, worth $0.50 per share, is payable upon achieving net sales of GOCOVRI of $225 million in any four consecutive quarters between closing and the end of 2025.

In addition, the assets acquired from the acquisitions, 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. The fair value of these contingent consideration liabilities and the CVR is determined as of the acquisition date using estimated or forecast inputs. 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.

We completed the Adamas Acquisition in November 2021 and the USWM Acquisition in June 2020. As part of the acquisitions, 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 or significant changes occur in the competitive landscape and slower growth rates in industry segments in which we participate. For example, in February 2022 the FDA approved the first generic of APOKYN (apomorphine hydrochloride injection) to treat hypomobility "off" episodes ("end-of-dose wearing off" and

unpredictable "on/off" episodes) associated with advanced Parkinson's disease. The approval is for an application of the drug cartridges only, which are compatible for use with the APOKYN Pen, the brand-name pen injector. At this time, we cannot forecast what impact, if any, the FDA's approval of this generic may have on sales of APOKYN, or the value of our intangible asset associated with APOKYN. 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.

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, 2021, we had retained earnings of approximately $379.9 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 2022 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.

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, 2021, we had outstanding 53,256,094 shares of common stock, of which approximately 2,126,552 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, 2021, we had outstanding options to purchase 5,774,076 shares of common stock that, if exercised, would result in these additional shares becoming available for sale. Approximately 6.3% of these shares and options are held by senior management of the Company. We have also registered all common stock subject to options, restricted stock units and performance stock units outstanding or reserved for issuance under our 2005 Stock Plan, 2012 Equity Incentive Plan, 2021 Equity Incentive Plan and 2012 Employee Stock Purchase Plan. An aggregate of 5,022,120 and 860,000 shares of our common stock are reserved for future issuance under the 2021 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, Qelbree, APOKYN, and GOCOVRI, 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 and restricted stock units and performance stock units vest there will be dilution to new investors.

As of December 31, 2021, we had issued options to purchase 5,774,076 shares of common stock outstanding, with exercise prices ranging from $5.74 to $58.15 per share and a weighted average exercise price of $24.15 per share, as well as 21,110 unvested restricted stock units and 89,125 performance stock units. Upon the

vesting of each of these options, the holder may exercise his or her options, and upon the vesting of the restricted stock units and performance stock units the holder will receive shares of common stock, which would, in any case, 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 control 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 control 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, Supernus Pharmaceuticals, Inc. ("Company") and any of its subsidiaries may be subject to various claims, charges and litigation. Parent and any of its subsidiaries may be required to file infringement claims against third parties for the infringement of our patents.

Oxtellar XR®

Supernus Pharmaceuticals, Inc. v. Apotex Inc., et al., C.A. No. 20-cv-7870 (FLW)(TJB) (D.N.J.)

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 as 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 the Company's receipt of the Paragraph IV Notice Letter. On September 4, 2020, Apotex answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. 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. On January 27, 2022, the Court issued an Order staying all litigation proceedings and administratively terminated the action until the stay is lifted. As of the date of this submission, this case remains administratively terminated.

Supernus Pharmaceuticals, Inc. v. Apotex Inc., et al., C.A. No. 3:22-cv-00322-FLW-TJB (FLW)(TJB) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug makers Apotex Inc. and Apotex Corp. (collectively, "Apotex") dated December 10, 2021 directed to one of its Oxtellar XR® Orange Book patents. Supernus's U.S. Patent No. 11,166,960 generally covers once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. The FDA Orange Book lists U.S. Patent No. 11,166,960 as expiring on April 13, 2027. On January 24, 2022, the Company filed a lawsuit against Apotex alleging infringement of U.S. Patent No. 11,166,960. 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 U.S. Patent No. 11,166,960. On January 27, 2022, in related Civil Action No. 20-cv-7870 (FLW)(TJB) (D.N.J.), the Court issued an Order staying all litigation proceedings and administratively terminated that related action until the stay is lifted. That Order further indicated that this action, i.e., Civil Action No. 22-cv-00322 (FLW)(TJB) (D.N.J.), will also be stayed. As of the date of this submission, this case remains administratively terminated.

Supernus Pharmaceuticals, Inc. v. RiconPharma LLC, et al., C.A. No. 21-cv-12133 (FLW)(TJB) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug maker RiconPharma LLC dated April 20, 2021 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 as expiring on April 13, 2027. On June 3, 2021, the Company filed a lawsuit against RiconPharma LLC and Ingenus Pharmaceuticals, LLC (collectively, "Ricon") alleging infringement of the Company's nine Oxtellar XR® patents. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Ricon 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 3, 2021 Complaint within 45 days of receiving Ricon's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Ricon's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On August 30, 2021, Ricon answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. Ricon also asserted Counterclaims seeking declaratory judgments of non-infringement for the nine Oxtellar XR® Orange Book patents. Supernus filed a motion to strike the jury demand in Ricon's answer. On December 6, 2021, the Court signed an Order withdrawing the Jury demand from Ricon's answer. On December 13, 2021, Ricon filed an amended Answer to Supernus's Complaint. On December 15, 2021, the Company filed its reply, denying the substantive allegations of Ricon's Counterclaims. Following the initial Rule 16 Scheduling Conference, the Court issued a case schedule that provides for the Final Pretrial Order being submitted on June 9, 2023, and a trial in July 2023. Pretrial discovery is ongoing as of the date of this submission.

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

The Company received a second Paragraph IV Notice Letter directed to its Oxtellar XR® Orange Book Patent Nos. 7,722,898; 7,910,131; 8,617,600; 8,821,930; 9,119,791; 9,351,975; and 9,370,525 from generic drug maker TWi Pharmaceuticals, Inc. on February 16, 2017. On March 31, 2017, the Company filed a lawsuit against TWi Pharmaceuticals, Inc. and TWi International LLC (collectively "TWi") alleging infringement of United States Patent Nos. 7,722,898; 7,910,131; 8,617,600; 8,821,930; 9,119,791; 9,351,975; and 9,370,525. TWi filed a motion to dismiss the Company's March 31, 2017 Complaint on May 10, 2017. On May 11, 2017, the district court administratively terminated TWi's motion to dismiss for failure to comply with the Court's Individual Rules and Procedures. On May 19, 2017, the district court "administratively terminate[d] this matter pending this Court's decision in the First TWi Action [concerning United States Patent Nos. 7,722,898, 7,910,131, 8,617,600, and 8,821,930]." As of the date of this submission. Civil Action No. 17-2164 (RMB)(JS) (D.N.J.) remains administratively terminated.

Trokendi XR®

Supernus Pharmaceuticals, Inc. v. Ajanta Pharma Limited, et al., C.A. No. 21-cv-6964 (FLW)(LHG) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug maker Ajanta Pharma Limited dated February 10, 2021 directed to ten of its Trokendi XR® Orange Book patents. Supernus's 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 generally cover once-a-day topiramate formulations and methods of treating or preventing seizures and migraines using those formulations. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on April 4, 2028 and United States 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 as expiring on November 16, 2027. On March 26, 2021, the Company filed a lawsuit against Ajanta Pharma Limited and Ajanta Pharma USA Inc. (collectively "Ajanta") alleging infringement of the Company's Trokendi XR® Orange Book patents. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Ajanta infringed the Company's Trokendi XR® patents by submitting to the FDA an Abbreviated New Drug Application ("ANDA") seeking to market a generic version of Trokendi XR® prior to the expiration of the Company's patents. Filing its March 26, 2021 Complaint within 45 days of receiving Ajanta's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Ajanta's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On June 7, 2021, Ajanta answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. Ajanta also asserted Counterclaims seeking

declaratory judgments of non-infringement and invalidity for the Trokendi XR® Orange Book patents. On June 28, 2021, the Company filed its reply, denying the substantive allegations of Ajanta's Counterclaims. Following the initial Rule 16 Scheduling Conference, the Court issued a case schedule. On December 17, 2021, the Court issued an order consolidating this lawsuit and the lawsuit against Torrent, discussed in Section VI, below, under which this lawsuit is the lead case and the 30 month stay preventing the FDA from approving Ajanta's ANDA was extended to December 16, 2023. Under the amended scheduling order, the Final Pretrial Conference is set for April 24, 2023. A trial date has not been set. Pretrial discovery is ongoing as of the date of this submission.

Supernus Pharmaceuticals, Inc. v. Torrent Pharmaceuticals Ltd., et al., C.A. No. 21-cv-14268 (FLW)(LHG) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug maker Torrent Pharmaceuticals Ltd. dated June 15, 2021 directed to ten of its Trokendi XR® Orange Book patents. Supernus's 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 generally cover once-a-day topiramate formulations and methods of treating or preventing seizures and migraines using those formulations. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on April 4, 2028 and United States 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 as expiring on November 16, 2027. On July 28, 2021, the Company filed a lawsuit against Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent") alleging infringement of the Company's Trokendi XR® Orange Book patents. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Torrent infringed the Company's Trokendi XR® patents by submitting to the FDA an Abbreviated New Drug Application ("ANDA") seeking to market a generic version of Trokendi XR® prior to the expiration of the Company's patents. Filing its July 28, 2021 Complaint within 45 days of receiving Torrent's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Torrent's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On September 29, 2021, Torrent answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. Torrent also asserted Counterclaims seeking declaratory judgments of non-infringement for the Trokendi XR® Orange Book patents. On November 3, 2021, the Company filed its reply, denying the substantive allegations of Torrent's Counterclaims. Following the initial Rule 16 Scheduling Conference, the Court issued a case schedule. On December 17, 2021, the Court issued an order consolidating this lawsuit with the lawsuit against Ajanta, discussed in Section V, above, under which the Ajanta lawsuit is the lead case. Under the amended scheduling order, the Final Pretrial Conference is set for April 24, 2023. A trial date has not been set. Pretrial discovery is ongoing as of the date of this submission.

Supernus Pharmaceuticals, Inc. v. Lupin Limited, et al., C.A. No. 21-cv-1293 (MN) (D. Del.)

The Company received a Paragraph IV Notice Letter from generic drug maker Lupin Limited dated July 29, 2021 directed to ten of its Trokendi XR® Orange Book patents. Supernus's 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 generally cover once-a-day topiramate formulations and methods of treating or preventing seizures and migraines using those formulations. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on April 4, 2028 and United States 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 as expiring on November 16, 2027. On September 10, 2021, the Company filed a lawsuit against Lupin Limited, Lupin Atlantis Holdings S.A., Nanomi B.V., Lupin Inc., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") alleging infringement of the Company's Trokendi XR® Orange Book patents. The Complaint—filed in the U.S. District Court for the District of Delaware—alleges, inter alia, that Lupin infringed the Company's Trokendi XR® patents by submitting to the FDA an Abbreviated New Drug Application ("ANDA") seeking to market a generic version of Trokendi XR® prior to the expiration of the Company's patents. Filing its September 10, 2021 Complaint within 45 days of receiving Lupin's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Lupin's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On December 20, 2021, Lupin answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. Lupin also asserted Counterclaims seeking declaratory judgments of non-infringement and

invalidity for the Trokendi XR® Orange Book patents. On January 10, 2022, the Company filed its reply, denying the substantive allegations of Lupin's Counterclaims. On February 11, 2022, the Court instructed the parties to submit a proposed scheduling order that would provide for a trial that begins on June 20, 2023. As of the date of this submission. the date for the initial Rule 16 Scheduling Conference has not been set.

Supernus Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc., et al., C.A. No. 21-cv-17104 (FLW)(LHG) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug maker Zydus Pharmaceuticals (USA) Inc. dated August 5, 2021 directed to ten of its Trokendi XR® Orange Book patents. Supernus's 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 generally cover once-a-day topiramate formulations and methods of treating or preventing seizures and migraines using those formulations. The FDA Orange Book currently lists United States Patent No. 8,298,576 as expiring on April 4, 2028 and United States 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 as expiring on November 16, 2027. On September 17, 2021, the Company filed a lawsuit against Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, "Zydus") alleging infringement of the Company's Trokendi XR® Orange Book patents. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Zydus infringed the Company's Trokendi XR® patents by submitting to the FDA an Abbreviated New Drug Application ("ANDA") seeking to market a generic version of Trokendi XR® prior to the expiration of the Company's patents. Filing its September 17, 2021 Complaint within 45 days of receiving Zydus's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Zydus's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. The August 5, 2021 Paragraph IV Notice Letter from Zydus Pharmaceuticals (USA) Inc. concerns Zydus's proposed generic equivalent of the 200 mg strength of Trokendi XR®[1]. The August 5, 2021 Paragraph IV Notice Letter referenced herein does not concern the same ANDA as the one that was at issue in the previous lawsuit. On December 28, 2021, Zydus answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. As of the date of this submission, the date for the initial Rule 16 Scheduling Conference has not been set and the Court has not issued a case schedule.

XADAGO®

On June 10, 2021, Newron Pharmaceuticals S.p.A. ("Newron"), Zambon S.p.A. ("Zambon") and Supernus Pharmaceuticals, Inc. (the "Company"), through its subsidiary MDD US Operations, LLC (collectively, "Plaintiffs"), initiated litigation against generic drug makers Aurobindo Pharma Limited, Aurobindo Pharma USA Inc., MSN Laboratories Private Limited ("MSN"), Optimus Pharma Pvt Ltd, Prinston Pharmaceutical, Inc., RK Pharma, Inc. and Zenara Pharma Private Limited (collectively, "Defendants") for infringement of three FDA Orange Book patents covering XADAGO®, Parent's once-daily product indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's Disease experiencing "off" episodes. U.S. Patent Nos. 8,076,515, 8,278,485 and 8,283,380 (collectively, the "XADAGO Patents") cover the pharmaceutical formulation of and methods of treatment with safinamide. The XADAGO Patents expire between June 2027 and March 2031. The Company has a license agreement with Zambon, Newron's partner, related to the XADAGO Patents, and as a new chemical entity, XADAGO is under the 5-year FDA exclusivity period that expires on March 21, 2022. The Complaint—filed in the U.S. District Court for the District of Delaware—alleges that the Defendants infringed the XADAGO Patents by submitting to the U.S. Food and Drug Administration (FDA) Abbreviated New Drug Applications (ANDAs) seeking to market a generic version of XADAGO prior to the expiration of the patents. Filing the Complaint within 45 days of receiving each of the Defendants' Paragraph IV notice letters entitles the Plaintiffs to an automatic stay preventing the FDA from approving the Defendants' ANDAs for 30 months from the date of the Plaintiffs'

[1] Previously, the Company was in a lawsuit against Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited concerning an Abbreviated New Drug Application ("ANDA") for Zydus's proposed generic equivalents of the 25 mg, 50 mg, and 100 mg strengths of Trokendi XR®. A settlement agreement was entered into between the Company and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited concerning the previous lawsuit. *See* https://www.sec.gov/Archives/edgar/data/1356576/000110465917031191/a17-10293_1ex10d1.htm.

receipt of the Paragraph IV Notice Letters. The parties agreed on a case schedule. Fact discovery is ongoing. A trial has been set for January 8, 2024.

Adamas Litigation

In November 2012, Adamas Pharmaceuticals, Inc. (Adamas) granted Forest Laboratories Holdings Limited, an indirect wholly-owned subsidiary of Allergan plc (Forest), an exclusive license to certain of Adamas's intellectual property rights relating to human therapeutics containing memantine in the United States. Under the terms of that license agreement, Forest has the right to enforce such intellectual property rights which are related to its right to market and sell Namzaric and NAMENDA XR for the treatment of moderate to severe dementia related to Alzheimer's disease. Adamas has a right to participate in, but not control, such enforcement actions by Forest.

Since 2018 multiple generic companies have launched generic versions of NAMENDA XR. A number of companies have submitted ANDAs including one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv) to the FDA requesting approval to manufacture and market generic versions of Namzaric, on which Adamas became entitled to receive royalties from Forest beginning in May 2020.

Adamas and Forest have settled with all such Namzaric ANDA filers, including all first filers on all the available dosage forms of Namzaric. Subject to those agreements, the earliest date on which any of these agreements grant a license to market a Namzaric ANDA filer's generic version of Namzaric is January 1, 2025 (or earlier in certain circumstances). Alternatively, the Namzaric ANDA filers with the earliest date have the option to launch an authorized generic version of Namzaric beginning on January 1, 2026 instead of launching their own generic version of Namzaric on January 1, 2025. Adamas and Forest intend to continue to enforce the patents associated with Namzaric.

On April 1, 2019, Adamas was served with a complaint filed in the United States District Court for the Northern District of California (Case No. 3:18-cv-03018-JCS) against it and several Allergan entities alleging violations of federal and state false claims acts (FCA) in connection with the commercialization of NAMENDA XR and Namzaric by Allergan. The lawsuit is a *qui tam* complaint brought by a named individual, Zachary Silbersher, asserting rights of the Federal government and various state governments. The lawsuit was originally filed in May 2018 under seal, and Adamas became aware of the lawsuit when it was served. The complaint alleges that patents held by Allergan and Adamas covering NAMENDA XR and Namzaric were procured through fraud on the United States Patent and Trademark Office and that these patents were asserted against potential generic manufacturers of NAMENDA XR and Namzaric to prevent the generic manufacturers from entering the market, thereby wrongfully excluding generic competition resulting in artificially high price being charged to government payors. Adamas's patents in question were licensed exclusively to Forest. The complaint includes a claim for damages of "potentially more than $2.5 billion dollars," treble damages and statutory penalties. To date the federal and state governments have declined to intervene in this action. This case is currently stayed pending Adamas's and Allergan's interlocutory appeal of the District Court's December 11, 2020 order denying Adamas's and Allergan's motion to dismiss the complaint. The appeal is pending in the United States Court of Appeals for the Ninth Circuit (Case No. 21-80005). Argument was held on January 10, 2022 and no decision has been reached as of the date of this filing.

