Dear Supernus Stockholder,

We are very pleased with our performance in 2023 as we continued to successfully transition from our mature brands and set the stage to deliver growth in 2025 and beyond. Supernus finished the year in a position of strength with both Qelbree® and GOCOVRI®—our two growth products—achieving record sales with strong prescription growth. Our performance underscored our strong execution and emphasis on growing our revenue base despite the loss of exclusivity on Trokendi XR®. I am very proud of what the Supernus team continues to accomplish scientifically, commercially, and operationally putting Supernus in the best possible position to execute on a successful transition.

Excluding Trokendi XR, Supernus delivered strong growth of 26% in total revenues in 2023 compared to 2022. Specifically, our growth products, Qelbree and GOCOVRI, delivered robust 57% growth in combined net sales compared to 2022. In addition, combined full year 2023 net sales for Qelbree and GOCOVRI reached approximately $260 million, which significantly exceeded the $167 million decline in net sales of Trokendi XR. As a result of our emphasis on growing the rest of our portfolio throughout 2023, we were able to significantly mitigate the impact of reduced net product sales of Trokendi XR, with its net product sales representing less than 13% of total revenues during the last quarter of 2023.

In 2023, the Company held an R&D Day sharing an overview of its emerging CNS pipeline of novel product candidates and highlighting an exciting pipeline of new chemical entities, some of which are first-in-class mechanisms of action to treat multiple therapeutic areas in CNS. These product candidates include SPN-820 that is currently in Phase IIb for the treatment of depression, and SPN-817 that is in Phase IIa for the treatment of epilepsy.

Qelbree®—A Novel Non-Stimulant ADHD Product

2023 represented the first full year with both the pediatric and adult indications for Qelbree. We launched Qelbree in 2021 with the pediatric indication and expanded the market opportunity by launching in 2022 with the adult indication. As a well-differentiated product that is a non-controlled medication, Qelbree provides a novel and unique treatment option for the millions of patients who suffer from ADHD. Qelbree addresses a multi-billion-dollar market opportunity between pediatrics and adults and continues to show great potential to grow in both segments.

For full year 2023, Qelbree's prescriptions as reported by IQVIA increased 91% compared to 2022, while net sales recorded an even stronger growth rate of 129% benefiting from the prescription growth and the steady improvement in gross to net throughout the year. In 2024, we will be placing more emphasis on the adult segment that represents approximately 67% of the total ADHD market. We expect the ADHD market to have a prescription growth rate in line with the 3% growth rate it had in 2023 when it reached an all-time high of 93.4 million annual prescriptions.

Additional Highlights and Achievements in 2023

We continue to be pleased with the performance of GOCOVRI based on its unique position in the marketplace treating both off episodes and dyskinesia. In 2023, prescriptions increased by 10% compared to 2022 and net sales increased by 15% reaching a record of $120 million. Oxtellar XR® and APOKYN® net sales were $113 million and $75 million, respectively for full year 2023, essentially stable compared to 2022. In addition, we look forward to working with the U.S. Food and Drug Administration in 2024 to address the Complete Response Letter we received in April 2024 and to successfully resubmit the New Drug Application (NDA) for SPN-830, our investigational apomorphine infusion device for the continuous treatment of motor fluctuations ("off" episodes) in Parkinson's disease (PD). SPN-830 represents a third potential future growth driver for the Company.

2024 Key Milestones

We finished 2023 in a position of strength with both Qelbree and GOCOVRI achieving record sales with strong prescription growth. We believe we are well positioned for continued growth beyond the current transition and are focused on three key strategic areas:

- Driving significant growth with Qelbree and GOCOVRI, and together with the rest of the portfolio, generating strong cash flow allowing us to continue our investments in our pipeline.
- Working towards resubmission of the NDA for SPN-830.
- Advancing our innovative R&D portfolio of differentiated, first-in-class molecules that has several exciting and upcoming clinical milestones.

We will also continue to be active in looking for strategic opportunities in corporate development with the goal of further strengthening our future growth and leadership position in CNS. This includes in-licensing products, co-development partnerships for novel pipeline products and growth opportunities through value-creating and transformative merger and acquisition transactions.

2023 was an important year for Supernus, with significant corporate achievements that will prepare us for the next step as a growth company. We look forward to driving growth behind Qelbree, GOCOVRI and our pipeline products, and successfully managing our transition away from our legacy products.

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

Sincerely,

Jack A. Khattar,
President & Chief Executive Officer 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, 2023

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	**(301) 838-2500**	**20850**
(Address of Principal Executive Offices)	(Registrant's telephone number, including area code)	(zip code)

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

TITLE OF EACH CLASS:	Outstanding at February 20, 2024	Trading Symbol	NAME OF EACH EXCHANGE ON WHICH REGISTERED:
Common Stock, $0.001 Par Value	54,734,956	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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, 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 $1,639,709,489.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2024 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 2023 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, 2023

TABLE OF CONTENTS

Unless the content requires otherwise, the words "Supernus," "we," "our" and "the Company" refer to Supernus Pharmaceuticals, Inc. and/or one or more of its subsidiaries, as the case may be. These terms are used solely for the convenience of the reader. Supernus Pharmaceuticals, Inc. and each of its subsidiaries are distinct legal entities. For example, MDD US Operations, LLC, a wholly-owned indirect subsidiary of Supernus Pharmaceuticals, Inc., is the exclusive licensee and distributor of APOKYN in the United States and its territories. Adamas Operations, LLC ("Adamas Operations"), a wholly-owned indirect subsidiary of Supernus Pharmaceuticals, Inc., wholly owns the patents and patent applications related to GOCOVRI and Osmolex ER and has a license agreement with Supernus Pharmaceuticals, Inc., granting Supernus Pharmaceuticals, Inc. rights to market and sell GOCOVRI and Osmolex ER.

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 U.S. Food and Drug Administration (FDA) concerning the New Drug Applications (NDA) for SPN-830, the outcome of any additional device testing associated with the SPN-830 NDA submission, the potential approval of SPN-830 following resubmission, and the potential benefits and commercialization of 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; 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, 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 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.

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 marketed products.
- *Advance product candidates toward commercialization.* Several product candidates in our pipeline are in early-to-late stage clinical testing, and moving toward being commercially available to patients.
- *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:

Qelbree®

Qelbree (viloxazine extended-release capsules) is a novel non-stimulant product indicated for the treatment of ADHD in adults and pediatric patients 6 years and older. 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, the Company launched Qelbree for pediatric patients in the U.S. On April 29, 2022, the FDA approved Qelbree for treatment of ADHD in adult patients. The Company launched Qelbree for adult patients in May 2022.

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 these 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.

Oxtellar XR®

Oxtellar XR is indicated for treatment of partial-onset seizure in adults and children 6 years of age and older. 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-onset 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.

The Company has entered into settlement and license agreements with third parties permitting the sale of a generic version of Oxtellar XR beginning in September 2024, or sooner under certain conditions, and entitling the Company to receive royalties on those sales. For more information, refer to *Part I, Item I—Business—Intellectual Property and Exclusivity* in this annual Report on Form 10-K.

Trokendi XR®

Trokendi XR is indicated for (1) epilepsy: initial monotherapy for the treatment of partial-onset and primary generalized tonic-clonic (PGTC) seizure in patients 6 years of age and older (1.1); adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut Syndrome in patients 6 years of age and older (1.2); and for (2) preventive treatment of migraine in patients 12 years of age and older. 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.

The Company entered into settlement agreements with third parties permitting the sale of a generic version of Trokendi XR beginning in January 2023 and entitling the Company to receive royalties on those sales. For more information, refer to *Part I, Item I—Business—Intellectual Property and Exclusivity* in this annual Report on Form 10-K.

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.

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. XADAGO was approved by the FDA in March 2017.

The Company has entered into settlement agreements with third parties permitting the sale of a generic version of XADAGO beginning in December 2027, or sooner under certain conditions. For more information, refer to *Part I, Item I—Business—Intellectual Property and Exclusivity* in this annual Report on Form 10-K.

MYOBLOC®

MYOBLOC (rimabotulinumtoxinB) is a product indicated for the treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults and treatment of chronic sialorrhea in adults. MYOBLOC is the only Type B toxin available on the market. MYOBLOC injections must be administered by a physician.

MYOBLOC was approved by the FDA in August 2019 for the treatment of chronic sialorrhea in adults and in December 2000 for the treatment of adults with cervical dystonia.

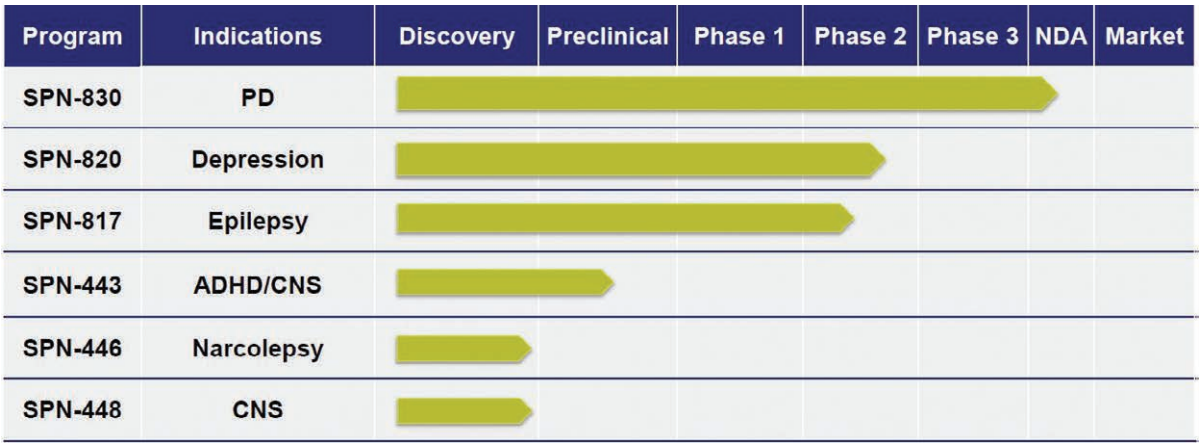
Osmolex ER®

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.

In December 2023, the Company submitted to the FDA a notification of discontinuance to withdraw Osmolex ER from distribution, stating that manufacturing has been discontinued and distribution of the product will cease by April 1, 2024.

Research and Development

We are committed to the development of innovative product candidates in neurology and psychiatry, including the following:



We also engage in a variety of additional research and development efforts including development of a pipeline of novel CNS product candidates for the treatment of various CNS conditions. 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 our intellectual property portfolio. Our expectations regarding our research and development programs are subject to the risks described under *Item 1A—Risk Factors—Risks Related to Our Industry and Business*, which includes the risk that the Company's financial condition and results of operations for fiscal year 2023 and beyond may be materially and adversely affected by delays and failures in the completion of clinical development of our product candidates, which could increase our costs or delay or limit our ability to generate revenues.

SPN-830 (apomorphine infusion device)

SPN-830 is a late-stage drug/device combination product candidate for the continuous treatment of motor fluctuations ("off" episodes) in PD patients that are not adequately controlled with oral levodopa and one or more adjunct PD medications. 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 slow infusion may also limit some of the side effects of a bolus injection of apomorphine.

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 was considered as a Standard Review and was assigned a PDUFA target action date in early October 2022. In October 2022, the FDA issued a Complete Response Letter (CRL) regarding the NDA for SPN-830. In February 2023, the FDA granted the Company a Type C meeting request to discuss the CRL with the meeting scheduled in April 2023. In October 2023, we resubmitted the NDA for SPN-830. In November 2023, the FDA accepted the resubmission of the NDA for SPN-830. The resubmission is now considered filed, with a user fee goal date (PDUFA date) of April 5, 2024.

SPN-820 (NV-5138)

SPN-820 is a first-in-class, orally active small molecule that activates the brain mechanistic target of rapamycin complex 1 (mTORC1), 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.

The mTORC1 activity governs the pace and ability of the cell to synthesize protein and other cellular components. This complex may be suppressed in people suffering from depression. 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.

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 mechanism of action (MOA) in depression may improve symptoms of depression in patients who have failed other agents.

An Investigational New Drug (IND) application was submitted to the FDA in September 2021. We initiated a Phase II multi-center, 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 270 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. Additionally, we initiated a Phase II multi-center open label study in 40 subjects with Major Depressive Disorder (MDD) in the fourth quarter of 2023. The study will evaluate the efficacy of SPN-820 in MDD, with the change from baseline in the Hamilton Depression Rating scale-6 (HAM-D6) total score as the primary efficacy assessment.

SPN-817 (huperzine A)

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

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.

We have commenced an open-label Phase IIa clinical study of SPN-817 in patients with treatment-resistant seizures.