On December 10, 2019, a putative class action lawsuit alleging violations of the federal securities laws was filed by Ali Zaidi against Adamas and certain of Adamas's former directors and officers in federal court in the Northern District of California (Case No. 4:19-cv-08051). This lawsuit alleges violations of the Securities Exchange Act of 1934 by Adamas and certain of Adamas's former directors and officers. On October 8, 2021, the presiding judge dismissed the litigation, and granted Plaintiffs leave to amend their complaint. On November 5, 2021, Plaintiffs filed their second amended class action complaint. On December 10, 2021, Adamas filed a motion to dismiss the Second Amended Complaint. Plaintiffs opposed the motion to dismiss. The motion to dismiss remains pending.

On March 16, 2020, a shareholder derivative lawsuit was filed by Patrick Van Camp in federal court in the Northern District of California (Case No. 4:20-cv-01815) naming Adamas and certain of Adamas's current and former directors and officers as defendants. This lawsuit alleges breaches of fiduciary duty and violations of the Securities Exchange Act of 1934 by certain of Adamas's current and former directors and

officers. Adamas is named as a nominal defendant only. On April 6, 2020, another, virtually identical, shareholder derivative lawsuit was filed by James Druzbik in federal court in the Northern District of California (Case No. 4:20-cv-02320) naming Adamas and certain of Adamas's current and former directors and officers as defendants. This lawsuit contains the same allegations, claims, and defendants as the first derivative action. Adamas is named as a nominal defendant only. In all of these actions, Plaintiffs seek unspecified monetary damages and other relief. These actions are ongoing.

On October 26, 2021, Elaine Wang, a purported stockholder of Adamas, filed a complaint for violations of federal securities laws in the Southern District of New York (Case No. 1:21-cv-8742) challenging the disclosures made in connection with the acquisition of Adamas by Parent. The complaint names each of Adamas's directors as a defendant and alleges that the disclosures in the solicitation statement filed on October 25, 2021 were materially false and misleading under Section 14 of the Securities Exchange Act. A second lawsuit by purported stockholder, Jeffrey D. Justice II, was filed on October 28, 2021 in the same court (Case No. 1:21-cv-08818) against the same defendants with similar claims. A third lawsuit by purported stockholder, Stourbridge Investments LLC, was filed on October 29, 2021 in the same court (Case No. 1:21-cv-08856) against the same defendants with similar claims. A fourth lawsuit by purported stockholder, Tran Tran, was filed on October 29, 2021 in the Northern District of California (Case No. 3:21-cv-08417) also against the same defendants and with similar claims. A fifth lawsuit by purported stockholder, Kelly Cook, was filed on November 2, 2021 in the Easter District of New York (Case No. 1:21-cv-06102) against the same defendants with similar claims. A sixth lawsuit by purported stockholder, Catherine Coffman, was filed on November 5, 2021 in the Northern District of California (Case No. 3:21-cv-08646) against the same defendants with similar claims. A seventh lawsuit by purported stockholder, Michael Kent, was filed on November 5, 2021 in the District of Delaware (Case No. 1:21-cv-01579) against the same defendants with similar claims. An eighth lawsuit by purported stockholder, Marc Waterman, was filed on November 8, 2021 in the Eastern District of Pennsylvania (Case No. 2:21-cv-04912) against the same defendants with similar claims. A ninth lawsuit by purported stockholder, Lori Vereker, was filed on November 10, 2021 in the Southern District of New York (Case No 1:21-cv-09319) against the same defendants with similar claims. A tenth lawsuit by purported stockholder, Michael McDevitt, was filed on November 11, 2021 in the Southern District of New York (Case No 1:21-cv-09343) against the same defendants with similar claims. In all of these actions, Plaintiffs sought injunctive relief, unspecified monetary damages, unspecified costs, and other relief. These actions have all been voluntarily dismissed and are no longer pending.

Adamas believes it has strong factual and legal defenses to all actions and intends to defend itself vigorously.

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, 2021, the closing price of our common stock on the NASDAQ Global Market was $29.16 per share. As of December 31, 2021, 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.

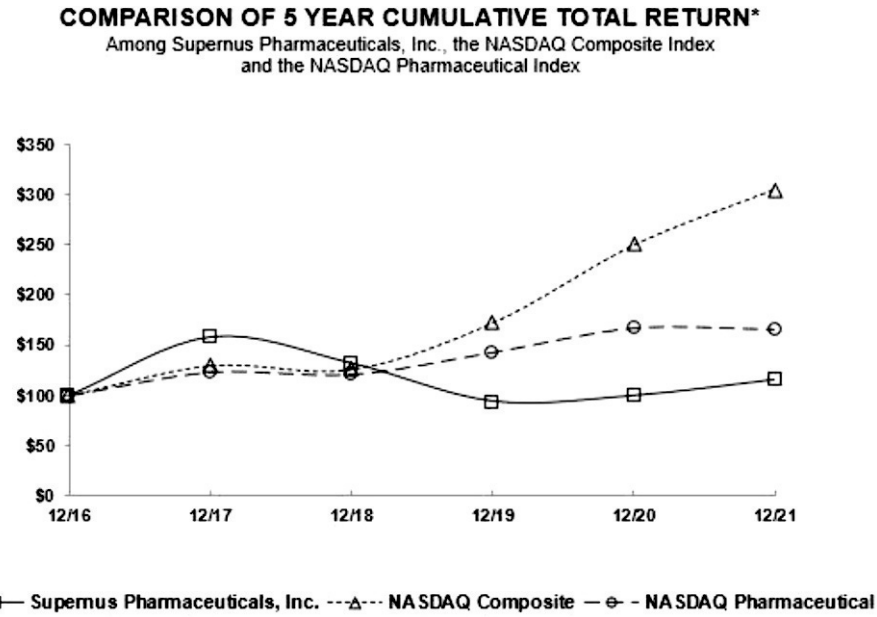
Option Grants

During the three-month period ended December 31, 2021, the Company granted options to employees to purchase an aggregate of 64,200 shares of common stock at a weighted average exercise price of $28.89 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, 2021.

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 12/31/2016 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, 2016	100.00	100.00	100.00
December 31, 2017	157.82	129.64	122.85
December 31, 2018	131.56	125.96	120.80
December 31, 2019	93.94	172.17	142.53
December 31, 2020	99.64	249.51	166.32
December 31, 2021	115.49	304.85	165.08

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. RESERVED.

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, attention-deficit hyperactivity disorder (ADHD), hypomobility in Parkinson's Disease (PD), cervical dystonia, chronic sialorrhea, dyskinesia in PD patients receiving levodopa-based therapy, and drug-induced extrapyramidal reactions in adult patients. We are developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in PD, epilepsy, depression, and other CNS disorders.

On February 18, 2022, the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) for SPN-830 (apomorphine infusion device) for the continuous treatment of motor fluctuations ("off" episodes) in PD and assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 7, 2022.

On October 10, 2021, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among the Company, Adamas Pharmaceuticals, Inc. (Adamas) and Supernus Reef, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Purchaser"). On November 24, 2021, the Purchaser was merged with and into Adamas (Merger), with Adamas continuing as the surviving corporation in the Merger as a wholly owned subsidiary of the Company (Adamas Acquisition). At the time of the Adamas Acquisition, Adamas held two established commercial products in its portfolio, GOCOVRI®, Osmolex ER®, and had royalty rights to Namzaric®. Allergan plc markets and sells Namzaric in the U.S.

Following the Adamas Acquisition, during the fourth quarter of 2021 and continuing into the first quarter of 2022, Adamas was reorganized with the interests of Adamas Pharmaceuticals, LLC, formerly Adamas Pharmaceuticals, Inc, in GOCOVRI and Osmolex ER effectively transferred to Adamas Operations, LLC (Adamas Operations), which, alongside Adamas Pharmaceuticals, LLC, is a wholly-owned subsidiary of Adamas Holdings, LLC (collectively, the "Adamas Subsidiaries"), which is itself a wholly-owned subsidiary of Supernus Pharmaceuticals, Inc. During the first quarter of 2022, Supernus Pharmaceuticals, Inc. was granted a license by Adamas Operations to market and sell GOCOVRI and Osmolex ER (such reorganization and licensing agreement, the "Adamas Reorganization"). Each of the Adamas Subsidiaries are distinct legal entities that contract with Supernus Pharmaceuticals, Inc. for the provision of certain corporate and other support services.

On April 2, 2021, the FDA approved Qelbree for the treatment of ADHD in pediatric patients 6 to 17 years of age. In May 2021, we launched Qelbree in the U.S. On September 2, 2021, the FDA has acknowledged receipt of the supplemental new drug application (sNDA) for adult patients with ADHD and assigned a PDUFA date of April 29, 2022.

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, the Company added three established commercial products, APOKYN, XADAGO, and MYOBLOC, and a product candidate in late-stage development to its portfolio, through its subsidiaries. In the second quarter of 2021 and within one year from the Closing Date, the Company finalized its accounting for the business combination, including the purchase price allocation.

On April 21, 2020, we entered into a Development and Option Agreement (Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor Inc.) and also acquired an ownership position in Navitor Inc. Under the terms of the Development Agreement, the Company and Navitor Inc. will jointly conduct a Phase II clinical program for NV-5138 (SPN-820) in treatment resistant depression (TRD). In March 2021, Navitor Inc. underwent a legal restructuring whereby Navitor Inc. became a wholly owned subsidiary of a newly formed limited liability company, Navitor Pharmaceuticals, LLC (Navitor LLC) (Navitor Restructuring) and our ownership position in Navitor Inc. was exchanged for an equivalent ownership position in Navitor LLC. In December 2021, we received a $12.9 million cash distribution pursuant to our ownership position in Navitor LLC following its sale of its subsidiary.

We, including through our subsidiaries, have a portfolio of commercial products and product candidates.

Commercial Products

- Trokendi XR is the first once-daily extended release topiramate product indicated for the treatment of epilepsy and the prophylaxis of migraine headache in the United States (U.S.) market.
- Oxtellar XR 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.
- Qelbree, a novel non-stimulant product candidate for the treatment of ADHD in pediatric patients 6 to 17 years of age.
- APOKYN 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 is a once-daily product indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
- MYOBLOC 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.
- GOCOVRI is the first and only FDA-approved medicine indicated for the treatment of dyskinesia in patients with PD receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and as an adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
- Osmolex ER extended release tablets is for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult patients.

Product Candidates

We have various product candidates in different stages of development. Our late-stage product candidates include:

- Qelbree, a novel non-stimulant product candidate for the treatment of ADHD in adult patients with ADHD.
- SPN-830 is a late-stage drug/device combination product candidate for the continuous prevention of "off" episodes in PD.

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.

Operational Highlights

Qelbree Launch Update

- Total IQVIA prescriptions were 34,328 in the fourth quarter of 2021, an increase of 122% compared to total prescriptions of 15,453 in the third quarter of 2021. In February 2022, total prescriptions reached 14,767.
- Total prescriptions are showing a quarter-to-date (first seven weeks) sequential growth rate of 42% in the first quarter 2022 versus the corresponding same seven-week period in the fourth quarter of 2021.
- Qelbree continues to expand its base of prescribers, with over 5,600 prescribers in the fourth quarter of 2021, up from 3,470 prescribers from the third quarter of 2021.

- Continued progress in securing and improving managed care coverage.
- Preparations for the potential launch in the adult market are well underway, assuming timely approval by the FDA of the sNDA for the adult indication.

Acquisition of Adamas Pharmaceuticals, Inc.

- We completed the acquisition of Adamas in late November 2021, and the Adamas Reorganization in the first quarter of 2022, strengthening our Parkinson's disease portfolio with two marketed products, including GOCOVRI extended release capsules, the first and only FDA-approved medicine indicated for the treatment of both "off" episodes and dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy. In addition, the acquisition diversifies and increases the Company's revenue base and cash flow.
- Total prescriptions for GOCOVRI in January 2022 grew by 30% compared to January 2021.

Product Pipeline Update

Qelbree (viloxazine, extended-release capsules)—Novel non-stimulant for the treatment of ADHD in adults

- In September 2021, the FDA acknowledged it received the sNDA for Qelbree for the treatment of ADHD in adult patients. The sNDA has a PDUFA date in late April 2022.

SPN-830 (apomorphine infusion device)—Continuous treatment of motor fluctuations ("on-off" episodes) in Parkinson's disease (PD)

- The Company received notice from the FDA that its New Drug Application (NDA) resubmission for SPN-830 for the continuous treatment of motor fluctuations ("off" episodes) in Parkinson's disease is considered a Standard Review, thereby assigning a timeline of 10 months for review by the FDA and establishing a PDUFA target action date of October 7, 2022.
- The Company will work closely with the FDA as it reviews the SPN-830 NDA. The Company is preparing for the commercial launch of SPN-830 in the first quarter of 2023, assuming timely approval by the FDA.

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

- The Company has initiated a Phase II multicenter, randomized double-blind placebo-controlled parallel design study of SPN-820 in adults with treatment resistant depression. The study will examine the efficacy and safety of SPN-820 over a course of five weeks of treatment in approximately 400 patients. The primary outcome measure is the change from baseline to end of treatment period on the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score, a standard depression rating scale.

SPN-817—A novel product candidate for the treatment of epilepsy

- A randomized Phase II clinical study of SPN-817 for the treatment of focal seizures is expected to start in the second half of 2022.

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, 2021, 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 Qelbree, 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 our 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, 2021, 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.

Ransomware Incident

On November 24, 2021, we announced we were the target of a ransomware attack. The Company currently believes unauthorized activity on its information technology systems began in late September 2021. Abnormal behavior on the Company's information technology systems was first detected by the Company in mid-November 2021. Based on the investigation, we believe the criminal ransomware groups (the "criminal groups") copied certain data from our systems, encrypted certain data on our systems and then deployed malware designed to impede access to our IT systems. Thereafter the criminal groups contacted the Company and threatened to publish certain data copied from our systems. Upon detection of the ransomware attack, we notified government authorities, engaged third-party cybersecurity experts through our outside counsel, and commenced its recovery process. We maintain redundant off-site data backups, which were verified to have not been compromised by the ransomware attack and were utilized to restore the data encrypted by the criminal groups. At this time, we have successfully recovered the impacted files and have taken additional steps designed to protect our networks and files.

We have not paid any ransom amounts and do not currently anticipate paying any ransom amounts. While we remain unaware of any actual or attempted misuse of information copied from our IT systems, our investigation into the incident remains ongoing and there can be no assurance that the information has not already been misused and will not be misused in the future.

While the attack had no significant impact on the business and did not cause any long-term disruption to our operations, the encryption of certain data did impact our use of our enterprise resource planning system (the "legacy ERP"). Following the attack, we:

(i) restored securely backed-up data from our redundant off-site data backups into our legacy ERP,

(ii) manually processed certain functions which were previously automated by our legacy ERP, and

(iii) simultaneously accelerated our planned transition to a more modern ERP software.

Although the ransomware attack has not significantly impacted our business and there was no long-term disruption to our operations, there can be no assurance that further attacks may not significantly impact our business or disrupt operations and that information improperly obtained by the criminal groups may not be exploited by the criminal groups or other third parties. For additional information on the risks we face

related to cybersecurity refer to Part I, Item 1A—Risk Factors—Cybersecurity incidents may adversely impact our financial condition, results of operations, and reputation for risks associated with cybersecurity.

While we have not been the subject of any legal proceedings involving the ransomware attack, it is possible we could be the subject of claims from persons alleging they suffered damages from the incident or actions by governmental authorities.

At the time of the ransomware attack we self-insured by assuming the full risk of costs related to cybersecurity incidents. Following the attack and a re-assessment of our likelihood of being the target of a cybersecurity attack, we are in the process of obtaining cyber insurance in addition to our business insurance coverage, however, it will not cover the 2021 ransomware attack. No claim has been made to date. We have incurred costs in 2021 and expect to continue to incur costs in the future, which may be significant, in connection with efforts designed to enhance our data security and take further steps designed to protect against unauthorized access to, or manipulation of, our systems and data. These costs were primarily comprised of certain employee related expenses and various third party consulting services, including forensic experts, legal counsel and other IT and accounting professional expenses and enhancements to our cyber security measures. We expect to incur additional costs related to the ransomware incident in the future, including costs related to our response to the ransomware incident and our efforts designed to enhance our security measures.

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;
- Impairment of intangible assets;
- Valuation of contingent consideration; 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 further discussion on each of the different sales deductions.

Rebates

Rebate amounts are typically based upon the volume of purchases using contractual or statutory prices, which may vary by product and by payer. For each type of rebate, the factors used in the calculations of the accruals for that rebate include the identification of the products subject to the rebate, applicable price terms and estimated lag time between sale and payment of the rebate, which can be significant. In order to establish the rebate accruals, we use both internal and external data to estimate the level of inventory in the distribution channel and the rebate claims processing lag time for each type of rebate. To estimate the rebate percentage or net price, we track sales by product and by customer or payer. We evaluate inventory data reported by wholesalers, available prescription volume information, product pricing, historical experience and other factors in order to determine the adequacy of our accruals. We regularly monitor our accruals and record adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in reserve is appropriate. Historically, adjustments to rebate accruals have not been material to net earnings.