SPN-443—Novel stimulant for the treatment of ADHD/CNS

We plan to initiate a Phase 1 single dose study in healthy adults in 2024 following submission of an Investigational New Drug Application. The primary objective of the study is to assess the safety and tolerability. This molecule, along with its major metabolites, is an inhibitor of norepinephrine, dopamine and serotonin, also known as a triple reuptake inhibitor.

Sales and Marketing

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

As a result of the acquisitions in 2021 and 2020, we established our commercial capabilities in the Parkinson's area with a focus on serving movement disorder specialists and other specialized health care providers in the U.S.

With the launches of Qelbree for both pediatric and adult patients, we expanded our sales efforts to market the commercial product to the relevant physician audience of psychiatrists, pediatricians, primary care physicians and allied health professionals. Our sales representatives who previously supported Trokendi XR and Oxtellar XR now devote their full efforts to the promotion of Qelbree.

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, GOCOVRI, and Osmolex ER are made to specialty pharmacies.

Each of our three major customers, Cencora, Inc., Cardinal Health, Inc., and McKesson Corporation, individually accounted for more than 20% of our total product revenue in 2023 and collectively accounted for more than 75% of our total product revenue in 2023.

Market and 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.

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 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, Concerta, Vyvanse, Intuniv, Kapvay and Strattera. Treatment options for ADHD in the U.S. market can be broadly classified as either stimulant or as non-stimulant products.

Our product, Qelbree is a novel nonstimulant taken once-daily for full-day exposure. Efficacy and symptom improvement was observed early in treatment in clinical studies. Also, it has a proven safety and tolerability profile, with no evidence of abuse potential in clinical studies. Qelbree is the first nonstimulant treatment for ADHD approved by the FDA in over a decade.

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. In addition, Trokendi XR's and Oxtellar 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. Extended-release products may help patients improve adherence and, consequently, help patients enjoy a better quality of life.

Trokendi XR competes with all immediate-release and extended-release topiramate products, including Topamax, Qudexy XR, and other generic topiramate products. Oxtellar XR competes with all immediate-release oxcarbazepine products, including Trileptal and its related generic products. Both Oxtellar XR and Trokendi XR compete with other anti-epileptic products, both branded and generic. Many medications are used to treat epilepsy, including topiramate, oxcarbazepine, acetazolamide, brivaracetam, carbamazepine, clobazam, lacosamide, phenytoin, valproic acid, lamotrigine, gabapentin, levetiracetam phenobarbital, and zonisamide.

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. 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 class of products first introduced in 2018; Botox; beta-blockers; valproic acid; and amitriptyline.

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.

The most commonly prescribed medicine for PD is levodopa. 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. 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. 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. 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. APOKYN competes with pro re nata therapies such as Inbrija, and other adjunctive therapies, including NOURIANZ. APOKYN also competes with other products for the treatment of PD, both branded and generic, including levodopa products.

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. The NDA for SPN-830 has been resubmitted and accepted for review by the FDA with a PDUFA date in April 2024.

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. 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. XADAGO competes with other MAO-B inhibitors used to treat "off" episodes in PD, including rasagiline (AZILECT) and selegiline (Zelapar and EMSAM). XADAGO also competes with other products for the treatment of PD, both branded and generic, including levodopa products.

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. 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. 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 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. 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.

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.

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.

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.

Manufacturing

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

We have agreements with CMOs headquartered in North America, including: Patheon Pharmaceuticals, Inc. (a subsidiary of Thermo Fisher Scientific Inc.), Packaging Coordinators, Inc., Aphena Pharma Solutions, and Catalent Pharma Solutions, Europe, and Asia for the manufacturing and packaging of some of our commercial products, including those of our subsidiaries, as well as for our pipeline product candidates. For Qelbree, Trokendi XR, GOCOVRI, and Oxtellar XR we currently rely on third-party CMOs for the manufacturing and packaging of final commercial products. We rely on third-party CMOs in Asia for the manufacturing of bulk drug substance for Trokendi XR and Oxtellar XR and rely on a third-party CMO in Europe for the raw materials and manufacturing of Qelbree and GOCOVRI. With respect to GOCOVRI, we have an additional manufacturer of bulk drug substance. These CMOs offer a comprehensive range of contract manufacturing and packaging services.

We purchase APOKYN, MYOBLOC, XADAGO, and Osmolex ER as finished goods. APOKYN is manufactured and packaged in Europe for the U.S. market and is supplied to us 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 in Europe 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 manufactured and packaged in Europe by Zambon S.p.A. (Zambon). Osmolex ER is manufactured and packaged in the U.S. 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—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* 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 New Chemical Entities (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 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, and GOCOVRI. 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.

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 the U.S., 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 the issued patents and the pending patent applications.

Trokendi XR

We currently have 10 U.S. patents that cover Trokendi XR. We own all 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 beginning in January 2023 and entitling the Company to receive royalties on those sales.

Oxtellar XR

Our extended-release oxcarbazepine patent portfolio currently includes 14 U.S. patents, 11 of which cover Oxtellar XR. The 11 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.

The Company has entered into settlement and license agreements with a third parties permitting the sale of a generic version of Oxtellar XR beginning in September 2024, or sooner under certain conditions, and entitling the Company to receive royalties on those sales.

XADAGO

The patent portfolio covering XADAGO has three U.S. patents licensed from Zambon. These patents will expire from 2027 to 2031.

The Company has entered into settlement agreements with third parties, permitting the sale of a generic version of XADAGO beginning in December 2027, or earlier under certain circumstances.

GOCOVRI

The patent portfolio covering GOCOVRI includes 18 U.S. patents. We have additional pending applications containing method and composition claims relating to the pharmacokinetic profile and dosing, and formulations of amantadine extended release. The issued patents expire through 2038. These patents and patent applications are 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 amantadine extended release.

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 covered for its FDA-approved indications by 18 issued U.S. patents and additional applications containing method and composition claims relating to the pharmacokinetic profile and dosing, and formulations of amantadine extended release. These issued patents expire through 2038. These patents 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.

SPN-830 (apomorphine infusion device)

Our SPN-830 development program is potentially eligible to receive the Orphan Drug Designation in the U.S. The Company plans to file for such designation with the FDA in 2024. 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 one patent issued in the U.S., and in China and certain other countries relating to extended-release formulations of huperzine. We additionally have pending patent applications in the U.S. and certain foreign countries.

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.

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 used 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.

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.