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. A significant portion of rebates we pay are on state Medicaid programs. We participate in state Medicaid programs wherein the lag time from the date of sale of our product when we accrue for provision for rebates and the ultimate invoicing by the individual state Medicaid program can occur up to several quarters after the sale of our product. Because of the time lag for Medicaid, in any particular quarter, our adjustments may incorporate revisions of accruals for prior periods. Estimates associated with our participation in state Medicaid programs are particularly susceptible to adjustment given the extensive time lag.

Returns

Consistent with industry practice, we maintain a return policy that allows our customers to return products within a specified period of time. Sales of our products are not subject to a general right of return; however, we will accept return of expired product 6 months prior to and up to 12 months subsequent to the product's expiry date for certain products. Our products have a shelf life of up to 48 months from date of manufacture. The product return accrual is estimated principally based on historical experience, the level and estimated shelf life of inventory in the distribution channel, our return policy and expected market events, including generic competition. The time lag from date of sale of our products when we accrue our provision for product returns and the time at which we issue credit for expired product can occur up to several years after the sale of our product. Estimates associated with our provision for product returns are particularly susceptible to adjustment given the extensive time lag. In regards to Trokendi XR, the Company has entered into settlement agreements with third parties, permitting the sale of a generic version of Trokendi XR on or after January 1, 2023, or earlier under certain circumstances. The Company is actively monitoring returns activity in light of the expected patent expiration and potential sales decline based on timing of generic entry. The entry of a generic competitor may cause our future Trokendi XR product return rates to change from historical trends, and this change could have a material effect on the future provision for product returns.

Sales discounts

The estimated sales discounts have historically been predictable and less subjective due to the limited number of assumptions involved, the consistency of historical experience and the fact that we generally settle these amounts upon receipt of payment from the customer.

For a roll-forward of the sales deductions, see the section entitled *Results of Operations—Revenues—Sales deductions and related accruals*.

Business Combination Accounting and Valuation of Acquired Assets

The Company completed the USWM Acquisition on June 9, 2020, and the Adamas Acquisition on November 24, 2021. Each transaction was accounted for 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. 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.

The acquisition method of accounting requires that we recognize the assets acquired and liabilities assumed at their acquisition date fair values. Goodwill is measured as the excess of consideration transferred over the acquisition date net fair values of the assets acquired and the liabilities assumed. The purchase price allocation is a critical accounting policy because the estimation of fair values of acquired assets and assumed liabilities is judgmental and requires various assumptions. Further, the amounts and useful lives assigned to depreciable and amortizable assets versus amounts assigned to Goodwill, which is not amortized, can significantly affect the results of operations in the period of and for periods subsequent to a business combination.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction, and therefore represents an exit price. When identifiable intangible assets, including in-process research and development (IPR&D) assets, 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, is used in estimating the fair value of the acquired intangible assets. These cash flow projections are based on management's estimates of economic and market conditions including: the timing and probability of success of clinical events or regulatory approvals for the IPR&D assets; the estimated future cash flows from revenues of acquired assets; the timing and projection of costs and expenses, including the costs to complete the IPR&D assets; discount rates; and tax rates.

While we use our best estimates and assumptions as part of the process to value assets acquired and liabilities assumed at the acquisition date, our estimates are inherently uncertain and subject to refinement. During the measurement period, which occurs before finalization of the purchase price allocation, changes in assumptions and estimates that result in adjustments to the fair values of assets acquired and liabilities assumed, if based on facts and circumstances existing at the acquisition date, are recorded on a retroactive basis as of the acquisition date, with the corresponding offset to Goodwill. Any adjustments not based on facts and circumstances existing at the acquisition date, or if subsequent to the conclusion of the measurement period, will be recorded to our consolidated statements of earnings.

Impairment of Intangible Assets

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. In performing the qualitative assessment, we consider events and circumstances, focusing on the significant inputs affecting the fair value of an indefinite-lived intangible asset to determine whether it is necessary to perform the quantitative impairment test. 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.

In connection with the USWM acquisition in June 2020, we acquired the right to further develop and commercialize SPN-830 (apomorphine infusion device), a late-stage product candidate (IPR&D intangible asset). The significant inputs and assumptions used to estimate the fair value of the IPR&D intangible asset include: 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. We believe that the timing and probability of success of clinical and regulatory approval for the IPR&D asset is key and directly drives the timing and realization of the estimated future cashflows from product sales and the incurrence of costs and expenses. The drug regulatory approval process is inherently uncertain, lengthy, and

difficult. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. In addition, the actual review and approval process time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Any adverse action by the FDA can potentially impact our estimated fair value of the IPR&D intangible asset. In February 2022, the NDA for SPN-830 was accepted for review by the FDA. The FDA assigned a PDUFA target action date of October 7, 2022. We consider the positive results of clinical trials, industry benchmarks, available market data, and recent communications with the FDA regarding SPN-830 in determining the probability of technical and regulatory success input and assumption. The carrying amount of the indefinite-lived intangible asset was $124.0 million as of December 31, 2021.

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 in the business combinations section above for estimating fair value of the acquired intangible assets in a business combination. The carrying amount of the definite-lived intangible assets, net was $660.7 million as of December 31, 2021.

The assumptions and estimates used in evaluating and estimating impairment can be complex and often subjective. These can include a variety of factors, including external factors such as industry and economic trends, and internal factors such as changes in our business strategy or our internal forecasts. Although we believe the assumptions, judgments, and estimates we have used in our assessments are reasonable and appropriate, a material change in any of our assumptions or external factors could lead to impairment charges.

Valuation of Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. During the measurement period, if we obtain new information regarding facts and circumstances that existed as of the respective USWM or Adamas Closing Dates 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 will revalue the contingent consideration liability and record increases or decreases in their fair value as an adjustment to operating earnings. 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.

As of December 31, 2021 and December 31, 2020, the Company reported $80.5 million and $76.7 million, respectively, in its consolidated balance sheets related to the USWM Acquisition and the Adamas Acquisition.

The USWM contingent consideration of $70.2 million and $76.7 million as of December 31, 2021 and December 31, 2020, respectively, is primarily associated with the fair value of the regulatory and developmental contingent consideration payments. The key assumptions considered in estimating the fair value include the estimated probability and timing of milestone achievement, such as the probability and timing of obtaining regulatory approval. The drug regulatory approval process is inherently uncertain, and any adverse action taken by the FDA can potentially impact our estimated fair value of these regulatory and commercial activities milestones. The possible outcomes for the contingent consideration range $0 to $230.0 million on an undiscounted basis.

The remaining $10.3 million of contingent consideration liabilities as of December 31, 2021 is associated with the estimated fair value of contingent consideration related to the Adamas Acquisition. The contingent consideration is related to two non-tradable contingent value rights (CVRs) which represents the contractual right to receive a contingent payment upon the achievement of the applicable sales-based milestones. The

estimated fair value of the contingent consideration was determined using the Monte Carlo simulation. The key assumptions considered include the estimated amount and timing of projected cash flows, volatility, estimated discount rates and risk-free interest rate. The possible outcomes for the contingent consideration range from $0 to $50.9 million on an undiscounted basis.

Refer to Note 6, *Fair Value of Financial Instruments and Contingent Consideration*, for further information.

Income taxes

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 determining whether it is probable that sufficient future taxable income will be available against which a deferred tax asset can be utilized. In determining future taxable income, we are required to make assumptions including the amount of taxable income in the various jurisdictions in which we operate. These assumptions require significant judgment about forecasts of future taxable income. Actual operating results in future years could differ from our current assumption of the recoverability of deferred tax assets.

We recorded a valuation allowance of $70.5 million as of December 31, 2021, of which $69.7 million is associated with the Adamas Acquisition. The valuation allowance is primarily related to federal and state net operating losses carryforwards acquired from the Adamas Acquisition that are not expected to be realizable in the future.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2021, compared to the year ended December 31, 2020. Our Annual Report on Form 10-K for the year ended December 31, 2020, includes a discussion and analysis of our financial condition and results of operations for the year ended December 31, 2019, 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	
	2021	2020	Amount	Percent
Net product sales				
Trokendi XR	$304,817	$319,640	$(14,823)	(5)%
Oxtellar XR	110,708	98,725	11,983	12%
APOKYN	99,233	74,296	24,937	34%
XADAGO	13,387	6,943	6,444	93%
MYOBLOC	19,514	9,746	9,768	100%
Qelbree	9,879	—	9,879	**
GOCOVRI	9,778	—	9,778	**
Osmolex ER	188	—	188	**
Total net product sales	567,504	509,350	58,154	11%
Royalty revenues	12,271	11,047	1,224	11%
Total revenues	$579,775	$520,397	$ 59,378	11%

Net Product Sales

Net product sales increased by $58.2 million from $509.4 million in 2020 to $567.5 million in 2021. The increase in net product sales was primarily due to a $51.1 million increase in net product sales of the acquired commercial products from both the USWM Acquisition in June 2020 and Adamas Acquisition in November 2021, as well as a $12.0 million increase in net product sales of Oxtellar XR and $9.9 million net product sales from Qelbree, which was launched in May 2021. Partially offsetting this increase was $14.8 million decrease in net product sales of Trokendi XR.

Trokendi XR net product sales decreased by $14.8 million, from $319.6 million in 2020 to $304.8 million in 2021. This decrease was attributable to a decline in unit demand partially offset by the favorable impact of the price increase taken in January 2021 and favorable improvements in sales deductions. Oxtellar XR net product sales increased by $12.0 million, from $98.7 million in 2020 to $110.7 million in 2021. This increase was primarily attributable to the favorable impact of both unit demand and a price increase in January 2021.

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 reduction 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, 2021 and 2020 (dollars in thousands):

	Accrued Product Returns and Rebates			
	Product Rebates	Product Returns	Allowance for Sales Discounts	Total
Balance at December 31, 2020	$ 96,589	$ 29,603	$ 11,404	$ 137,596
Adamas Acquisition liabilities assumed	2,194	223	271	2,688
Provision				
Provision for sales in current year	370,273	15,762	69,383	455,418
Adjustments relating to prior year sales	1,335	(3,069)	19	(1,715)
Total provision	371,608	12,693	69,402	453,703
Less: Actual payments/credits	(372,794)	(7,392)	(67,540)	(447,726)
Balance at December 31, 2021	$ 97,597	$ 35,127	$ 13,537	$ 146,261
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

Accrued product returns and rebates

The accrued product rebates balance increased from $96.6 million as of December 31, 2020 to $97.6 million as of December 31, 2021 primarily due to Adamas liabilities assumed in 2021.

The accrued product returns balance increased from $29.6 million as of December 31, 2020 to $35.1 million as of December 31, 2021 due to timing of related return activity whereby the provision for product return exceeds actual returns by $5.3 million in 2021.

Provision for returns and rebates

The provision for product rebates increased from $350.1 million in 2020 to $371.6 million in 2021. The increase was primarily attributable to greater utilization of our patient co-pay programs primarily with the launch of Qelbree in May 2021, and higher per patient payments under both Medicaid and commercial managed care programs.

The provision for product returns decreased from $23.9 million in 2020 to $12.7 million in 2021. This decrease was primarily due to the 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 from $67.9 million in 2020 to $69.4 million in 2021. The increase is due to higher gross sales.

Adjustments related to prior year sales

Adjustments related to prior year sales in 2021 of $1.7 million was less than 1% of both net product sales and total provision, compared to $13.8 million or 3% in 2020. Adjustments related to prior year sales in 2020 was primarily due to the aforementioned unfavorable return experience for discontinued Trokendi XR commercial blister pack configurations.

Royalty Revenue

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

			Change	
	2021	2020	Amount	Percent
Mydayis[1]	$ 1,962	$ 2,504	$ (542)	(22)%
Orenitram[2]	9,392	8,543	849	10%
Namzaric[3] and other	917	—	917	**
Total	$12,271	$11,047	$1,224	11%

(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.

(3) Namzaric is currently marketed in the U.S. by Allergan plc under an exclusive license agreement.

Royalty revenue increased by approximately $1.2 million, or 11%, in 2021 compared to 2020, primarily due to increased product sales of Orenitram and royalties from Namzaric associated with the Adamas Acquisition.

Cost of Goods Sold

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

			Change	
	2021	2020	Amount	Percent
Cost of goods sold	$75,061	$52,459	$22,602	43%

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. Royalty payments associated with both the acquired commercial products, APOKYN and XADAGO, made up the majority of the cost of goods sold.

Cost of good sold increased from $52.5 million in 2020 to $75.1 million in 2021. The increase was primarily due to higher cost recorded in 2021 for the acquired commercial products which is attributable to the timing of the USWM Acquisition that was completed in June 2020 and costs of $7.3 million for rejected MYOBLOC inventory lots in 2021. Refer to Part I, Item 8, Consolidated Financial Statements, Note 15, *Commitments and Contingencies* in the Notes to the Consolidated Financial Statements for discussion regarding annual minimum purchase quantity requirements of MYOBLOC.

Also included in cost of goods sold in 2021 are de minimis costs for Qelbree inventory sold. We manufacture Qelbree inventory for commercial sale and for use in our samples program. Manufacturing costs related to Qelbree inventory build-up incurred before FDA approval and prior to first quarter of 2020, when the Company began capitalizing pre-launch inventory, were expensed to *Research and development expense*. The manufactured Qelbree inventory prior to FDA approval consisted of $8.6 million raw materials inventory, which was expensed as *research and development expense* in 2020. Therefore, cost of goods sold for Qelbree for 2021 does not include raw material cost that was previously expensed. We have sold as commercial inventory or consumed as samples all of the reduced-cost inventory in 2021.

Research and Development Expenses

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

			Change	
	2021	2020	Amount	Percent
Research and development expense	$90,467	$75,961	$14,506	19%

R&D expenses increased from $76.0 million in 2020 to $90.5 million in 2021. The increase was primarily due to the $15.0 million write-down of the investment in Navitor LLC in 2021; increased spending on SPN-820, which has advanced to a Phase II clinical program; increased spending on MYOBLOC post-marketing commitment studies; and higher regulatory activities related to the acquired products. These increases are partially offset by reduced spending on SPN-812 (Qelbree) Phase III programs and the $10 million option fee paid in 2020. Refer to Note 5, *Investments* in the Notes to the Consolidated Financial Statements in Part II, Item 8 of this report for further discussion of the write-down of the investment in Navitor LLC in 2021 and the option fee payment in 2020.

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):

			Change	
	2021	2020	Amount	Percent
Selling and marketing expense	$199,709	$134,753	$ 64,956	48%
General and administrative expense	105,050	65,924	39,126	59%
Total	$304,759	$200,677	$104,082	52%

Selling and Marketing Expense

Selling and marketing expenses increased from $134.8 million in 2020 to $199.7 million in 2021. The increase was primarily attributable to increased marketing expenses and professional consulting spend for the launch of Qelbree and the acquired commercial products from the USWM Acquisition. Further, employee-related expenses also increased due to higher headcount to support the launch of Qelbree and due to non-recurring employee-related acquisition costs of approximately $5.1 million.

The reduced-cost Qelbree samples were also included in selling and marketing expenses in 2021. At full cost, these Qelbree samples would have resulted in $4.3 million higher selling and marketing expenses in 2021. At this time, we have sold as commercial inventory or consumed as samples all of the reduced-cost inventory in 2021.

General and Administrative Expense

General and administrative expenses increased from $65.9 million in 2020 to $105.1 million in 2021. The increase was primarily attributable to increased professional consulting spend and increased headcount to support the integration of MDD and Adamas and higher acquisition-related costs incurred in 2021. Acquisition-related costs incurred in 2021 was $22.3 million, which includes $6.7 million in transaction costs and approximately $8.2 million of employee-related expenses in general and administrative expense. Acquisition -related costs in 2020 was $8.4 million which primarily represents transaction 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	
	2021	2020	Amount	Percent
Amortization of intangible assets	$29,989	$15,702	$14,287	91%

Amortization of intangible assets increased for the year ended December 31, 2021, primarily due to the timing of the USWM Acquisition, which was completed in June 2020 and the amortization of acquired intangibles from the Adamas Acquisition in November 2021.

Contingent Consideration Expense

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

			Change	
	2021	2020	Amount	Percent
Contingent consideration (gain) expense	$(6,530)	$1,900	$(8,430)	**

Contingent consideration gain recorded for the year ended December 31, 2021 of $6.5 million reflects the reduction of the USWM Acquisition sales based contingent consideration liabilities recorded in the second quarter of 2021, offset by an increase in the estimated fair value of regulatory and developmental milestones due to the passage of time. The Company assessed that the sales-based milestones that are part of the USWM Acquisition will not be achieved based on the revised net sales projections.

Other (Expense) Income

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

			Change	
	2021	2020	Amount	Percent
Interest and other income, net	$ 10,569	$ 18,704	$(8,135)	(43)%
Interest expense	(19,696)	(19,435)	(261)	1%
Interest expense on nonrecourse liability related to sale of future royalties	(3,727)	(4,319)	592	(14)%
Total	$(12,854)	$ (5,050)	$(7,804)	**

Interest income includes primarily interest earned from cash, cash equivalents, and marketable securities holdings. Interest income decreased from $18.7 million 2020 to $10.6 million in 2021. The decrease in interest

income was primarily due to lower interest income on marketable securities holdings in 2021 and lower gains generated from sales of our marketable securities in 2021 compared to 2020. Specifically, in 2020, we sold securities at a gain of $4.4 million to finance the up-front cash payment for the USWM Acquisition. In 2021, we sold securities at a gain of $0.3 million to finance the up-front cash payment for the Adamas Acquisition.

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 2020 to 2021.

Income Tax Expense

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

			2021 vs 2020 Change	
	2021	2020	Dollar	Percent
Income tax expense	$19,751	$41,698	$(21,947)	(53)%
Effective tax rate	27.0%	24.7%		

The decrease in our income tax expense was primarily due to year over year decrease in earnings. The increase in the effective tax rate is primarily due to a larger research and development benefit in 2020 as compared to 2021 partially offset by higher stock option exercise shortfall and forfeiture in 2021.

Net Earnings

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

			Change	
	2021	2020	Amount	Percent
Net earnings	$53,424	$126,950	$(73,526)	(58)%

The decrease in net earnings was primarily due to higher costs associated with the Qelbree launch and integration costs related to both the USWM and Adamas acquisitions and higher acquisition-related costs incurred in 2021 . Further, overall costs and expenses were higher in 2021 compared to 2020 due to the timing of the USWM acquisition.

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,		Change
	2021	2020	Amount
Net cash provided by (used in):			
Operating activities	$ 127,127	$138,399	$ (11,272)
Investing activities	(81,913)	(34,699)	(47,214)
Financing activities	(130,420)	3,559	(133,979)
Net change in cash and cash equivalents	$ (85,206)	$107,259	$(192,465)

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 was $127.1 million in 2021 compared to $138.4 million in 2020. The year over year change was primarily driven by decreased operating earnings, offset by an increase in working capital and non-cash items.

Investing Activities

Net cash used in investing activities was $81.9 million in 2021 compared to $34.7 million in 2020. The year over year change of $47.2 million was primarily attributed to the following:

- Cash outflows related to marketable securities activity were higher by $63.6 million in 2021 compared to 2020;
- Cash outflows related to acquisitions were higher by $13.2 million in 2021 compared to 2020;
- Cash inflow from cash distribution received in 2021 of $12.9 million, offset by cash outflow in 2020 of $15.0 million related to investment in Navitor.

Financing Activities

Net cash used in financing activities was $130.4 million in 2021 compared to $3.6 million provided in the same period in 2020. This year over year change is primarily attributable to the repayment of the acquired debt from the Adamas Acquisition partially offset by the increase in proceeds from the issuance of common stock.

Liquidity and Capital Resources

Cash and cash equivalents, marketable securities, and long term marketable securities presented below are as follows (dollars in thousands):

	December 31, 2021
Cash and cash equivalents	$203,434
Marketable securities	136,246
Long term marketable securities	119,166
Total	$458,846

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, as well as the success of our product candidates if approved by the 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 due to the commercial launch of Qelbree in May 2021; future commercial launches of Qelbree for the treatment of ADHD in adults and SPN-830 (apomorphine infusion device), in each case, if approved by the FDA; continued market and payor pressures for our commercial products; and the likely unfavorable impact of the upcoming loss of patent exclusivity for Trokendi XR in January 2023, or sooner under certain conditions.

The Company believes its balances of cash, cash equivalents and unrestricted marketable securities, which totaled $458.8 million as of December 31, 2021, along with cash generated from ongoing operations and continued access to debt markets, will be sufficient to satisfy its cash requirements over the next 12 months and beyond.

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.

Our material cash requirements include the following contractual and other obligations.

Convertible Notes due 2023

As of December 31, 2021, 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, 2021. 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, we also entered into separate warrant transactions, issuing a total of 6,783,939 warrants (the Warrant Transactions). Refer to Note 8, *Convertible Senior Notes Due 2023* in the Notes to the Consolidated Financial Statements in Part II, Item 8 of this report.

Leases

Our operating lease commitments include leases of fleet vehicles, leases of certain facilities, including the lease of the current headquarters office and laboratory space. As of December 31, 2021, we have fixed lease payment obligations of $57.3 million, with $7.8 million payable within 12 months. Refer to Note 12, *Leases* in the Notes to the Consolidated Financial Statements in Part II, Item 8 of this report.

Manufacturing Purchase Obligations

In October 2021, we entered into an amendment to the Merz Agreement which increased the price of the annual purchase commitment of MYOBLOC from €3.0 million to approximately €3.9 million. For further discussion on the embedded operating lease related to the Merz Agreement, refer to Note 12, *Leases* in the Notes to the Consolidated Financial Statements in Part II, Item 8 of this report.

In addition, USWM Enterprises had an existing license and distribution agreement for XADAGO. This included an annual minimum promotional spend to support the marketing of XADAGO until July 2022. As of December 31, 2021, the remaining contractual commitment for XADAGO is $0.3 million for the period from June 2021 to July 2022. Refer to Note 3, *Acquisitions*, for further discussion on the USWM Acquisition.

Milestone Payment Obligations

The Company has contingent consideration milestones payable related to the Adamas Acquisition. The possible outcomes for the contingent consideration range, on an undiscounted basis, from $0 to $50.9 million. One Milestone Payment is payable (subject to certain terms and conditions) upon the first occurrence of the achievement of aggregate worldwide net sales of GOCOVRI in excess of $150 million during any consecutive 12-month period ending on or before December 31, 2024 (Milestone 2024). Another Milestone Payment is payable (subject to certain terms and conditions) upon the first occurrence of the achievement of aggregate worldwide net sales of GOCOVRI in excess of $225 million during any consecutive 12-month period ending on or before December 31, 2025 (Milestone 2025 and, together with Milestone 2024, the Milestones). Each Milestone may only be achieved once.

We also have contingent consideration milestones payable related to the USWM Acquisition. The regulatory and developmental contingent consideration payments include a $25 million milestone due upon the FDA acceptance of the SPN-830 NDA for review. On February 18, 2022, the FDA accepted the SPN-830 NDA for review and we paid the resulting $25 million milestone in the first quarter of 2022. In addition, there are two other regulatory and developmental contingent consideration milestone payments: the first is a $25 million milestone due upon the FDA's regulatory approval and $30 million upon commercial launch of SPN-830. If SPN-830 is approved by the FDA and commercially launched, we expect these milestones to become due and be paid in between 2022 and 2023.

Navitor Development Agreement

We have obligations from the Development Agreement with Navitor we entered into in April 2020. 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.

Royalty Payments

We obtained exclusive licenses from third parties for proprietary rights to support our commercial products and product candidates. We are obligated to pay royalties to third parties, computed as a percentage of net product sales, for each respective product under a license agreement, beginning upon commercialization. As of December 31, 2021, we have outstanding royalty liabilities of $13.8 million of which the majority was paid in the first quarter of 2022. The amount of future royalty obligations are dependent on future net product sales of each of the respective products under a license agreement.

Other Obligations

We have other obligations in which the timing, likelihood and, in some situations, the amount of such payments are not known, which include the following:

- 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.
- any future royalty payments to third parties.
- 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.

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 and cash equivalents, marketable securities, and long term marketable securities. As of December 31, 2021, we had unrestricted cash and cash equivalents, marketable securities, and long term marketable securities of $458.8 million.

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

Our cash and cash equivalents consist primarily of cash held at banks 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, which is being conducted outside the U.S. for SPN-817. 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, 2021, and December 31, 2020, 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, 2021, and 2020 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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, 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, 2021, 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 April 13, 2022 expressed an adverse 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 Matter

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

Accrued sales deductions related to product returns

As disclosed in Notes 2 and 13 to the consolidated financial statements, the Company recorded accrued product returns of $35,127 (dollars in thousands) as of December 31, 2021. 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 for certain products. 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 assessed the Company's long-term return rate assumptions by evaluating the consistency of those assumptions with the trend of actual historical return rates. We compared prior period expected long-term return rate assumptions against actual return rates experience.

/s/ KPMG LLP

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

Baltimore, Maryland
April 13, 2022

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, 2021, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weaknesses, described below, on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2021, 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 , 2021 and 2020, 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, 2021, and the related notes (collectively, the consolidated financial statements), and our report dated April 13, 2022 expressed an unqualified opinion on those consolidated financial statements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses related to the Company not having sufficient resources and as a result, the Company did not adequately perform the following: assess, redesign and timely evaluate performance of controls over financial reporting risks as a result of existing circumstances; train, monitor, and supervise newly hired contractors and employees; and generate real time information across the organization to allow the finance department to perform timely controls; which in the aggregate, create a reasonable possibility that material misstatements in substantially all financial reporting processes and financial statement accounts in the consolidated financial statements will not be prevented or detected on a timely basis, have been identified and included in management's assessment. The material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2021 consolidated financial statements, and this report does not affect our report on those consolidated financial statements.

The Company acquired Adamas Pharmaceuticals, Inc. during 2021, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2021, Adamas Pharmaceuticals, Inc's internal control over financial reporting associated with 8% of total assets (excluding the goodwill and other intangible assets, which are included within the scope of the assessment) and 2% of total revenues included in the consolidated financial statements of the Company as of and for the year ended December 31, 2021. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of Adamas Pharmaceuticals, Inc.

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
April 13, 2022

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 203,434	$ 288,640
Marketable securities	136,246	133,893
Accounts receivable, net	148,932	140,877
Inventories, net	85,959	48,325
Prepaid expenses and other current assets	27,019	18,682
Total current assets	601,590	630,417
Long term marketable securities	119,166	350,359
Property and equipment, net	16,955	37,824
Intangible assets, net	784,693	364,342
Goodwill	117,516	77,911
Other assets	49,232	43,249
Total assets	$1,689,152	$1,504,102
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 117,683	$ 78,934
Accrued product returns and rebates	132,724	126,192
Contingent consideration, current portion	44,840	30,900
Other current liabilities	20,132	9,082
Total current liabilities	315,379	245,108
Convertible notes, net	379,252	361,751
Contingent consideration, long term	35,637	45,800
Operating lease liabilities, long term	41,298	28,579
Deferred income tax liabilities, net	85,355	35,215
Other liabilities	16,380	42,791
Total liabilities	873,301	759,244
Stockholders' equity		
Common stock, $0.001 par value; 130,000,000 shares authorized; 53,256,094 and 52,868,482 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	53	53
Additional paid-in capital	434,337	409,332
Accumulated other comprehensive earnings, net of tax	1,539	8,975
Retained earnings	379,922	326,498
Total stockholders' equity	815,851	744,858
Total liabilities and stockholders' equity	$1,689,152	$1,504,102

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Earnings
(in thousands, except share and per share data)

	Years Ended December 31,		
	2021	**2020**	**2019**
Revenue			
Net product sales	$ 567,504	$ 509,350	$ 383,400
Royalty revenue	12,271	11,047	9,355
Total revenues	579,775	520,397	392,755
Costs and expenses			
Cost of goods sold[(a)]	75,061	52,459	16,660
Research and development	90,467	75,961	69,099
Selling, general and administrative	304,759	200,677	153,246
Amortization of intangible assets	29,989	15,702	5,179
Contingent consideration (gain) expense	(6,530)	1,900	—
Total costs and expenses	493,746	346,699	244,184
Operating earnings	86,029	173,698	148,571
Other (expense) income			
Interest expense	(23,423)	(23,754)	(22,707)
Interest and other income, net	10,569	18,704	21,623
Total other expense	(12,854)	(5,050)	(1,084)
Earnings before income taxes	73,175	168,648	147,487
Income tax expense	19,751	41,698	34,431
Net earnings	$ 53,424	$ 126,950	$ 113,056
Earnings per share			
Basic	$ 1.01	$ 2.41	$ 2.16
Diluted	$ 0.98	$ 2.36	$ 2.10
Weighted-average shares outstanding			
Basic	53,099,330	52,615,269	52,412,181
Diluted	54,356,744	53,689,743	53,816,754

[(a)] Excludes amortization of acquired intangible assets.

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Earnings
(in thousands)

	Years Ended December 31,		
	2021	2020	2019
Net earnings	$53,424	$126,950	$113,056
Other comprehensive earnings (loss):			
Unrealized gain (loss) on marketable securities, net of tax	(7,436)	1,558	10,575
Other comprehensive earnings (loss), net of tax	(7,436)	1,558	10,575
Comprehensive earnings	$45,988	$128,508	$123,631

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2019, 2020 and 2021
(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, 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
Share-based compensation	—	—	17,910	—	—	17,910
Issuance of common stock in connection with the Company's equity award plans	387,612	—	7,095	—	—	7,095
Net earnings	—	—	—	—	53,424	53,424
Unrealized loss on marketable securities, net of tax	—	—	—	(7,436)	—	(7,436)
Balance, December 31, 2021	53,256,094	$53	$434,337	$ 1,539	$379,922	$815,851

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities			
Net earnings	$ 53,424	$ 126,950	$ 113,056
Adjustments to reconcile net earnings to net cash provided by operating activities:			
Depreciation and amortization	32,595	18,141	6,659
Navitor investment R&D expense	15,000	—	—
Amortization of deferred financing costs and debt discount	17,501	16,581	15,708
Share-based compensation expense	17,910	16,561	14,846
Realized gains from sales of marketable securities	(347)	(4,352)	(301)
Amortization of premium/discount on marketable securities	418	(2,889)	(4,034)
Changes in fair value of contingent consideration	(6,530)	1,900	—
Other noncash adjustments, net	(1,420)	1,454	2,226
Deferred income tax (benefit) provision	(4,994)	568	(5,832)
Changes in operating assets and liabilities:			
Accounts receivable	3,867	(34,607)	15,751
Inventories	(14,580)	(10,124)	(969)
Prepaid expenses and other assets	(8,398)	(10,442)	(2,864)
Accrued product returns and rebates	4,502	10,386	566
Accounts payable and other liabilities	18,179	8,272	(11,683)
Net cash provided by operating activities	127,127	138,399	143,129
Cash flows from investing activities			
Sales and maturities of marketable securities	530,509	378,422	253,170
Purchases of marketable securities	(311,573)	(95,890)	(409,707)
Acquisition of USWM, net of cash acquired	(950)	(298,541)	—
Acquisition of Adamas, net of cash acquired	(310,742)	—	—
Distribution from (investment in) Navitor	12,888	(15,000)	—
Purchase of property and equipment and deferred legal fees paid	(2,045)	(3,690)	(1,387)
Net cash used in investing activities	(81,913)	(34,699)	(157,924)
Cash flows from financing activities			
Proceeds from issuance of common stock	7,095	4,361	3,928
Proceeds from governmental loan and grant	800	—	—
Repayment of acquired Adamas loan	(138,315)	—	—
Payments on finance lease liability	—	(802)	—
Net cash (used in) provided by financing activities	(130,420)	3,559	3,928
Net change in cash and cash equivalents	(85,206)	107,259	(10,867)
Cash and cash equivalents at beginning of year	288,640	181,381	192,248
Cash and cash equivalents at end of year	$ 203,434	$ 288,640	$ 181,381
Supplemental cash flow information:			
Cash paid for interest on convertible notes	$ 2,516	$ 2,516	$ 2,516
Cash paid for operating leases	$ 11,908	$ 6,949	$ 5,337
Income taxes paid	$ 25,190	$ 45,428	$ 51,540
Noncash investing and financing activity:			
Contingent consideration liability related to acquisitions	$ 10,307	$ 76,700	$ —
Lease assets and tenant receivable obtained for new operating leases	$ 10,868	$ 2,478	$ 35,594
Lease assets obtained for new finance lease	$ —	$ 22,747	$ —
Property and equipment additions from utilization of tenant improvement allowance	$ 25	$ —	$ 10,151

See accompanying notes.

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, attention-deficit hyperactivity disorder (ADHD), hypomobility in Parkinson's Disease (PD), cervical dystonia, chronic sialorrhea, dyskinesia in PD patients receiving levodopa-based therapy, and drug-induced extrapyramidal reactions in adult patients. The Company is developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in PD, epilepsy, depression, and other CNS disorders.

The Company has eight commercial products: Trokendi XR®, Oxtellar XR®, Qelbree®, APOKYN®, XADAGO®, MYOBLOC®, GOCOVRI®, and Osmolex ER®. In addition, the Company has two late-stage development products included in its product candidates portfolio, including SPN-830 (apomorphine infusion device), an acquired product candidate from the USWM Acquisition.

In February 2022, the Company's New Drug Application (NDA) for SPN-830 (apomorphine infusion device) was accepted for review by the U.S. Food and Drug Administration (FDA) and was assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 7, 2022.

2021 Adamas Acquisition

On October 10, 2021, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among the Company, Adamas Pharmaceuticals, Inc. (Adamas) and Supernus Reef, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (Purchaser). On November 24, 2021, the Purchaser was merged with and into Adamas (the "Merger"), with Adamas continuing as the surviving corporation in the Merger as a wholly owned subsidiary of the Company (the Adamas Acquisition). At the time of the Adamas Acquisition, Adamas had two established commercial products in its portfolio, GOCOVRI and Osmolex ER, in addition to royalty rights to Namzaric. Refer to Note 3, *Acquisitions*, for further discussion on the Adamas Acquisition.

Navitor Development Agreement

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 5, *Investments*, for further discussion on the Navitor Development Agreement.

2020 USWM Acquisition

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) (the 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 device), to its portfolio. Refer to Note 3, *Acquisitions*, for further discussion on the USWM Acquisition.

Ransomware Incident

On November 24, 2021, we announced that we were the target of a ransomware attack. The attack had no significant impact on our business and did not cause any long-term disruption to our operations. Based on the preliminary results of the ongoing investigation, the Company believes the criminal ransomware groups ("criminal groups") copied certain data from our systems, encrypted certain data on the Company's systems, and then deployed malware designed to impede access to our systems. Thereafter the criminal groups

1. Organization and Business (Continued)

contacted the Company and threatened to publish certain data copied from the Company's systems. Upon detection of the ransomware attack, the Company notified government authorities, engaged third-party cybersecurity experts through our outside counsel, and commenced its recovery process. The Company maintains redundant off-site data backups, which were verified to have not been compromised by the ransomware attack and were utilized to restore the data encrypted by the criminal groups. At this time, the Company has successfully recovered the impacted files and has taken additional steps designed to further protect its networks and files. We have not paid any ransom amounts. We have incurred costs in 2021 and expect to continue to incur costs in the future, which may be significant, in connection with efforts designed to enhance our data security and take further steps designed to protect against unauthorized access to, or manipulation of, our systems and data. These costs were primarily comprised of certain employee related expenses and various third party consulting services, including forensic experts, legal counsel and other IT and accounting professional expenses, and enhancements to our cyber security measures. We expect to incur additional costs related to the ransomware attack in the future, including costs related to our response to the ransomware incident and our efforts designed to enhance our security measures.