Alternatively, a patent's term may be shortened if a patent is terminally disclaimed over another patent. The mechanism for doing this is the filing by the applicant of a terminal disclaimer in order to overcome an issue of obviousness type double patenting. Obviousness-type double patenting is a bar to patentability that is present when a patent application is deemed to be an obvious variant of a separate patent also assigned

to the applicant. The filing of a terminal disclaimer overcomes the issue which may allow a patent application to issue or preserve the validity of a patent but disclaims any portion of the second patent that extends beyond the expiration of the first patent and prevents the assertion of either patent against a defendant unless the patents are co-owned. Because the filing of a terminal disclaimer is within the control of a patent, patent applicants generally avoid filing them when doing so would have a material adverse impact on the applicant's interests.

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.

Collaborations and Licensing Arrangements

We, including our subsidiaries, obtained exclusive licenses from third parties for proprietary rights to support our, and our subsidiaries', commercial products and product candidates. Under these in-licensing 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 out-licensing agreements to license our intellectual property and technology or that of our subsidiaries to third parties. Under these out-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 pay Britannia a royalty 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. 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 by the Company in the U.S. 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. certain product that compete with XADAGO. Also, 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 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 a third party resulting in us owning the worldwide rights to MYOBLOC in exchange for us paying a low double digit royalty based on U.S. annual net sales of MYOBLOC. We make royalty payments to Elan Pharmaceuticals, LLC, a subsidiary of Perrigo Pharma International DAC. While we currently have no intention of seeking approval in the U.S. for cosmetic use, if MYOBLOC is so approved, a milestone payment would be due and the royalty rate will become subject to certain reductions based on cosmetic use net sales. We also have the right under the agreement to make use of, develop and offer for sale worldwide products containing Botulinum Toxin Type B. The agreement may not be terminated for convenience.

In June 2023, we terminated the agreement with Elan and Eisai related to the marketing and distribution of NerBloc in Japan by Eisai.

We have a contract manufacturing agreement with Merz Pharma GmbH & Co. KGaA (Merz) for the manufacture and supply of MYOBLOC 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). 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. In December 2023, the Company submitted to the FDA a notification of discontinuance to withdraw Osmolex ER from distribution, stating that manufacturing has been discontinued and distribution of the product will cease by April 1, 2024.

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 to NV-5138 on mTORC1 in the central nervous system.

See *Part II, Item 8, Financial Statements and Supplementary Data*, Note 4, *Investments*, in the Notes to the Consolidated Financial Statements.

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 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.

License Agreements with Other Third Parties

The Company has granted other companies, including United Therapeutics Corporation and Takeda Pharmaceuticals Company Ltd., rights to utilize certain of its proprietary technologies in the development of certain of their products. These technologies were used by these companies to develop certain other products, including Orenitram (treprostinil) and Mydayis. We receive royalties under these arrangements based on net product sales of certain products developed using the licensed technologies. In some cases, we are also entitled to milestone payments.

With respect to Oxtellar XR, Trokendi XR, and Qelbree, we have entered into collaboration and licensing agreements with third parties to commercialize these products outside of the U.S. Under certain licensing arrangements, we are eligible to receive royalties based on net product sales as defined in the agreements and in some cases, we are also entitled to milestone payments. We currently receive royalties from third parties related to agreements for Trokendi XR.

The Company has also entered into settlement and licensing agreements with generic companies to settle patent litigation and to grant non-exclusive licenses to market generic versions of Trokendi XR and Oxtellar XR in the U.S. Under certain licensing arrangements, the Company is eligible to receive royalties based on net product sales as defined in the and the number of generic equivalent products on the market in the U.S. We currently receive royalties from third parties related to certain agreements for Trokendi 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. If clinical testing is to initiate

in the United States, 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 becomes effective following a waiting period, we may not start the clinical trials. This is typically followed by additional preclinical laboratory and animal testing, and adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use. The satisfaction of FDA approval requirements typically takes many years. The actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

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

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

- Phase I—Involves the first human tests of the drug, in a small number of healthy volunteers or in patients, to assess safety, tolerability, potential dosing, and if possible, early evidence on effectiveness.
- Phase II—Involves trials in a relatively small group of patients to determine the effectiveness of the drug for a particular indication(s); dosage tolerance, and optimum dosage; and to identify common adverse effects and safety risks.
- Phase III—Involves tests confirming favorable results in earlier phases, in a significantly larger patient population, and to further demonstrate efficacy and safety. 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 not only the objectives of the trial, but also the parameters to be used in monitoring safety of study participants, and/or 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 or Biological License Application (BLA) (hereinafter "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. Most NDAs are subject to a substantial user fee at the time of submission; rarely applications meet conditions or gain a waiver which negates the need for the user fee. A holder of an approved NDA may also be subject to annual program and/or establishment 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. Sponsors will be notified if the application's review will proceed. 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. A priority review designation means FDA's goal is to take action on an application within six months, compared to 10 months under standard review. The review process may be extended by the FDA for their initial review, and, if new information submitted during the review, the review period may be extended.

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 timely 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 may rely on a recent inspection of the facility, or they may decide to 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, as a condition to product approval, the FDA may require substantial post-marketing 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. Certain of the Company's commercial products have post-marketing commitments.

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 or post approval marketing of commercial use.

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 adverse events 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 Federal Food, Drug, and Cosmetic Act (FDCA) can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain 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 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), which are 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, with the final Reporting Period ending in April 2024, and imposes material burdens on the Company, its officers and directors to take actions designed to ensure 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. Effective with the 2022 report filing, 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 the 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 the federal government, the states, and certain foreign governments 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 for 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 I, 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 Inflation Reduction Act of 2022 ("IRA") includes measures intended to lower the cost of prescription drugs and related healthcare reforms, such as limits on price increases and subjecting an escalating number of drugs to annual price negotiations with CMS. Specifically, the IRA authorizes and directs HHS to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs announced on August 29, 2023. The negotiated maximum fair prices for such drugs is scheduled to be announced by September 1, 2024, with the first year of maximum price applicability to begin in calendar year 2026. The IRA also authorizes HHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. The IRA also creates significant changes to the Medicare Part D benefit design by capping Part D beneficiaries' annual out-of-pocket spending.

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.

Over the past several years an increasing number of U.S. states have passed, or are in the process of passing, new regulations designed to increase pricing transparency associated with pharmaceutical manufacturers. Many states have determined that it's in their preferred interest to take legislative action in order to curb drug price increases and to decrease their annual pharmaceutical spend. This momentum is likely to continue in the years ahead. Many of the enacted state price transparency regulations fall into the following categories: advance notice of price increases; price increase reporting; periodic price reports; new drug reporting; price information disclosures to Health Care Professionals and state agencies. The potential penalties for noncompliance vary by state regulation. While certain regulations do not contain specific penalty clauses, most do and can contain penalties that can be significant per violation for noncompliance.