The Company continues to monitor the situation. Refer to Note 15, *Commitments and Contingencies*.

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, 2021, 2020, and 2019.

Consolidation

The Company's consolidated financial statements include the accounts of: Supernus Pharmaceuticals, Inc.; Supernus Europe Ltd.; Biscayne Neurotherapeutics, Inc. and its wholly owned subsidiaries; MDD US Enterprises, LLC (formerly USWM Enterprises, LLC) and its wholly owned subsidiaries; and Adamas Holdings, 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.

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

2. Summary of Significant Accounting Policies (Continued)

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 (i.e., provision for estimated rebates, provision for estimated future product returns, and an estimated provision for discounts), the creditworthiness of customers entering into revenue arrangements, the valuation of the assets and liabilities acquired in the acquisitions, 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.

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 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 evaluates these estimates and assumptions. The Company records measurement period adjustments to the Company's preliminary estimates to goodwill based on the facts and circumstances existing as of the acquisition date.

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 Consideration

Business combinations often include provisions for additional consideration to be transferred to former shareholders based upon the achievement of certain milestones, referred to as contingent consideration. Contingent consideration from product development milestones and sales-based milestone payments on future product sales are included in the purchase price for business combinations. The fair value of the contingent consideration liability is determined as of the acquisition date using estimated or forecasted inputs.

2. Summary of Significant Accounting Policies (Continued)

These inputs include the estimated amount and timing of projected revenues, probability and timing of milestone achievement, probability of in-process research & development ("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.

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 (gain) expense*.

Additional information regarding contingent consideration is included in Note 3, *Acquisitions*.

Accounts Receivable, Net

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

The Company writes off uncollectible receivables when the customer has had a change in creditworthiness and the likelihood of collection is remote. 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	
	2021	2020	2019	2021	2020
Customer A	28%	29%	32%	34%	31%
Customer B	29%	31%	32%	31%	32%
Customer C	29%	29%	34%	18%	22%
	86%	89%	98%	83%	85%

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, and include materials, labor, direct costs and indirect costs. These are valued using the first-in, first-out method. The Company writes down

2. Summary of Significant Accounting Policies (Continued)

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.

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. Patent defense costs are charged to expense in the event of an unsuccessful litigation outcome, or if they are deemed to not provide an increase in the value of the patent.

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.

2. Summary of Significant Accounting Policies (Continued)

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 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.

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 (during the fourth quarter of each fiscal year) 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 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. Evaluating for 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. 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.

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

2. Summary of Significant Accounting Policies (Continued)

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. 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. 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.

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 14). 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, 2021, or 2020.

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.

2. Summary of Significant Accounting Policies (Continued)

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.

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 when our customer dispenses 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.

2. Summary of Significant Accounting Policies (Continued)

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 may issue 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.

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 and accounts receivable, net.

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

2. Summary of Significant Accounting Policies (Continued)

(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 15). 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 14). 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 for the right to use the Company's intellectual property as a functional license. The Company has a royalty arrangement with Takeda Pharmaceutical Company Ltd., based on net product sales of Takeda's product, Mydayis, and with Allergan, based on net product sales of Namzaric. For these arrangements that include sales-based royalties on the licensed intellectual property to which the royalties relate, royalty revenue is only recognized when the underlying product sale has occurred. Sales-based royalties are recorded based on estimated quarterly net sales of the underlying product. Differences between actual results and estimated amounts are adjusted in the period in which they become known, which typically follows the quarterly period in which the estimate is made. To date, actual royalties received have not differed materially from estimates.

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.

2. Summary of Significant Accounting Policies (Continued)

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, 2021, and 2020, 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.

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.

2. Summary of Significant Accounting Policies (Continued)

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

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.

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.

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.

2. Summary of Significant Accounting Policies (Continued)

The Company incurred approximately $86.0 million, $54.5 million, and $40.8 million in advertising expense for the years ended December 31, 2021, 2020, and 2019, 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 of assets and liabilities, and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. When appropriate, valuation allowances are established to reduce deferred tax assets to the amounts expected to be realized.

The Company accounts for uncertain tax positions in its consolidated financial statements when it is more-likely-than-not that the position will be sustained upon examination by the tax authorities. Such tax positions 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, assuming full knowledge of the position and relevant facts. The Company's policy is to recognize any interest and penalties related to income taxes as income tax expense in the relevant period.

The Company's policy is to recognize any interest and penalties related to income taxes as income tax expense in the relevant period.

Recently Issued Accounting Pronouncements

Accounting Pronouncements Adopted in 2021

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. The Company adopted the guidance on January 1, 2021, on a prospective basis. The adoption of the new standard did not have a material impact to the 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 for 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. The adoption of the new standard as of January 1, 2021 did not have a material impact to the financial statements.

Accounting Pronouncements Adopted in 2020

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.

2. Summary of Significant Accounting Policies (Continued)

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 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 for certain financial instruments with characteristics of liabilities and equity, including convertible debt instruments with cash conversion and beneficial conversion features. ASU 2020-06 eliminates requirements to separately account for liability and equity components of such convertible debt instruments and eliminates the ability to use the treasury stock method for calculating diluted earnings per share for convertible instruments whose principal amount may be settled in whole or in part with equity. Instead, ASU 2020-06 requires (i) the entire amount of the security to be presented as a liability on the balance sheet and (ii) application of the "if-converted" method for calculating diluted earnings per share. This new standard also removes certain settlement conditions required for equity contracts to qualify for the derivative scope exception. This guidance will be effective for fiscal years beginning after December 15, 2021, with early adoption permitted but no earlier than fiscal years beginning after December 15, 2020.

The Company will adopt the new guidance on January 1, 2022 using the modified retrospective method of transition which allows for a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. As a result, the Company will account for the 2023 Notes wholly as debt and will not separately account for the embedded conversion feature (equity component) of its 2023 Notes in additional paid-in capital. Using the modified retrospective method of transition, the cumulative effect of the accounting change is expected to increase net debt by approximately $20.6 million, increase retained earnings by approximately $40.6 million, reduce additional paid-in capital by approximately $56.2 million and decrease deferred tax liabilities by approximately $5.0 million. In addition, the Company will no longer record interest expense on the previously recorded discount for the embedded conversion feature on the 2023 Notes. Due to the adoption, the Company also expects non-cash interest expense related debt discount accretion of the 2023 Notes will be decreased by approximately $16.4 million for fiscal year 2022, compared to the debt discount accretion recorded prior to adoption. The Company also expects an increase of approximately 6.8 million shares to be included in its diluted weighted-average shares of common stock

2. Summary of Significant Accounting Policies (Continued)

outstanding for the purposes of calculating diluted earnings per share. All estimates are based on the balance of the 2023 Notes outstanding as of December 31, 2021 and could change as we continue with our implementation efforts.

ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*—The new standard, issued in October 2021, amended guidance on accounting for contract assets and contract liabilities from contracts with customers in a business combination. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with Topic 606, *Revenue from Contracts with Customers*, as if the acquiree had initially applied recognition and measurement in their financial statements. This guidance is effective for fiscal years beginning after December 15, 2022 on a prospective basis. Early adoption is permitted.

ASU 2021-10, *Government Assistance (Topic 832)*—The new standard, issued in November 2021, requires the disclosure of information about transactions with a government that are accounted for by applying a grant or contribution model by analogy. This could include various forms of government assistance, but excludes transactions in the scope of specific US GAAP, such as tax incentives accounted for under ASC 740, *Income Taxes*. For transactions in the scope of the new standard, information about the nature of the transaction, including significant terms and conditions, as well as the amounts and specific financial statement line items affected by the transaction are required to be disclosed. This guidance is effective for fiscal years beginning after December 15, 2021 on a prospective basis. Early adoption is permitted. The Company will adopt the standard effective January 1, 2022. It is not expected to have a material effect on our consolidated financial statements.

3. Acquisitions

Adamas Acquisition

On November 24, 2021 (the Adamas Closing Date), the Company completed its purchase of all of the outstanding equity of Adamas, a publicly-held pharmaceutical company, pursuant to the Agreement and Plan of Merger among the Company, Adamas and Supernus Reef, Inc., a wholly owned subsidiary of the Company, dated October 10, 2021 (the Adamas Agreement). On the Adamas Closing Date, Adamas owned two marketed products: GOCOVRI (amantadine) extended release capsules, the first and only U.S. FDA-approved medicine indicated for the treatment of both "off" episodes and dyskinesia in patients with PD receiving levodopa-based therapy and as an adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes; and Osmolex ER (amantadine) extended release tablets, approved for the treatment of PD and drug-induced extrapyramidal reactions in adult patients. Adamas also owns the right to receive royalties from Allergan plc for sales of Namzaric (memantine hydrochloride extended release and donepezil hydrochloride) in the United States.

The Company paid the Seller $400.8 million and two non-tradable contingent value rights (CVRs) each of which represents the contractual right to receive a contingent payment of $0.50 per share in cash, less any applicable withholding taxes and without interest, upon the achievement of the applicable milestone (each such amount, a Milestone Payment) in accordance with the terms of a Contingent Value Rights Agreement entered into among the Company and American Stock Transfer & Trust Company, LLC, as rights agent, (CVR Agreement). One Milestone Payment is payable (subject to certain terms and conditions) upon the first occurrence of the achievement of aggregate worldwide net sales of GOCOVRI in excess of $150 million during any consecutive 12-month period ending on or before December 31, 2024 (Milestone 2024). Another Milestone Payment is payable (subject to certain terms and conditions) upon the first occurrence of the achievement of aggregate worldwide net sales of GOCOVRI in excess of $225 million during any consecutive 12-month period ending on or before December 31, 2025 (Milestone 2025 and, together with Milestone 2024, the Milestones). Each Milestone may only be achieved once.

3. Acquisitions (Continued)

In connection with the two CVRs, the Company recorded a contingent consideration liability of $10.3 million as of the date of the acquisition, to reflect the estimated fair value of the contingent consideration. The estimated fair value of the contingent consideration was determined using the Monte Carlo simulation for the sales-based milestones. 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. The key assumptions considered include the estimated amount and timing of projected cash flows, volatility, estimated discount rates and risk-free interest rate. In each reporting period after the acquisition, the Company will revalue the contingent consideration liability and will record increases or decreases in the fair value of the liability in its consolidated statements of earnings. Changes in fair value will result from changes in actual and projected milestone achievement, as well as changes to forecasts. The inputs and assumptions may not be observable in the market, but reflect the assumptions the Company believes would be made by a market participant. The possible outcomes for the contingent consideration range from $0 to $50.9 million on an undiscounted basis.

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 Adamas 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 Adamas 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 Adamas 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 Adamas Closing Date. In addition, the Company continues to analyze and assess relevant information necessary to determine, recognize and record at fair value the assets acquired and liabilities assumed in the following areas: intangible assets, lease assets and liabilities, tax assets and liabilities, and certain existing or potential reserves, including those for legal or contract-related matters. The activities the Company is currently undertaking, include but are not limited to the following: review of acquired contracts and other contract-related and legal matters; review and evaluation of the accounting policies, tax positions, and other tax-related matters. Further, the Company is in the process of obtaining input from third party valuation firms with respect to the fair value of the acquired tangible and intangible assets, and other information necessary to record and measure the assets acquired and liabilities assumed. Accordingly, the preliminary recognition and measurement of assets acquired and liabilities assumed as of Adamas Closing Date are subject to change.

The following preliminary purchase price allocation table presents the Company's preliminary estimates of the fair value of assets acquired and liabilities assumed as of the Adamas Closing Date (dollars in thousands):

3. Acquisitions (Continued)

	Amount (in thousands)
Cash and cash equivalents	$ 90,064
Accounts receivable	11,156
Inventories	20,200
Prepaid expenses and other current assets	5,077
Property and equipment	1,254
Intangibles	450,100
Other assets[1]	6,442
Total fair value of assets acquired	**584,293**
Accounts payable	(4,592)
Accrued expenses and other current liabilities[1]	(8,014)
Current debt	(138,315)
Operating lease liability, long-term[1]	(5,224)
Deferred income tax liabilities, net[2]	(56,588)
Total fair value of liabilities assumed	**(212,733)**
Total identifiable net assets	**371,560**
Goodwill	39,553
Total purchase price	**$ 411,113**
Cash consideration paid	$ 400,806
Fair value of contingent consideration	10,307
Total purchase price	**$ 411,113**

(1) Acquired operating lease asset was $6.4 million and corresponding assumed operating lease liability was $7.2 million. Refer to Note 12, *Leases*, for further discussion of the acquired lease asset and assumed lease liability.

(2) Includes tax attributes that are subject to tax limitations.

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 dispose of the inventory, as well as a profit on the sale.

Acquired Intangible Assets

The acquired intangible assets include the acquired developed technology and product rights to GOCOVRI and Osmolex ER, as well as the right to receive royalties from Allergan plc for sales of Namzaric. The Company determined the estimated fair values for the acquired intangible assets as of the Adamas Closing Date using the income approach. This is a valuation technique that provides an estimate of fair value of the assets, based on the market participant's expectations of the cash flows that the assets are forecasted to generate. The cash flows were discounted at a rate commensurate with the level of risk associated with its 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

3. Acquisitions (Continued)

inputs and assumptions used in the intangible assets valuation includes: the estimated future cash flows from product sales, the timing and projection of costs and expenses, discount rates and tax rates.

Acquired intangible assets consist of developed technology and property rights and are amortized over their estimated useful lives on a straight-line basis. The following table summarizes the preliminary purchase price allocation, and the average remaining useful lives for identifiable intangible assets (dollars in thousands):

	Estimated Fair Value	Estimated Useful Life as of Closing Date (in years)
Acquired developed technology and property rights . .	$450,100	3.1 - 8.1

Goodwill

Goodwill was calculated as the excess of the consideration transferred over the net assets recognized and represents the future economic benefits arising from the other assets acquired that could not be individually identified and separately recognized. Goodwill is primarily attributable to the anticipated cost synergies, additional growth platforms, and an expanded revenue base with the addition of the assets from the Adamas Acquisition. The goodwill is not expected to be deductible for tax purposes.

Acquired Deferred Income Tax Liabilities, net

The deferred income tax liabilities, net relates to the difference between the financial statement carrying amount and the tax basis of acquired intangible assets and inventory, partially offset by acquired net operating loss carryforwards and other temporary differences. The acquired federal and state net operating loss carryforwards is reduced by a valuation allowance for amounts that are not expected to be realizable in the future. Refer to Note 11, *Income Taxes*.

Acquisition-related Costs

For the year ended December 31, 2021, the Company incurred acquisition-related costs of $22.3 million of which the majority were included in the *Selling, general and administrative expense* in the consolidated statements of earnings. These costs include, $15.6 million of employee-related expenses and $6.7 million in transaction costs, which primarily consisted of regulatory fees, advertisement fees, financial advisory and legal fees, and other consulting fees, to complete the acquisition.

Revenue and Net Earnings of Adamas

The operations of Adamas and its subsidiaries have been included in the Company's consolidated statements of earnings for the period subsequent to the Adamas Closing Date, and through December 31, 2021. Total revenues of $10.9 million and net loss of $18.1 million were recorded for the year ended December 31, 2021.

Pro Forma Information

The following table presents the unaudited pro forma combined financial information for each of the periods presented, as if the Adamas Acquisition had occurred on January 1, 2020 (dollars in thousands):

	Year Ended December 31,	
	2021	2020
	(unaudited)	
Pro forma total revenues	$663,729	$594,858
Pro forma net loss	$ (28,040)	$ (16,186)

3. Acquisitions (Continued)

The unaudited pro forma combined financial information is based on historical financial information and the Company's preliminary allocation of purchase price; therefore, it is subject to subsequent adjustment upon finalization of the purchase price allocation. In order to reflect the occurrence of the acquisition on January 1, 2020, the unaudited pro forma combined financial information reflects the recognition of additional amortization expense on intangible assets and estimated additional cost of products sold related to the inventory step-up adjustment; the estimated reduction in the Company's interest income generated from marketable securities that were liquidated to fund the purchase price of the Acquisition, and the estimated tax impact of the pro forma adjustments.

The unaudited pro forma combined financial information also reflects the recognition of non-recurring costs incurred directly as a result of the Acquisition for the year ended December 31, 2021 primarily pertaining to the following:

- Acquisition-related costs incurred by the Company of $22.3 million and incurred by Adamas of $10.5 million;
- Stock-based compensation expense of $12.7 million for Adamas incurred to accelerate the vesting of certain equity awards under the terms of the Merger Agreement.

The unaudited pro forma combined financial information should not necessarily 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.

USWM Acquisition

On June 9, 2020 (the USWM Closing Date), the Company completed its acquisition of all 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 USWM Agreement). Under the terms of the Agreement, the Company acquired the right to further develop and commercialize APOKYN, XADAGO, and the apomorphine infusion device (SPN-830; the IPR&D asset) 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 FDA acceptance of the SPN-830 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. 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. Refer to the contingent consideration discussion in Note 6, *Fair Value of Financial Instruments and Contingent Consideration*.

In the second quarter of 2021 and within one year from the USWM Closing Date, the Company finalized its accounting for the business combination, including the purchase price allocation; the Company recorded measurement period adjustments related to the purchase price consideration, finalization of the accounting for the lease (refer to Note 12, *Leases*), the fair values of inventory and intangible assets, and deferred tax liabilities based on refinements to inputs used in the estimates.

3. Acquisitions (Continued)

Purchase Price Consideration

	Amount
Cash consideration	$306,485
Fair value of contingent consideration	74,800
Total purchase consideration	$381,285
Cash consideration to Seller—net of cash acquired	$299,491

The Company paid the Seller $297.2 million in cash at the USWM Closing Date. As of December 31, 2021, the Company paid the Seller an additional $2.3 million for working capital adjustments on the purchase price consistent with the Agreement resulting in an increase to the original cash consideration paid to the Seller. Of the $2.3 million additional payments, $1.0 million was incurred in the second quarter of 2021 and the remainder was reported and paid in 2020.

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 million on an undiscounted basis if all milestones are achieved.

The Company initially recorded a contingent consideration liability of $115.7 million as of the USWM Closing Date to reflect the estimated fair value of the contingent consideration based on information available at that time. The estimated fair value of the contingent consideration was determined using a Monte Carlo simulation for the sales-based contingent consideration payments and an income approach for the regulatory and developmental contingent consideration payments. The key assumptions considered in estimating the fair value include the estimated probability and timing of milestone achievement, such as the probability and timing of obtaining regulatory approval, discount rate, the estimated revenue volatility and the estimated amount and timing of projected revenues from the Products. 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. As a result, the Company recorded in the fourth quarter of 2020, a measurement period adjustment of $40.9 million, which decreased the estimated fair value of the contingent consideration liability as of Closing Date to $74.8 million. Refer to the contingent consideration discussion in Note 6, *Fair Value of Financial Instruments and Contingent Consideration*.

3. Acquisitions (Continued)

Fair Value of Net Assets Acquired

The following table presents the total purchase price and the fair value of the assets acquired and liabilities assumed as of the USWM Closing Date (dollars in thousands):

	Fair Value
Cash and cash equivalents	6,994
Accounts receivable, net	18,474
Inventories, net	11,600
Prepaid expenses and other current assets	3,564
Property and equipment, net	454
Operating lease asset[1]	11,029
Intangible assets	355,000
Other assets	340
Total fair value of assets acquired	407,455
Accounts payable	(2,573)
Accrued expenses and other current liabilities	(23,339)
Operating lease liability[1]	(11,029)
Deferred income tax liabilities, net[2]	(67,192)
Total fair value of liabilities assumed	(104,133)
Total identifiable net assets	303,322
Goodwill	77,963
Total purchase price	381,285

(1) Refer to Note 12, *Leases*, for further discussion of the acquired lease asset and assumed lease liability.

(2) Includes tax attributes that are subject to tax limitations.

Acquired Inventory

The 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.

Acquired Intangible Assets

The acquired intangible assets include the acquired IPR&D asset and the acquired developed technology, and product rights. The Company determined the fair value of the acquired intangible assets as of the USWM Closing Date using the income approach. The fair value measurements of the acquired intangible assets were determined based on significant unobservable inputs and therefore, represent a Level 3 fair value measurement. Some of the more significant inputs and assumptions used in the intangible assets valuation include: 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.

3. Acquisitions (Continued)

The following table summarizes the purchase price allocation, and the 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	$124,000	n/a
Acquired Developed Technology and Product Rights	231,000	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 other 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 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 for the year ended December 31, 2020.

MDD Enterprises Operations

The operations of MDD US Enterprises, LLC ("MDD Enterprises") (formerly USWM Enterprises, LLC) and its subsidiaries have been included in the Company's consolidated statements of earnings for the period subsequent to the USWM Closing Date. The following table summarizes the total revenues for MDD Enterprises (dollars in thousands):

	December 31,	
	2020	2021
Net product sales	$132,134	$90,985

The Company is unable to provide the results of operations attributable to MDD US Enterprises, LLC and its subsidiaries as those operations were substantially integrated into our business.

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):

3. Acquisitions (Continued)

	December 31,	
	2020	2019
	(unaudited)	
Pro forma total revenues	$583,657	$542,807
Pro forma net earnings	133,423	110,842

4. Disaggregated Revenues

The following table summarizes the disaggregation of revenues by product or source (dollars in thousands):

	Years Ended December 31,		
	2021	2020	2019
Net product sales			
Trokendi XR	$304,817	$319,640	$295,214
Oxtellar XR	110,708	98,725	88,186
APOKYN	99,233	74,296	—
XADAGO	13,387	6,943	—
MYOBLOC	19,514	9,746	—
Qelbree	9,879	—	—
GOCOVRI	9,778	—	—
Osmolex ER	188	—	—
Total net product sales	567,504	509,350	383,400
Royalty revenues	12,271	11,047	9,355
Total revenues	$579,775	$520,397	$392,755

Trokendi XR accounted for more than 50% of the Company's total net product sales in 2021, more than 60% in 2020, and more than 70% in 2019.

The Company recognized noncash royalty revenue of $9.4 million, $8.5 million, and $6.9 million for the years ended December 31, 2021, 2020, and 2019, 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. (These amounts are reflected in the 2020 Trokendi net product sales of $319.6 million in the table above.) As a result, the Company changed its estimated provision for product returns, based on the most recent experience.

Adjustments related to prior year sales in 2021, 2020 and 2019 were decreased by $1.7 million, increased by $13.8 million and decreased by $0.4 million, respectively, compared to net product sales of $567.5 million, $509.4 million and $383.4 million, respectively. Adjustments related to prior year sales in 2020 of $13.8 million included the $10.7 million aforementioned adjustment for discontinued Trokendi XR configuration.

For the year ended December 31, 2021, 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. Investments

Marketable Securities

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

	December 31, 2021	December 31, 2020
Corporate and U.S. government agency and municipal debt securities		
Amortized cost	$ 253,301	$ 472,306
Gross unrealized gains	2,349	11,987
Gross unrealized losses	(238)	(41)
Total fair value	$ 255,412	$ 484,252

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

	December 31, 2021
Less than 1 year	$ 136,246
1 year to 2 years	110,869
2 years to 3 years	8,297
3 years to 4 years	—
Greater than 4 years	—
Total	$ 255,412

There was no impairment on any available-for-sale marketable securities as of December 31, 2021 and December 31, 2020.

Investment in Navitor

Development Agreement

In April 2020, the Company entered into a 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 TRD. 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 could be incurred by the Company. 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. In the second quarter of 2020, the Company paid Navitor a one time, nonrefundable, and non-creditable fee of $10 million for this option to acquire or license NV-5138 (SPN-820) which was expensed and recorded in *Research and development expense* in the consolidated statement of earnings.

Equity Investment

In addition to entering into the Development Agreement, the Company acquired Series D Preferred Shares of Navitor Inc. for $15 million in April 2020, representing an approximately 13% ownership position in Navitor Inc.

5. Investments (Continued)

In March 2021, Navitor Inc. underwent a legal restructuring. In the restructuring, Navitor Inc. became a wholly owned subsidiary of a newly formed limited liability company, Navitor LLC, and the outstanding shares of stock in Navitor Inc. were exchanged for units of membership in Navitor LLC having equivalent rights and preferences (Navitor Restructuring). As part of the Navitor Restructuring, the Series D Preferred Shares previously held by the Company were exchanged for Series D Preferred Shares in Navitor LLC. In addition, certain assets that did not relate to NV-5138 (SPN-820) were transferred from Navitor Inc. to a newly formed entity that became a separate, wholly owned subsidiary of Navitor LLC.

The Company had determined that Navitor LLC is a VIE. The Company does not consolidate this VIE because the Company lacks the power to direct the activities that most significantly impact the investee's economic performance.

Prior to the Navitor Restructuring, the investment was 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 in Navitor Inc. Following the legal restructuring and exchange of the preferred shares for member equity units of Navitor LLC, the investment was accounted for under the equity method of accounting due to the Company's ability to exert significant influence and the specific ownership accounts under the new Navitor LLC legal structure, but not control the financial and operating decisions of Navitor LLC. As a result of the change from cost method investment to an equity method investment, the Company was required to measure its investment initially in accordance with the guidance in ASC 805. The majority of the assets and liabilities recorded in Navitor LLC's financial statements represent working capital items and cash that are being used for research and development purposes and are significantly lower than the Company's investment in Navitor LLC, which created a significant basis difference for the Company's investment in the underlying net assets. The Company has determined that substantially all of the fair value of the investment is attributable to a single IPR&D asset. As a result, the investee is not considered a business as defined in ASC 805. In the first quarter of 2021, the $15 million investment, which was previously recorded in *Other assets* in the consolidated balance sheets, was expensed and recorded in *Research and development expense* in the consolidated statements of earnings.

The Company records its share of the results of its investee, a private company, on a quarter lag as the financial information of the investee is not sufficiently and timely available for the Company to apply the equity method of accounting. In December 2021, the investee sold one of its subsidiaries in Navitor LLC and distributed cash to its members, including the Company, in connection with each member's share of the proceeds from the sale. Therefore, the Company received a cash distribution of $12.9 million in December 2021 from Navitor LLC in connection with this sale. As the Company's policy is to record our equity method investment on a quarter lag as previously indicated, the Company recorded the cash amount received in *Other current liabilities* in the consolidated balance sheets as of December 31, 2021. The Company expects to reverse the liability recorded and record a gain based on the financial information of the investee becoming available in the first quarter of 2022. The cash distribution of the Company is classified as a cash inflow from investing activities in the statement of cash flows similar to a return of investment using the cumulative earnings method.

The maximum exposure to losses related to the investee is 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.

The Company has provided no financing to the investee other than the amounts required under the Development Agreement.

6. Fair Value of Financial Instruments and Contingent Consideration

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.

6. Fair Value of Financial Instruments and Contingent Consideration (Continued)

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, 2021, or December 31, 2020.

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, 2021	
	Total Fair Value at December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash and cash equivalents			
Cash	$ 148,863	$ 148,863	$ —
Money market funds	54,571	54,571	—
Marketable securities			
Corporate debt securities	136,246	251	135,995
Long term marketable securities			
Corporate debt securities	119,166	—	119,166
Other noncurrent assets			
Marketable securities—restricted (SERP)	630	7	623
Total assets at fair value	$ 459,476	$ 203,692	$255,784

6. Fair Value of Financial Instruments and Contingent Consideration (Continued)

		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
U.S. government agency and municipal debt securities	—		
Other noncurrent assets			
Marketable securities—restricted (SERP)	547	3	544
Total assets at fair value	$ 773,439	$ 288,899	$484,540

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

Financial Liabilities Recorded at Fair Value

Contingent Consideration

The Company's contingent consideration liabilities are measured at fair value on a recurring basis. The Company classifies its contingent consideration liabilities as Level 3 fair value measurements based on the significant unobservable inputs used to estimate fair value. These reflect the inputs and assumptions the Company believes would be made by market participants. Changes in any of those inputs together or in isolation may result in significantly lower or higher fair value measurement. Refer to Note 3, *Acquisitions*, for further discussion of significant inputs and assumptions used for the valuation of the contingent consideration.

During the measurement period, changes in the fair value of contingent consideration related to the USWM Acquisition and Adamas Acquisition are recorded against goodwill if such changes are related to facts and circumstances that existed at the acquisition date. In each reporting period after the acquisition, the Company remeasures the fair value of contingent consideration liabilities and records in its consolidated statements of earnings the increases or decreases in the fair value of the liabilities.

In the fourth quarter of 2020, the Company recorded a measurement period adjustment of $40.9 million related to the USWM Acquisition. Refer to Note 3, *Acquisitions*.

The Company recorded a $6.5 million gain due to the change in fair value of the USWM contingent consideration liability during the year-ended December 31, 2021. The change in fair value of $6.5 million was reported on the consolidated statement of earnings in *Contingent consideration (gain) expense*. The change in fair value was primarily due to the write-down of the sales based contingent consideration liabilities offset by an increase in the estimated fair value of regulatory and developmental milestones due to the passage of time. The Company assessed that these sales-based milestones will not be achieved based on the

6. Fair Value of Financial Instruments and Contingent Consideration (Continued)

revised net sales projections. The probability of achieving these milestones were significantly lower compared to prior estimates. The Company updated its projected net sales of the Products based on recent historical sales trend experience.

As mentioned in Note 1, the Company received notice from the FDA on February 18, 2022 of its acceptance for review of the NDA for SPN-830. The regulatory and developmental contingent consideration payments include a $25 million milestone due upon the FDA acceptance of the SPN-830 NDA for review, which was paid in the first quarter of 2022.

The following table provides the reconciliation of the contingent consideration liabilities balance as of December 31, 2021 (dollars in thousands):

	Adamas Acquisition	USWM Acquisition	Total
Balance at December 31, 2020	$ —	$76,700	$76,700
Initial estimate of contingent consideration at Closing Date	10,307	—	10,307
Change in fair value recognized in earnings	$ —	$ (6,530)	$ (6,530)
Balance at December 31, 2021	10,307	70,170	80,477

Reported under the following captions in the consolidated balance sheets:	December 31, 2021	December 31, 2020
Contingent consideration, current portion	44,840	30,900
Contingent consideration, long term	35,637	45,800
Total	80,477	76,700

	Adamas Acquisition	USWM Acquisition	Total
Regulatory and developmental contingent consideration liabilities	$ —	$ 70,170	$ 70,170
Sales-based contingent consideration liabilities	10,307	—	10,307
Balance at December 31, 2021	$ 10,307	$ 70,170	$ 80,477

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, 2021		December 31, 2020	
	Carrying Value	Fair Value (Level 2)	Carrying Value	Fair Value (Level 2)
Convertible notes, net	$379,252	$400,236	$361,751	$383,381

The fair value has been estimated based on actual trading information, and quoted prices, both provided by bond traders.

7. Goodwill and Intangible Assets, Net

The following table sets forth the gross carrying amounts and related accumulated amortization of intangible assets and goodwill as of December 31, 2021 (dollars in thousands):

		December 31, 2021			December 31, 2020		
Description	Remaining Weighted-Average Amortization Period (Years)	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net
Goodwill		$117,516	$ —	$117,516	$ 77,911	$ —	$ 77,911
Acquired in-process research and development		124,000	—	124,000	123,000	—	123,000
Intangible assets subject to amortization:							
Acquired developed technology and product rights	8.73	681,100	(35,550)	645,550	232,000	(10,651)	221,349
Capitalized patent defense costs	4.48	43,820	(28,677)	15,143	43,579	(23,586)	19,993
Total intangible assets	8.63	$848,920	$(64,227)	$784,693	$398,579	$(34,237)	$364,342

Goodwill

The majority of the increase in goodwill was a result of the Adamas Acquisition. Refer to Note 3, *Acquisitions*.

The remaining increase represents measurement period adjustments recorded in the second quarter of 2021, which related to the finalization of the business combination accounting of the USWM Acquisition. Refer to Note 3, *Acquisitions*.

As of December 31, 2021, 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; acquired developed technology and product rights, and acquired IPR&D assets associated with the Company's acquisitions. The Company amortizes intangible assets over their useful lives, except for the acquired IPR&D asset.

The acquired IPR&D asset pertains to SPN-830 (apomorphine infusion device) which was acquired as part of the USWM acquisition in 2020. Refer to Note 3 for further discussion of the acquired IPR&D asset. As discussed in Note 1, in February 2022, the Company received notice from the FDA on the acceptance for review of the NDA for SPN-830 and assigned a PDUFA target action date of October 7, 2022.

U.S. patents covering Oxtellar XR and Trokendi XR will expire no earlier than 2027. In regards to 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.

As a result of the USWM and Adamas acquisitions, the Company acquired developed technology and product rights for APOKYN, XADAGO, MYOBLOC, GOCOVRI, Osmolex ER and Namzaric.

Amortization expense for intangible assets was approximately $30.0 million, $15.7 million, and $5.2 million for the years ended December 31, 2021, 2020, and 2019, respectively.

7. Goodwill and Intangible Assets, Net (Continued)

Anticipated annual amortization expense for intangible assets in 2022 is estimated at $82.6 million. Anticipated annual amortization expense for intangible assets from 2023 to 2024 is estimated at $79.8 million per year. Anticipated annual amortization expense for intangible assets in 2025 to 2026 is estimated at $75.0 million per year.

In February 2022, the FDA approved the first generic of Apokyn (apomorphine hydrochloride injection) to treat hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease. Refer to Note 17, *Subsequent Events*.

8. 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

8. Convertible Senior Notes Due 2023 (Continued)

each of the call spread 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 $80.91 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, 2021	December 31, 2020
2023 Notes	$402,500	$402,500
Unamortized debt discount and deferred financing costs	(23,248)	(40,749)
Total carrying value	$379,252	$361,751

No 2023 Notes were converted as of December 31, 2021, or December 31, 2020.

9. Share-Based Payments

Common Stock

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

Equity Incentive Plan

The Company has adopted the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan (2021 Plan) which was approved by the stockholders in June 2021. The 2021 Plan is the successor and replaced the 2012 Equity Incentive Plan, as amended (the 2012 Plan). The 2021 Plan is administered by the Company's Board of Directors and the Company's Compensation Committee of the Board. The 2021 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 maximum number of shares that can be issued under the 2021 Plan shall not exceed 4,951,859 shares, which is the sum of (i) 2,000,000 shares and (ii) the approximately 2,951,859 shares that were available for grant under the 2012 Plan as of April 16, 2021. Option awards are granted with an exercise price equal to the closing price of the Company's common stock as of the grant date. Options and awards granted have a 10 year contractual term. Options and awards granted to employees,

9. Share-Based Payments (Continued)

consultants and advisors generally vest in four equivalent annual installments, starting on the first anniversary of the grant's date. Options and awards granted to the directors generally vest over a one year term.