Environmental Matters

Our operations and those of our third-party manufacturers and suppliers are subject to national, state and local environmental laws. We have made, and intend to continue to make, expenditures and undertake efforts to comply with applicable laws. We believe the safety procedures utilized by us for the handling and disposing hazardous materials comply with the standards prescribed by applicable laws and regulations.

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, 2023, we employed 652 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, 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. 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.

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 was 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 is focused on generating, maintaining and/or expanding the revenue generated by our approved products in the U.S. Our major products Qelbree®, GOCOVRI®, Oxtellar XR®, and APOKYN®, represented approximately 24%, 21%, 20%, and 13% of our total net revenues for the year ended December 31, 2023, respectively. If any of our major products, including 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. As noted in the "Business" section of this report, sales of a generic version of Trokendi XR® began in January 2023 and those competitive products have significantly impacted the sales of Trokendi XR and have had an adverse impact on our revenue and profit. 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 do not appear to be related to the drug itself. Any safety issues could cause us to suspend or to cease marketing of our approved products; cause us to modify how we market our approved products; subject us to substantial liabilities; and adversely affect our revenues and financial condition. In the event of a withdrawal of 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 generics or other versions of our products including generics containing oxcarbazepine. topiramate, apomorphine hydrochloride, amantadine, safinamide 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 Company has entered into settlement agreements with third parties permitting the sale of a generic version of Trokendi XR on January 1, 2023. Sales of generic versions of Trokendi XR® began in 2023. The Company has also entered into settlement and license agreements with third parties permitting the sale of the first generic version of Oxtellar XR beginning in September 2024, or sooner under certain conditions, and entitling the Company to receive royalties on those sales. The Company has also entered into settlement and license agreements with third parties permitting the sale of the first generic version of XADAGO beginning in December 2027, or sooner under certain conditions. We have the right to defend our products against third parties who may infringe or are infringing our patents.

Other third parties in the future may receive approval to manufacture and market their own versions of extended-release oxcarbazepine or generics of Oxtellar XR 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 a generic or 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 APOKYN.

If any third party is successful in obtaining approval to manufacture and market a generic or its own version of safinamide in the U.S., we may not be able to prospectively realize revenues from XADAGO.

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 Qelbree 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 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. 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.

We expect that private insurers and managed care organizations will consider the efficacy, cost effectiveness, and safety of our products or product candidates 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.

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 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.

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. For additional information, see "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." 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.

As evidenced by the passage of the American Rescue Plan Act of 2021 and IRA of 2022, discussed in greater detail below, we expect these challenges to continue and to potentially intensify in 2024 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.

We depend on wholesalers, distributors, and specialty pharmacies for the 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 Qelbree, 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, Cencora, Inc., Cardinal Health, Inc., and McKesson Corporation, individually accounted for more than 20% of our total product revenue in 2023 and collectively accounted for more than 75% of our total product revenue in 2023.

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 expanding our sales and marketing capabilities in the U.S. to commercialize new 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 new 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 a new product candidate, we may re-prioritize our marketing and sales efforts, including reassigning our sales representatives who support existing products to devote their full efforts to the launch of the new product candidate. This could have a detrimental impact on the future sales performance of existing products.

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 for many reasons. For example, the FDA

- Could reject or delay the marketing application for an NCE;
- Could determine that we cannot rely on Section 505(b)(2) for any approval of our product candidates;
- Could determine that the information provided by us was inadequate, contained clinical deficiencies, or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for a specific indication;
- May not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S.;
- May find the clinical and other benefits of our product candidates do not outweigh their safety risks;
- May disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies, and/or clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our trials; the outcome and measurement scale used in the trials; or the clinical protocols whether with or without a special protocol assessment process;
- May determine that we have identified the wrong reference listed drug or drugs, or that approval of our Section 505(b)(2) application of our product candidate is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;
- May identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of raw materials, including the active pharmaceutical ingredient (API) or formulated product used in our product candidates, wherein those deficiencies may result in a delay in obtaining FDA approval or in an interruption in the ability to supply product;
- Could reject or delay approval of a "prior approval supplement" required prior to distribution of the drug product made using changes that may impact product quality, identity strength, purity, or potency (i.e., major changes);
- 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.

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 during February 2022. In October 2022, we received a Complete Response Letter ("CRL") from the FDA regarding the NDA for SPN-830 requesting additional information and analysis related to the infusion device and drug product across several areas of the NDA. In October 2023, the Company resubmitted its NDA for SPN-830. In November 2023, the FDA acknowledged it received the resubmitted NDA for SPN-830 and assigned PDUFA target action date in early April 2024.

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, and the manufacture of our commercial products. 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 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 materials 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 currently own or operate manufacturing facilities for the commercial production of any of our products or for production of clinical supplies of our product candidates, nor do we have plans to do so in the 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 raw materials and drug substances for our preclinical research and clinical trials. For most of our products and product candidates, we rely on single source suppliers to produce and package final dosage forms for our products and raw materials, including API. 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.

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 or geopolitical events affecting our suppliers. At this time while we do not know of any geopolitical events impacting our supply chain, we cannot determine the impact of current or future geopolitical events which may ultimately have an impact on our supply chains or may 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., as is the case for example for SPN-830, Qelbree, 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 and their suppliers 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 all 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.

Currently, the Company has a five-year and seven-year marketing exclusivity period for Qelbree and GOCOVRI, respectively.

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 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, certain of our products, including Qelbree, Trokendi XR, Oxtellar XR and MYOBLOC, were approved on the basis of post-approval commitments.

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 toward meeting these post-marketing commitments for Qelbree in a timely manner.

We have post-marketing commitments for Trokendi XR, Oxtellar XR, and MYOBLOC. Although we have initiated work on some of these post-marketing commitments, we have not been able to accomplish them. 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.

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 discover 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, revenues, and profits.

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 unable to adapt on a timely basis, or at all, to changes in existing requirements or to adopt new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we have obtained, adversely affecting our business, prospects, and ability to achieve or sustain profitability.

We depend on collaborators to work with us to develop, manufacture and commercialize their and our products and product candidates. We have 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 the benefit of such collaborative relationships, including licenses or intellectual property rights.

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 other commercial products and the API for such products. 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. The Company is eligible to receive, and has received royalties under this agreement based on net product sales of United Therapeutics Corporation's product, Orenitram (treprostinil). We are entitled to receive milestones and royalties for the use of this formulation in indications other than arterial hypertension.

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 and Forest Laboratories Holdings Limited ("Forest"), an indirect, wholly-owned subsidiary of Allergan plc (collectively, "Allergan") in the United States. Adamas Pharmaceuticals LLC receives royalties on net sales of Namzaric.

We rely on third-party collaborators and strategic partners to market and commercialize our products and product candidates outside the U.S. We are party to and rely on several arrangements with third parties which provide us with rights to intellectual property 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, of if third parties fail to adequately perform their respective obligations, these arrangements could be terminated which could result in our inability to develop, manufacture, market and sell products that are covered by such intellectual properties. We may not have sufficient resources to successfully establish future collaborations or license future 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.

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.

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 longer 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.

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

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

In 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. In October 2022 we received a CRL from the FDA regarding the NDA for SPN-830 requesting additional information and analysis related to the infusion device and drug product across several areas of the NDA. In October 2023, the Company resubmitted its NDA for SPN-830. In November 2023, the FDA acknowledged it received the resubmitted NDA for SPN-830 and assigned a PDUFA target action date in early April 2024.

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.

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.

Additionally, the current inflationary environment, unstable economic conditions and geopolitical events may delay our trials or significantly increase our product development costs.

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. As required by the FDA, the labels for our products include precautions and warnings about side effects, and in certain cases, the need for monitoring patients receiving the product.

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. and certain states have shown significant, increased interest in pursuing healthcare reform and changes to the healthcare delivery system. Numerous major markets outside the US, including the EU, Japan, and China, have widespread governmental involvement in healthcare funding, including with regard to pricing and reimbursement of pharmaceuticals. 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 the Company's ability to set prices at launch, increase prices after launch, generate revenues, achieve profitability, and/or maintain profitability. In addition to healthcare reform initiatives in the U.S. and in other countries, there are (i) new laws, regulations, and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (ii) changes in intellectual property laws; (iii) changes in accounting standards; (iv) new and increasing data privacy regulations and enforcement; (v) legislative mandates or preferences for local manufacturing of pharmaceutical products; and (vi) emerging and new global regulatory requirements for reporting payments and other value transfers to healthcare professionals. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial condition and prospects of the Company. The Company believes that the healthcare industry will continue to be subject to increasing regulation as well as legal and political action, as future proposals to reform the healthcare system are considered by the U.S. Executive branch, Congress, and state legislatures.

In March 2010, a comprehensive change to the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010 (ACA) was enacted, as amended by the Health Care and Education Reconciliation Act of 2010. These laws and their regulations (collectively "HealthCare Reform Law") have far reaching consequences for pharmaceutical companies like the Company. Possible revisions to the HealthCare Reform Law are the subject of ongoing legislative debates and litigation.

The HealthCare Reform Law exerts 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 the Company's 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. On December 21, 2020, the Centers for Medicare & Medicaid Services (CMS) 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, and provide funding for such research.

In 2021 the American Rescue Plan Act ("ARPA") was signed into law, which includes a provision eliminating the statutory cap on rebates that drug manufacturers pay to Medicaid beginning in January 2024. These rebates function as a discount off the list price and eliminating the cap means that manufacturer discounts paid to Medicaid can increase. Prior to this change, manufacturers have not been required to pay more than 100% of the Average Manufacturer Price ("AMP") in rebates to state Medicaid programs for Medicaid-covered drugs. As a result of this provision, beginning in 2024 it is possible that manufacturers may have to pay state Medicaid programs more in rebates than they receive on sales of particular products. This change could present a risk to the Company in the future for drugs that have high Medicaid utilization and rebate exposure that is more than 100% of the AMP. ARPA may push certain pharmaceutical manufacturers to reconsider pricing strategies and overall business in Medicaid and other federal programs.

In 2022 the IRA was enacted, which made significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028.

Additional changes to the HealthCare Reform Law include The American Taxpayer Relief Act of 2012, which 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 addition to those changes discussed above, in recent years there have also 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.

Executive orders have changed certain provisions of the HealthCare Reform Law, while other provisions have been subject to court challenges. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the HealthCare Reform Law, brought by several states, without specifically ruling on the constitutionality of the HealthCare Reform Law. Prior to the U.S. Supreme Court ruling, President Biden issued an executive order instructing certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create barriers to obtaining access to health insurance coverage through Medicaid or the HealthCare Reform Law. Congress may consider other legislation to repeal or replace elements of the HealthCare Reform Law. It is difficult to predict the extent to which any of these changes to the HealthCare Reform Law, or additional changes if made, may impact the Company's business or any financial condition.

The Company's activities, including research, preclinical testing, clinical trials, and the manufacturing and marketing of its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the U.S., including the FDA, and by foreign regulatory authorities. In the U.S., the FDA administers requirements covering the testing, approval safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals and vaccines. In some instances, the FDA requirements have increased the amount of time and resources necessary to develop new products and bring them to market in the U.S. FDA statutes, regulations, and guidance often are revised or reinterpreted by the FDA in ways that may significantly affect the Company's business and products.

The FDA Reauthorization Act of 2017 (FDARA) amended the FDCA to revise and extend the user-fee programs for drugs, medical devices, generic drugs, and biosimilar biological products, and for other programs. FDARA reauthorized the various user fees to facilitate the FDA's review and oversight relating to prescription drugs, generic drugs, medical devices, and biosimilars. FDA's authority, including, among others, pediatric study requirements, orphan drug exclusivity, and the approval process for generic drugs.

The FDA also has enhanced its post-marketing authority, including the authority to require post-marketing studies and clinical trials, make labeling changes based on new safety information, or to require compliance with risk evaluation and mitigation strategies. 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 increase costs during product development and regulatory review. It could also result in increased costs to assure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of any approved product. 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 the Company to maintain or attain approval to develop and commercialize its products and technologies.

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.

The Company's products are dependent on 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 the Company develops a promising new product, there may be limited demand for the product unless appropriate reimbursement approval is obtained from private and governmental third-party payors. Additional legislative or administrative reforms to the reimbursement systems in the U.S. and other countries that significantly reduce reimbursement for the Company's 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 the Company's business, financial condition or results of operations.

Certain U.S. states have become increasingly active in enacting statutes 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, which creates additional compliance challenges for the Company. 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 increasingly are 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 the Company's business, results of operations, financial condition, and prospects. These price controls could prevent the Company from being able to commercialize its products or to generate an acceptable return on its investment.