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,		
	2021	2020	2019
Research and development	$ 2,403	$ 2,431	$ 2,599
Selling, general and administrative	15,507	14,130	12,247
Total	$ 17,910	$ 16,561	$ 14,846

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,		
	2021	2020	2019
Fair value of common stock	$25.09 - $30.45	$21.13 - $23.99	$22.99 - $37.78
Expected volatility	60.62% - 61.80%	61.56% - 62.27%	61.36% - 63.28%
Dividend yield	0%	0%	0%
Expected term	5.63 years - 6.56 years	5.72 years - 6.54 years	5.53 years - 6.18 years
Risk-free interest rate	0.72% - 1.30%	0.27% - 1.34%	1.69% - 2.55%

As of December 31, 2021, the total unrecognized compensation expense was approximately $23.8 million. The Company expects to prospectively recognize these expenses over a weighted-average period of 2.54 years.

9. Share-Based Payments (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, 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
Granted	1,055,525	$28.93		
Exercised	(266,987)	$18.47		
Forfeited	(466,324)	$27.74		
Outstanding, December 31, 2021	5,774,076	$24.15	5.95	$41,530
As of December 31, 2021				
Vested and expected to vest	5,774,076	$24.15	5.95	$41,530
Exercisable	3,651,824	$21.29	4.53	$37,196

The weighted-average grant date fair value of options granted for the years ended December 31, 2021, 2020, and 2019 were $16.25, $13.44, and $21.50 per share, respectively.

The aggregate intrinsic value of shares exercised for the years ended December 31, 2021, 2020, and 2019 were $2.8 million, $2.3 million, and $2.4 million, respectively. Proceeds from the option exercise for the years ended December 31, 2020, 2019, and 2018 were $4.9 million, $2.3 million, $1.5 million, respectively.

The total fair value of the underlying common stock related to shares that vested during the years ended December 31, 2021, 2020, and 2019 were approximately $13.9 million, $14.1 million, and $10.8 million, respectively.

Restricted Stock Units

The following table summarizes restricted stock unit (RSU) activities:

	Number of RSUs	Weighted-Average Grant Date Fair Value per Share	Aggregate Intrinsic Value (in thousands)	Aggregate Fair Value (in thousands)
Nonvested, December 30, 2019	—	$ —		
Granted	26,055	$23.99		
Vested	—	$ —	$ —	$ —
Forfeited	—	$ —		
Nonvested, December 31, 2020	26,055	$23.99		
Granted	21,110	$29.61		
Vested	(26,055)	$23.99	$146.4	$625.1
Forfeited	—	$ —		
Nonvested, December 31, 2021	21,110	$29.61		

9. Share-Based Payments (Continued)

The RSUs generally vest one year from the date of grant.

As of December 31, 2021, the total unrecognized compensation expense was $0.1 million. The Company expects to prospectively recognize these expenses over a weighted-average period of 0.1 years.

Performance Stock Units

The following table summarizes performance share unit (PSU) activities:

	Performance-Based Units		Market-Based Units		Total PSUs	
	Number of PSUs	Weighted-Average Grant Date Fair Value per Share	Number of PSUs	Weighted-Average Grant Date Fair Value per Share	Number of PSUs	Weighted-Average Grant Date Fair Value per Share
Nonvested, December 31, 2019	—	—	—	—	$ —	
Granted	31,250	$21.35	15,625	$23.41	46,875	$22.04
Vested	(31,250)	$21.35	—	$ —	(31,250)	$21.35
Forfeited	—	$ —	—	$ —	—	$ —
Nonvested, December 31, 2020	—	$ —	15,625	$23.41	15,625	$23.41
Granted	95,000	$29.74	20,000	$28.63	115,000	$29.55
Vested	(40,000)	$29.61	—	$ —	(40,000)	$29.61
Forfeited	(1,500)	$30.45	—	$ —	(1,500)	$30.45
Nonvested, December 31, 2021	53,500	$29.82	35,625	$26.34	89,125	$28.43

The total fair value of PSUs that vested during the years ended December 31, 2021, 2020, and 2019 were $1.2 million, $0.7 million, and $0, respectively. The total intrinsic value of PSUs that vested during the years ended December 31, 2021, 2020, and 2019 were $0, $0.1 million, and $0, respectively.

Performance-Based Awards

The performance-based PSU 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, 2021, the total unrecognized compensation expense was $0.7 million. The Company expects to prospectively recognize these expenses over a weighted-average period of 0.2 years. The total fair value of vested PSUs during the year ended December 31, 2021, was $1.2 million.

Market-Based Awards

The market-based PSU awards are subject to achievement of market-based performance targets in order to vest. There was no unrecognized compensation expense as of December 31, 2021. The Company used a Monte-Carlo Simulation to determine the fair value and expected term of the awards. The expected term of the awards granted in 2021 was 0.9 years.

10. 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.

10. Earnings per Share (Continued)

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 8, *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 $80.91 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, $80.91 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,		
	2021	2020	2019
Stock options, RSUs, PSUs	1,275,114	2,888,785	1,145,446

The following table sets forth the computation of basic and diluted net earnings per share for the years ended December 31, 2021, 2020, and 2019 (dollars in thousands, except share and per share amounts):

	Years Ended December 31,		
	2021	2020	2019
Numerator, dollars in thousands:			
Net earnings	$ 53,424	$ 126,950	$ 113,056
Denominator:			
Weighted average shares outstanding, basic	53,099,330	52,615,269	52,412,181
Effect of dilutive securities:			
Stock options, RSUs and SARs	1,257,414	1,074,474	1,404,573
Weighted average shares outstanding, diluted	54,356,744	53,689,743	53,816,754
Earnings per share, basic	$ 1.01	$ 2.41	2.16
Earnings per share, diluted	$ 0.98	$ 2.36	2.10

11. Income Taxes

The summary of the income tax expense (benefit) for the years ended December 31, 2021, 2020, and 2019 is as follows (dollars in thousands):

	Years Ended December 31,		
	2021	2020	2019
Current			
Federal	$16,606	$29,893	$29,333
State	8,196	11,234	10,930
Deferred			
Federal	(1,651)	2,200	(4,551)
State	(3,400)	(1,629)	(1,281)
Total income tax expense	$19,751	$41,698	$34,431

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,		
	2021	2020	2019
Income tax expense computed at U.S. federal statutory income tax rate	$15,367	$35,417	$30,972
State income taxes	3,088	7,281	7,543
Permanent items	1,465	2,654	1,332
Research and development credits	(1,016)	(3,602)	(2,071)
Uncertain income tax position	(314)	348	(2,992)
Change in valuation allowance	250	—	—
Other	911	(400)	(353)
Income tax expense	$19,751	$41,698	$34,431

11. 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,	
	2021	2020
Deferred tax assets:		
Convertible bond hedge	$ 6,910	$ 12,420
Accrued product returns and rebates	19,506	17,529
Accrued compensation and stock based compensation	17,802	13,547
Research and development credit carryforwards	4,448	3,151
Net operating loss carryforwards	126,333	13,164
Operating lease liability	12,146	14,542
Interest limitation	7,860	1,055
Investment	7,819	2,501
Charitable contributions	7,730	1,613
Other	4,256	3,911
Total deferred tax assets	214,810	83,433
Less: valuation allowance	(70,529)	(582)
Total deferred tax asset, net of valuation allowance	144,281	82,851
Deferred tax liabilities:		
Amortization of intangibles	(199,240)	(79,545)
Debt discount on 2023 Notes	(5,671)	(10,190)
Patent infringement legal costs	(10,689)	(10,897)
Operating lease assets	(9,099)	(10,674)
Other	(4,937)	(6,760)
Total deferred tax liabilities	(229,636)	(118,066)
Net deferred tax liabilities	$ (85,355)	$ (35,215)

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, management had determined it is not more-likely-than-not to realize all such net deferred tax assets.

11. Income Taxes (Continued)

A reconciliation of the deferred asset valuation allowance is as follows (dollars in thousands):

	Years Ended December 31,		
	2021	2020	2019
Beginning balance	$ 582	$ 11	$ 9
Acquisition Accounting[(1)]	69,697	573	—
Additions	250	—	2
Deductions	—	(2)	—
Ending balance	70,529	582	11

(1) Amount comprised principally of acquisitions and purchase accounting adjustments in connect with acquisitions

The Company recorded a valuation allowance of $70.5 million as of December 31, 2021, of which $69.7 million is associated with the Adamas Acquisition. The valuation allowance is primarily related to federal and state net operating losses carryforwards acquired from the Adamas Acquisition 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.

As of December 31, 2021, the U.S. federal and state NOL carryforwards amounted to approximately $449.3 million ($413.7 million related to the Adamas Acquisition) and $431.9 million ($387.3 million related to the Adamas Acquisition), respectively, and will expire in various years beginning in 2031. For the year ended December 31, 2021, the Company utilized federal NOLs of approximately $7.2 million and state NOLs of approximately $5.3 million.

As of December 31, 2021, the Company has available research and development credit carryforwards of $1.6 million, which became available in 2022 and will expire, if unused, starting in 2030.

The Company is no longer subject to U.S. Federal income tax examinations for years prior to 2018. Operating loss or tax credit carryforwards generated prior to 2018 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.

11. Income Taxes (Continued)

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

	Years Ended December 31,		
	2021	2020	2019
Balance as of January 1	$5,881	$ 5,978	$ 8,848
Gross increases related to current year tax positions	898	1,027	208
Gross increases related to prior year tax positions	—	221	—
Gross decreases related to prior year tax positions	(363)	—	(49)
Lapse of statute of limitations	(316)	(1,345)	(3,029)
Balance as of December 31	$6,100	$ 5,881	$ 5,978

The Company recorded $0.1 million, $0.6 million, and $3.0 million of net tax benefit in 2021, 2020 and 2019, respectively, as a result of the expiration of statutes of limitation. The Company also recorded $0.3 million, $0.3 million, and $0.2 million for uncertain tax positions related to research and development tax credits in 2021, 2020, and 2019, 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, 2021, 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.

12. Leases

Operating Leases

The Company has operating leases for its headquarters lease and its fleet vehicles. 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.

The Company's headquarters lease commenced on February 1, 2019 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. On August 23, 2021, the Company entered into an addendum to the original headquarters agreement to lease additional office space, referred to as the Expansion Premises. The Expansion Premises is separate from the lease space in the original lease agreement. The term of the lease with respect to the Expansion Premises commenced on September 1, 2021 and coincides with the lease term per the original lease agreement.

12. Leases (Continued)

As part of the Adamas Acquisition, the Company acquired a lease for office space. Adamas's operating lease for the office space term will continue until April 30, 2025. The lease contains an option to extend the term for one additional five-year period.

Contract Manufacturing 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 rimabotulinumtoxinB finished products (Merz Agreement). 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 which the Company accounts for as an embedded lease.

At the Closing Date of the USWM Acquisition, the Company preliminarily classified the embedded lease as a finance lease and preliminarily elected not to separate the lease and non-lease components. In the second quarter of 2021, the Company finalized its accounting of the USWM Acquisition. During the measurement period, the Company determined the fair market value of rent for the lease components and fair market value of the manufacturing facility associated with the Merz embedded lease. As a result, the Company made an accounting policy election, by class of underlying asset, to not combine lease and non-lease components for the manufacturing facility. A portion of the in-substance fixed contract consideration was allocated to the lease component based on the stand-alone selling price. Accordingly, the Company has finalized and updated the classification of the embedded lease from a finance lease to an operating lease. Refer to Note 3, *Acquisitions*, for further discussion.

12. 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, 2021	December 31, 2020
Assets			
Operating lease assets	Other assets	$35,365	$20,231
Finance lease asset	Property and equipment, net	—	20,874
Total lease assets		$35,365	$41,105
Liabilities			
Lease liabilities, current Operating lease liabilities, current portion	Accounts payable and accrued liabilities	$ 6,477	$ 3,760
Finance lease liability, current portion	Other current liabilities	—	3,761
Lease liabilities, long term			
Operating lease liabilities, long term	Operating lease liabilities, long term	41,298	28,579
Finance lease liability, long term	Other liabilities	—	20,235
Total lease liabilities		$47,775	$56,335

The components of operating and finance lease costs are as follows (dollars in thousands):

	December 31, 2021	December 31, 2020
Operating lease cost:		
Fixed lease cost	$ 8,929	$5,333
Variable lease cost	3,059	2,145
Total	$11,988	$7,478
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, 2021	December 31, 2020
Cash paid for operating leases	$11,908	$ 6,949
Cash paid for finance lease	—	802
Lease assets and tenant receivables obtained for new operating leases	10,868	2,478
Lease assets obtained for new finance lease	—	22,747

12. Leases (Continued)

Weighted average lease term, and weighted average discount rate for operating leases as of December 31, 2021, are as follows:

Operating leases	
Weighted-average remaining lease term (years)	8.9
Weighted-average discount rate	3.71%

Future minimum lease payments under noncancellable operating leases as of December 31, 2021, are as follows (dollars in thousands):

	Operating Leases
Year ending December 31:	
2022	$ 7,843
2023	7,733
2024	6,971
2025	5,333
2026	4,626
Thereafter	24,755
Total future minimum lease payments	$57,261
Less: Imputed interest[(1)]	(9,486)
Present value of lease liabilities	$47,775

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

13. Composition of Other Balance Sheet Items

The following details the composition of other balance sheet items (dollars in thousands for amounts in tables):

Accounts Receivable

As of December 31, 2021, and December 31, 2020, the Company has reduced gross accounts receivable by approximately $13.5 million and $11.4 million, respectively. Prompt pay discount and contractual service fees, which were originally recorded as reduction to revenues, represents estimated amounts not expected to be paid by our customers. The Company's customers are primarily pharmaceutical wholesalers and distributors and specialty pharmacies. The Company's customers are primarily pharmaceutical wholesalers and distributors, and specialty pharmacies.

Inventories

Inventories consist of the following (dollars in thousands):

	December 31, 2021	December 31, 2020
Raw materials	$ 7,325	$22,208
Work in process	45,711	8,985
Finished goods	32,923	17,132
Total	$85,959	$48,325

13. Composition of Other Balance Sheet Items (Continued)

In May 2021, the Company launched Qelbree for the treatment of ADHD in pediatric patients 6 to 17 years of age in the U.S. Capitalized pre-launch inventory costs for Qelbree were $0 and $19.1 million as of December 31, 2021 and December 31, 2020, respectively.

Inventories include the acquired inventories from the USWM Acquisition and Adamas Acquisition. Refer to Note 3 for further discussion of the Company's acquisitions.

Property and Equipment

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

	December 31, 2021	December 31, 2020
Lab equipment and furniture	$ 12,287	$ 12,526
Leasehold improvements	14,369	15,183
Software	4,776	2,295
Finance lease asset[1]	—	22,747
Computer equipment	1,944	2,113
Construction-in-progress	33	—
	33,409	54,864
Less accumulated depreciation and amortization	(16,454)	(17,040)
Total	$ 16,955	$ 37,824

(1) Refer to Note 12, *Leases*.

Depreciation and amortization expense on property and equipment was approximately $2.6 million, $4.3 million, and $1.5 million for the years ended December 31, 2021, 2020 and 2019, respectively. Depreciation and amortization expense of $4.3 million in 2020 includes $1.9 million of amortization expense associated with the finance lease asset. Refer to Note 12, *Leases*.

As of December 31, 2021, there were no identified indicators of impairment.

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of the following (dollars in thousands):

	December 31, 2021	December 31, 2020
Accrued compensation	$ 28,068	$16,008
Accrued royalties[1]	13,821	13,890
Accrued clinical trial costs[2]	9,125	12,842
Accrued product costs	18,460	9,587
Accrued professional fees	26,728	7,730
Accounts payable	9,331	6,147
Operating lease liabilities, current portion[3]	6,477	3,760
Other accrued expenses	5,673	8,970
Total	$117,683	$78,934

13. Composition of Other Balance Sheet Items (Continued)

(1) Refer to Note 15, *Commitments and Contingencies*.

(2) Includes preclinical and all clinical trial-related costs.

(3) Refer to Note 12, *Leases*.

Accrued Product Returns and Rebates

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

	December 31, 2021	December 31, 2020
Accrued product rebates	$ 97,597	$ 96,589
Accrued product returns	35,127	29,603
Total	$132,724	$126,192

Other Liabilities

Other liabilities consist of the following (dollars in thousands):

	December 31, 2021	December 31, 2020
Nonrecourse liability related to sale of future royalties, long term	$ 5,977	$13,410
Finance lease liability, long term[1]	—	20,235
Other liabilities	10,403	9,146
Total	$16,380	$42,791

(1) Refer to Note 12, *Leases*.

14. Other (Expense) Income

Interest expense consists of the following (dollars in thousands):

	Years Ended December 31,		
	2021	2020	2019
Interest expense	(19,696)	(19,435)	(18,207)
Interest expense on nonrecourse liability related to sale of future royalties	(4,319)	(4,500)	(3,727)
Total	$(23,423)	$(23,754)	$(22,707)

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 $17.5 million, $16.6 million, and $15.7 million for the years ended December 31, 2021, 2020 and 2019, respectively (see Note 8).

Interest income includes interest earned from cash, cash equivalents, and marketable securities of $8.8 million, $16.0 million, and $21.3 million for the years ended December 31, 2021, 2020, and 2019, respectively.