Other U.S. healthcare cost containment statutes include:

- The 2013 Drug Quality and Security Act (DQSA), which 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, the Compounding Quality Act, increased regulation of compounding drugs. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA) established requirements to facilitate improved tracking of prescription drug products through the supply chain with increased product identification requirements. DSCSA 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 during the fourth quarter of 2023. In August 2023, FDA announced final guidance pertaining to Title II, entitled "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies." This guidance describes FDA's compliance policies for enforcement of requirements for the interoperable, electronic, package level product tracing (enhanced drug distribution security requirements) under the Federal Food, Drug, and Cosmetic Act (FDCA), effective November 27, 2023.

- In 2016, the 21st Century Cures Act (Cures Act) was enacted and authorized increased funding for the FDA to spend on innovation projects, amended the Public Health Service Act (PHSA) to reauthorize and expand funding for the National Institutes of Health (NIH), established the NIH Innovation Fund to pay for the cost of development and implementation of a strategic plan, early stage investigations, and research; and charged the NIH with leading and coordinating expanded pediatric research. The Cures Act also directed the Centers for Disease Control and Prevention to expand surveillance of neurological diseases. There often are delays between the enactment of laws and the effective date of regulations for the enforcement of laws, and this was the case for the Cures Act. Although enacted in 2016, the Department of Health and Human Services (HHS), Office of Inspector General (OIG) did not publish a final rule amending the civil money penalty (CMP) regulations of HHS OIG until July 3, 2023. This final rule implements three statutory provisions: (1) the amendment of the PHSA by the Cures Act authorizing OIG to investigate claims of information blocking; (2) the amendment of the Civil Monetary Penalties Law (CMPL), authorizing HHS to impose CMPs, assessments, and exclusions upon individual and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements; and (3) the increase in penalty amounts in the CMPL effected by the Bipartisan Budget Act of 2018 (BBA 2018).
- The IRA includes measures intended to lower the cost of prescription drugs and related healthcare reforms, such as limits on price increases and subjecting an escalating number of drugs to annual price negotiations with CMS. Specifically, the IRA authorizes and directs HHS to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs announced on August 29, 2023. The negotiated maximum fair prices for such drugs is scheduled to be announced by September 1, 2024, with the first year of maximum price applicability to begin in calendar year 2026. The IRA also authorizes HHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. In February 2023, HHS released guidance on the implementation of the new Medicare Prescription Drug Inflation Rebate Program, and in June 2023, HHS and CMS announced a list of 43 prescription drugs for which Part B beneficiary coinsurances may be lower between July 1, 2023 and September 30, 2023. The IRA also creates significant changes to the Medicare Part D benefit design by capping Part D beneficiaries' annual out-of-pocket spending. In May 2023, CMS released a draft guidance and request for comment regarding the new Part D Manufacturer Discount Program, set to begin in calendar year 2025. HHS and CMS are continuing to announce drugs for price negotiation, produce draft guidance, and finalize regulations in an effort to implement to IRA. The Company cannot predict whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of the Company's products. There also may be future changes unrelated to the IRA that result in reductions in potential coverage and reimbursement levels for the Company's products, and we cannot predict the scope of any future changes or the impact that those changes may have on its business.

Future healthcare reform measures may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that the Company receives 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 the Company's product candidates or additional pricing pressures and may prevent the Company from being able to generate revenue, attain profitability or commercialize its drugs.

Future healthcare reforms in the U.S. and in other countries could limit the prices that can be charged for the Company's products and product candidates or may otherwise limit its commercial opportunities. The Company cannot predict what additional future changes in the healthcare industry in general, or the pharmaceutical industry in particular, will occur; however, any changes could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition, and prospects.

Any failure to comply with healthcare regulations, including implementation of any change in compliance with healthcare regulations and laws could cause us to incur significant compliance expenses and any failure to comply could subject us to substantial penalties and fines. 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 continue to 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 to which we are subject include the HealthCare Reform Law and others discussed below.

The assessment of the financial impact of the HealthCare Reform Law on the Company's business is on-going. There can be no assurance that the Company's business will not be materially harmed by future compliance with or changes to the HealthCare Reform Law.

The HealthCare Reform Law includes various provisions designed to strengthen fraud and abuse enforcement. These include increased 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 the Company's past or present operations are found to be in violation of any such laws or any other governmental regulations that may apply it, then the Company may be subject to penalties, both civil and criminal, damages, fines, exclusion from federal healthcare programs, and/or the curtailment or restructuring of its operations.

In addition, the Company could receive adverse publicity as a result of any such failure to comply with HealthCare Reform Law. Certain provisions of the HealthCare Law have not been fully interpreted by the regulatory authorities or the courts and certain provisions are subject to a variety of interpretations, which may complicate the Company's compliance with the HealthCare Laws. Any action against the Company for violation of the HealthCare Laws, even if successfully defended, could cause the Company to incur significant legal expenses and divert management's attention from the operation of its business.

The Company could be subject to allegations of healthcare fraud and abuse, as well as other violations of healthcare regulations by both the federal government and the states in which the Company conducts its business. Regulations include, but are not limited to:

- The federal healthcare program Anti-Kickback Statute (AKS), 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 federal AKS to have committed a violation. Further, the government may assert that a claim, including items and services resulting from a violation of the federal AKS, constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below. On December 2, 2020, additional AKS regulations were finalized and took effect in January 2021, which modified existing AKS safe harbors, created new AKS safe harbors, and created a new CMP law exception. Safe harbors protect certain arrangements from prosecution if each of the elements of the safe harbor is satisfied;

- The HHS OIG Special Fraud Alert published on November 16, 2020, which addresses the manufacturer Speaker Programs, and signals both a narrower government view of AKS compliance with respect to such programs as well as the potential for increased enforcement in the space by government oversight agencies such as OIG and the Department of Justice;
- 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;
- Federal physician payment transparency requirements under the ACA, commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report to HHS information related to physician payments, and to report other transfers of value, physician ownership, and investment interests;
- Federal price reporting laws, which require the Company 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 the Company's commercial products;
- The FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use, and regulates the distribution of drug samples;
- 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 the Company's business practices, including, but not limited to: (i) research, distribution, sales and marketing arrangements; (ii) claims for items or services reimbursed by any third-party payor, including commercial insurers; (iii) 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; and (iv) state laws that otherwise restrict payments that may be made to healthcare providers. Many of these state laws differ from one another in significant ways and often are not preempted by federal laws, thus complicating compliance efforts;
- Certain state laws require pharmaceutical companies to comply with voluntary compliance guidelines promulgated by a pharmaceutical industry association and relevant compliance guidance issued by HHS OIG, bar drug manufacturers from offering or providing certain types of payments or gifts to physicians and other healthcare providers, and/or require disclosure of gifts or payments to physicians and other healthcare providers;
- Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended (VHCA). If the Company's products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the VHCA, drug companies are required to offer certain pharmaceutical products at a reduced price to several federal agencies, including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service, and certain private Public Health Service—designated entities, in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations; and
- Similar healthcare laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