15. 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 statements of earnings.

Royalty Agreement

In the third quarter of 2014, the Company received $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 13).

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 €3.9 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 and will end in 2022. As of December 31, 2021, the total remaining contractual commitment through 2022 is $0.3 million. (See Note 3, *Acquisitions* for further discussion on the USWM Acquisition and Note 12, *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.

Data Breach-related Contingency

On November 24, 2021, we announced that we were the target of a ransomware attack. The attack had no significant impact on our business and did not cause any long-term disruption to our operations. Based on the investigation, the Company believes the criminal ransomware groups ("criminal groups") copied certain data from our systems, encrypted certain data on the Company's systems, and then deployed malware designed to impede access to our systems. Thereafter the criminal groups contacted the Company and

15. Commitments and Contingencies (Continued)

threatened to publish certain data copied from the Company's systems. Upon detection of the ransomware attack, the Company notified government authorities, engaged third-party cybersecurity experts through our outside counsel, and commenced its recovery process. The Company maintains redundant off-site data backups, which were verified to have not been compromised by the ransomware attack and were utilized to restore the data encrypted by the criminal groups. At this time, the Company has successfully recovered the impacted files and has taken additional steps designed to further protect its networks and files.

Furthermore, while the Company has not been the subject of any legal proceedings involving the attack, the likelihood that the Company could be the subject of claims from persons alleging they suffered damages from the incident, or actions by governmental authorities is possible, but the amount of such fines, penalties or costs, if any, cannot be estimated at this time.

Claims and Litigation

From time to time, the Company may be involved in various claims, litigation and legal proceedings. These matters may involve patent litigation, product liability and other product-related litigation, commercial and other matters, and government investigations, among others. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company will accrue a liability for the estimated loss. Because of uncertainties related to claims, legal proceedings and litigation, accruals will be based on the Company's best estimates based on available information. We do not believe that any of these matters will have a material adverse effect on our financial position. The Company may reassess the potential liability related to these matters and may revise these estimates. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters will adversely affect the Company, its results of operations, financial condition and cash flows,

NAMENDA XR/Namzaric Qui Tam Litigation

On April 1, 2019, Adamas was served with a complaint filed in the United States District Court for the Northern District of California (Case No. 3:18-cv-03018-JCS) against it and several Allergan entities alleging violations of federal and state false claims acts (FCA) in connection with the commercialization of NAMENDA XR and Namzaric by Allergan. The lawsuit is a *qui tam* complaint brought by an individual, asserting rights of the Federal government and various state governments. The lawsuit was originally filed in May 2018 under seal, and Adamas became aware of the lawsuit when it was served. The complaint alleges that patents held by Allergan and Adamas covering NAMENDA XR and Namzaric were procured through fraud on the United States Patent and Trademark Office and that these patents were asserted against potential generic manufacturers of NAMENDA XR and Namzaric to prevent the generic manufacturers from entering the market, thereby wrongfully excluding generic competition resulting in artificially high price being charged to government payors. Adamas's patents in question were licensed exclusively to Forest. The complaint includes a claim for damages of "potentially more than $2.5 billion dollars," treble damages and statutory penalties. To date the federal and state governments have declined to intervene in this action. This case is currently stayed pending Adamas's and Allergan's interlocutory appeal of the District Court's December 11, 2020 order denying Adamas's and Allergan's motion to dismiss the complaint. The appeal is pending in the United States Court of Appeals for the Ninth Circuit (Case No. 21-80005). Argument was held on January 10, 2022 and no decision has been reached as of the date of this filing. The Company intends to defend itself vigorously. However, the Company can offer no assurances that it will be successful in a litigation.

16. 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

15. Commitments and Contingencies (Continued)

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 $3.0 million, $2.6 million, and $2.3 million for the years ended December 31, 2021, 2020, and 2019, respectively.

17. Subsequent Events

As discussed on Note 1, *Organization and Business*, in February 2022, the Company received notice from the FDA of its acceptance for review of the NDA resubmission for SPN-830 (apomorphine infusion device).

In February 2022, the FDA approved the first generic of Apokyn (apomorphine hydrochloride injection) to treat hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced PD. This approval is for an application of the drug cartridges only, which are compatible for use with the APOKYN pen, the brand-name pen injector. Patients treated with generic apomorphine hydrochloride will need to separately obtain the APOKYN pen. The Company is in the process of analyzing the impact of the FDA's approval of a generic apomorphine hydrochloride injection drug cartridge to both the Company's operations and the corresponding intangible asset.

The 2023 Notes include a covenant requiring the Company to provide Noteholders copies of all reports that the Company is required to file with the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act within fifteen calendar days after the date that the Company is required to file or furnish such report (after giving effect to all applicable grace periods under the Exchange Act) (such date the "Outside Filing Date"). Although this Annual Report on Form 10-K was not filed with the SEC prior to the Outside Filing Date, it was so filed prior to the sixty-day cure period provided under the terms of the Notes.

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 required by Rule 13a-15(e) and 15d-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, 2021, the end of the

15. Commitments and Contingencies (Continued)

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 not effective as of December 31, 2021 due to the material weaknesses described below.

In light of the identified material weaknesses, we performed additional analyses and other procedures to ensure that the Consolidated Financial Statements included in this Annual Report on Form 10-K present fairly, in all material respects, the Company's financial position, results of operations and cash flows for the periods disclosed in conformity with U.S. generally accepted accounting principles (U.S. GAAP).

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, as defined in Exchange Act Rule 13a-15(f) and 15d-15(f), is a process designed under the supervision and with the participation of our management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

All internal control systems, no matter how well designed, have inherent limitations. Because of their inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our CEO and CFO, and under the oversight of our Board of Directors, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021 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).

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 Adamas Pharmaceuticals, Inc., a publicly traded biopharmaceutical company (Adamas Acquisition) on November 24, 2021. Management has excluded the acquisition of Adamas Pharmaceuticals, Inc. (Adamas) from its assessment of the effectiveness of internal control over financial reporting as of December 31, 2021. The acquired business represented approximately 8% of the total assets (excluding the goodwill and other intangible assets, which are included within the scope of the assessment) and 2% of total revenues as of and for the year ended December 31, 2021.

Based on management's assessment using the criteria set forth above, management concluded that the Company's internal control over financial reporting were not effective as of December 31, 2021 due to the material weaknesses described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

On November 24, 2021, the Company disclosed that it was the target of a ransomware attack. The 2021 ransomware attack resulted in the unauthorized encryption of certain data used by the Company's legacy enterprise resource planning ("ERP") system. In addition, the Company also announced on the same date that it had completed the closing of the Adamas acquisition. As a result of these events, the Company's financial and IT operations changed and the circumstances necessitated further re-consideration of the

15. Commitments and Contingencies (Continued)

Company's control environment, risk assessment, information and communication, control monitoring, and control activities. Specifically, commencing with the fourth quarter of 2021 and continuing into 2022, management was unable to adjust its controls, nor retain sufficient resources to reflect the needs arising from:

(a) the result of the ransomware incident, its effects and significant impact on the following:

  i) the Company's ability to access and reinstate its financial ERP system for an extended period to a new normal state of operation;

  ii) the resource needs to rebuild its financial information from backups as a result of the ransomware incident;

  iii) additional workload associated with process workflows that were previously automated but are currently manually performed as a result of the ransomware attack.

(b) the Adamas acquisition and the related preliminary purchase price accounting; and

(c) operating the financial reporting environment of Adamas.

These responsibilities were assigned to the finance organization in addition to their historical job responsibilities.

Due to the factors noted above, the Company did not have sufficient resources and as a result, the Company did not adequately perform the following:

(a) assess, redesign and timely evaluate performance of controls over financial reporting risks as a result of existing circumstances;

(b) train, monitor, and supervise newly hired contractors and employees; and

(c) generate real time information across the organization to allow the finance department to perform timely controls.

In the aggregate, these deficiencies create a reasonable possibility that material misstatements in substantially all financial reporting processes and financial statement accounts in our consolidated financial statements will not be prevented or detected on a timely basis and, therefore, we concluded that the deficiencies represent material weaknesses in our internal control over financial reporting.

KPMG LLP, our independent registered public accounting firm, has audited our 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, 2021. Their responsibility is to evaluate whether internal controls over financial reporting were designed and operating effectively. KPMG issued an adverse opinion on the effectiveness of our internal control over financial reporting as of December 31, 2021, which report appears on page 97 in this Annual Report.

Remediation Plan

We are committed to remediating the material weaknesses in a timely manner. Our remediation process includes, but is not limited to, the following:

(a) accelerated implementation of a new ERP to reduce resource constraints and to automate certain processes that are currently being performed manually as a result of the ransomware attack;

(b) reevaluation of all controls, including redesigning controls and control procedures, performing risk assessment procedures, as well as adding new controls as necessary;

15. Commitments and Contingencies (Continued)

(c) continue to actively recruit personnel or hire consultants that have requisite knowledge, experience, and expertise over financial reporting and internal control over financial reporting. We will continue to evaluate our current and future staffing needs to add personnel and/or create new roles to address our needs; and

(d) training/re-training, monitoring, and enhancing communication of control objectives to hired employees and contractors on internal control over financial reporting.

While the audit committee of our board of directors and senior management are closely monitoring the remediation efforts, until the remediation efforts discussed in this section, including any additional remediation efforts that our senior management identifies as necessary, are complete, tested and determined effective, we will not be able to conclude that the material weaknesses have been remediated. In addition, we may need to incur incremental costs associated with this remediation, primarily due to the hiring and training of additional personnel, and the improvements in our IT infrastructure. The material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that the controls are operating effectively.

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 quarter ended December 31, 2021.

In 2021, we began the process to integrate the financial reporting systems and processes of the business acquired through the Adamas 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 operations of Adamas, which may result in additions and changes in our internal controls over financial reporting.

Except for the above noted material weaknesses, remediation activities that have already begun including the implementation of a new ERP, and the integration of Adamas, 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, 2021 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 2022 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2021.

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 2022 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2021.

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 2022 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2021.

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, 2021:

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	5,774,076	$24.15	5,022,120
Equity compensation plans not approved by security holders	—	—	—
Total	5,774,076	$24.15	5,022,120

(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 2021 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 2022 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2021.

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 2022 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2021.

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, 2021 and 2020 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).
2.3#*	Agreement and Plan of Merger, dated as of October 10, 2021, by and among Supernus Pharmaceuticals, Inc., Supernus Reef, Inc. and Adamas Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Form 8-K filed on October 12, 2021, 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).
10.2*+	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).
10.4*+	Stock Restriction Agreement, dated December 22, 2005, by and between the Registrant and Jack Khattar (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.5*	Lease, dated as of April 19, 1999, by and between ARE Acquisitions, LLC and Shire Laboratories Inc. (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.6*	First Amendment to Lease, dated as of November 1, 2002, by and between ARE Acquisitions, LLC and Shire Laboratories Inc. (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
10.7*	Second Amendment to Lease, dated as of December 22, 2005, by and among ARE-East Gude Lease, LLC, Shire Laboratories Inc. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on December 23, 2010).
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).

Exhibit Number	Description
10.9†*	Asset Purchase and Contribution Agreement, dated as of December 22, 2005, by and among the Registrant, Shire Laboratories Inc. and Shire plc (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, File No. 333- 171375, as amended on March 16, 2012).
10.10†*	Guanfacine License Agreement, dated as of December 22, 2005, by and among the Registrant, Shire LLC and Shire plc, as amended (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.11†*	Exclusive License Agreement, dated as of June 6, 2006, by and between the Registrant and United Therapeutics Corporation (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.12†*	Exclusive Option and License Agreement, dated as of April 27, 2006, by and between the Registrant and Afecta Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1, File No. 333-171375, as amended on March 16, 2012).
10.13*	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).
10.19†*	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).
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).

Exhibit Number	Description
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).
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).

Exhibit Number	Description
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).
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).

Exhibit Number	Description
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).
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).
10.62††+*	Offer Letter to Timothy C. Dec (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on July 29, 2021, File No. 001- 35518).
10.63††*	Commercial Supply Agreement, dated May 12, 2021, by and between Supernus Pharmaceuticals, Inc. and Catalent Pharma Solutions, LLC (incorporated by reference to Exhibit 10.1 to the Form 10-Q filed on August 6, 2021, File No. 001-35518).
10.64††*	API Supply Agreement, dated July 13, 2021, by and between Supernus Pharmaceuticals, Inc. and Bachem Americas, Inc.(incorporated by reference to Exhibit 10.2 to the Form 10-Q filed on August 6, 2021, File No. 001-35518).
10.65+*	Form of Time-Based Incentive Stock Option Agreement, under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Form 10-Q filed on August 6, 2021, File No. 001-35518).
10.66+*	Form of Non-Statutory Time-Based Stock Option Agreement, under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Form 10-Q filed on August 6, 2021, File No. 001-35518).
10.67+*	Form of Restricted Stock Unit Award Agreement, under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Form 10-Q filed on August 6, 2021, File No. 001-35518).
10.68+*	Form of Performance Share Unit Award Agreement, under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Form 10-Q filed on August 6, 2021, File No. 001-35518).
10.69††*	Amendment to Deed of Lease, August 23, 2021, by and between Supernus Pharmaceuticals, Inc. and Key West MD Owner, LLC (incorporated by reference to Exhibit 10.1 to the Form 10-Q filed on November 5, 2021, File No. 001-35518)

Exhibit Number	Description
10.70††*	Amended and Restated API Supply Agreement by and between Adamas Pharma, LLC and Moehs Ibérica, S.L. (incorporated by reference to Exhibit 10.2 to the Form 10-Q filed by Adamas Pharmaceuticals, Inc. on November 2, 2017, File No. 001-36399)
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).

† 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 Section 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: April 13, 2022

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)	April 13, 2022
/s/ TIMOTHY C. DEC	Senior Vice-President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 13, 2022
/s/ CHARLES W. NEWHALL, III.	Director and Chairman of the Board	April 13, 2022
/s/ CARROLEE BARLOW, M.D., PH.D.	Director	April 13, 2022
/s/ GEORGES GEMAYEL, PH.D.	Director	April 13, 2022
/s/ FREDERICK M. HUDSON	Director	April 13, 2022
/s/ JOHN M. SIEBERT, PH.D.	Director	April 13, 2022

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
Adamas Pharmaceuticals, Inc.	Delaware
Adamas Operations, LLC	Delaware
Adamas Holdings, LLC	Delaware
Biscayne Neurotherapeutics, Inc.	Delaware

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (Nos. 333-181479, 333-201049, 333-216135, 333-239459, and 333-257392) on Form S-8 of Supernus Pharmaceuticals, Inc. of our report dated April 13, 2022, with respect to the consolidated balance sheets of Supernus Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Baltimore, Maryland
April 13, 2022

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

i 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: April 13, 2022

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

EXHIBIT 31.2

CERTIFICATION

I, Timothy C. Dec, 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: April 13, 2022

By: /s/ TIMOTHY C. DEC

Timothy C. Dec

Senior Vice-President and Chief Financial Officer

EXHIBIT 32.1

SUPERNUS PHARMACEUTICALS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. sec. 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Supernus Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2021 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: April 13, 2022

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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy C. Dec, Senior 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: April 13, 2022

By: /s/ TIMOTHY C. DEC
Timothy C. Dec
Senior Vice-President and Chief Financial Officer

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BOARD OF DIRECTORS

Charles W. Newhall, III
Chairman of the Board
Co-founded New Enterprise Associates, Inc. (retired)

Carrolee Barlow, M.D., Ph.D.
Chief Medical Officer of E-Scape Bio

Frederick M. Hudson
Partner KPMG, LLP (retired)

Jack A. Khattar
President, Chief Executive Officer and Secretary of Supernus Pharmaceuticals, Inc.

John M. Siebert, Ph.D.
Director Riverside Pharmaceuticals

Georges Gemayel, Ph.D.
Executive Chairman of Gemini Therapeutics

CORPORATE HEADQUARTERS

Supernus Pharmaceuticals, Inc.
9715 Key West Avenue
Rockville, MD 20850

STOCK LISTING

NASDAQ: SUPN

EXECUTIVE OFFICERS

Jack A. Khattar
President, Chief Executive Officer and Secretary

Timothy C. Dec
Senior Vice President, Chief Financial Officer

Padmanabh P. Bhatt, Ph.D.
Senior Vice President, Intellectual Property, Chief Scientific Officer

Tami T. Martin, R.N., Esq.
Senior Vice President Regulatory Affairs

Frank Mottola
Senior Vice President Quality, GMP Operations and Information Technology

Jonathan Rubin, M.D.
Senior Vice President, Chief Medical Officer, Research and Development

TRANSFER AGENT / REGISTRAR

Computershare
www.computershare.com

Shareholder Correspondence:

Computershare Trust Company,N.A.
P.O. Box 505000
Louisville, KY 40233

Overnight Correspondence:

Computershare Trust Company, N.A.
462 South 4th Street, Suite 1600
Louisville, KY 40202

OUTSIDE COUNSEL

Saul Ewing Arnstein & Lehr LLP
1919 Pennsylvania Avenue N.W.
Suite 550
Washington, D.C 20006

AUDITORS

KPMG LLP
750 East Pratt Street
Baltimore, MD 21202

ANNUAL MEETING

The annual meeting of shareholders will be held on June 17, 2022 at 10:00 A.M. EDT. The virtual only meeting may be accessed at meetnow.global/M59NRDM

FORM 10-K

The Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission and other information may be obtained without charge by writing, phoning or visiting our website:

Supernus Pharmaceuticals, Inc.
9715 Key West Avenue
Rockville, MD 20850
(301) 838-2500
www.supernus.com