As a supplier of pharmaceuticals, certain U.S. federal and state healthcare laws and regulations pertaining to patients' rights to privacy apply to the Company's business. The Company could be subject to allegations

of patient privacy violations by both the federal government and the states in which the Company's conducts its business. Regulations include, but are not limited to:

- The 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 AKS, a person or entity does not need to have actual knowledge or specific intent to violate HIPAA in order to have committed a violation. On December 10, 2020, HHS released proposed modifications to the HIPAA Privacy Rule, which, if adopted, would change rules related to patient access to HIPAA protected records, among others. In 2021 OCR sought feedback on the proposed HIPAA changes. Publication of the Final Rule has not yet occurred;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (commonly referred to as the HITECH Act), which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information; and
- Various state and foreign laws also govern the privacy and security of health information in some circumstances, and many of these laws differ from each other in significant ways and often are not preempted by HIPAA.

Efforts to ensure that the Company's business arrangements will comply with applicable healthcare laws and regulations could be costly. If the Company's 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, then it may be subject to penalties, including civil and criminal penalties, damages, fines, and the curtailment, or restructuring of its operations. Any penalties, damages, fines, curtailment or restructuring of the Company's operations could adversely affect its ability to operate its business and could impair its financial results.

Although compliance efforts can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. The risk of violating a law can increase when governmental interpretations and rule-making necessitate operating changes. Any action against the Company for violation of these laws, even if successfully defended, could cause the Company to incur significant legal expenses and divert management's attention from the operation of its 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 that 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 have received Paragraph IV Notice Letters from generic drug makers directed to the Orange Book patents of several of our products. We have filed lawsuits against the generic drug makers and intend to vigorously enforce our intellectual property rights relating to our products.

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 with 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
- Incurring the costs and expending the time necessary to defend against such litigation; 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 and variety of claims and the amount of damages claimed in litigation against the pharmaceutical industry have increased. For example, in recent years we or our subsidiaries have been involved in litigations alleging violation of federal and state false claims acts and antitrust laws. For more information, refer to Part I, Item 3—*Legal Proceedings* contained in this Annual Report Form 10-K. 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 612 employees in 2022 to 652 employees in 2023. Our need to effectively execute our growth strategy requires that we:

- Manage regulatory approvals and clinical trials effectively;
- Manage our internal developmental efforts efficiently 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, train, and retain additional qualified personnel, particularly in an inflationary economic environment. 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. Security breaches and other disruptions could compromise our information and expose us to liability which would cause our business and reputation to suffer.

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. 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 identifiable personal information of our employees and patients in our clinical trials. Hardware, software, or applications we develop or procure from third parties or through open source solutions may contain defects in design or other problems that could unexpectedly compromise information security. Additionally, 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. Additionally, a cyberattack or security breach may remain undetected for an extended period of time, potentially escalating the adverse effects of any such incident.

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.

In response to a cyberattack or security breach, as was the case following the 2021 ransomware attack, we accelerated previously planned information technology investments in ways designed to improve our information security and technology infrastructure. We have incurred costs 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 our security measures, our information technology and infrastructure may be vulnerable to additional attacks breached due to employee error, malfeasance, or other disruptions. 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 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, 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.

While integrating acquired businesses and operations and upgrading the Company's information technology systems, we may face an elevated cybersecurity risk.

As of January 1, 2023, we have cyber insurance in addition to our business insurance coverage, however, prior to that time we self-insured by assuming the full risk of costs related to cybersecurity incidents. Such cyber insurance does not provide coverage for incidents that occurred before January 1, 2023. There can be no assurance that our insurance coverage will be sufficient to cover the full impact of a cyberattack or that it can be renewed in the future at favorable terms, or at all.

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. In our industry, during the current inflationary economic environment, compensation levels for qualified personnel and competition among employers to recruit and retain such personnel have and continue to increase.

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, Takeda Pharmaceutical Company Limited, 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 may be materially and adversely affected by health pandemics.

The COVID-19 and any future pandemic may result in workforce limitations and travel restrictions resulting from related government actions taken to contain the spread of the disease, any of which 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 pandemic, our operations may be negatively impacted. During a pandemic, government restrictions and social distancing guidelines may drive an increased reliance on working from home for our employees. For example, during the COVID-19

pandemic, the Company's sales force was 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, during a pandemic, 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 during a pandemic. As a result, during a pandemic, 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 a pandemic that cannot be predicted. For example, in its CRL related to SPN-830, the FDA noted that approval of the NDA for SPN-830 requires inspections that could not be completed in a timely manner due to COVID-19 travel restrictions. 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, any 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 a pandemic could result in a material adverse effect on the Company's business, results of operations, financial condition, and prospects in the near and long terms.

There can be no assurance that any of the Company's plans will be effective in mitigating the effects of a 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, license agreements, development milestones, and 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;
- Increased costs as a result of inflation, unstable economic conditions and geopolitical events, including increases in compensation and professional expenses, cost of goods sold, and research and development expenses;
- Changes in reimbursement environment and regulatory changes; and
- Changes in the size of our investment portfolio and interest rates.

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 is currently limited and may be limited further, under Sections 382 of the Internal Revenue Code. 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. Our acquired tax attributes are subject to Section 382 limitations. As of December 31, 2023, we had U.S. Federal net operating loss carryforwards of approximately $374.0 million. Future changes in stock ownership may also trigger an additional ownership change and, consequently, another Section 382 limitation.

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

In the past, we have 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 disclosures.

Although as of December 31, 2023 remediation has been completed, in the past we identified material weaknesses in our internal control over financial reporting as of December 31, 2021 which persisted, on a narrower basis, as of December 31, 2022. We successfully implemented measures designed to ensure that the control deficiencies contributing to the material weaknesses were remediated. However, if we are unable to 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, financial condition and the 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 in the future reveal 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. Failure to maintain effective internal control over financial reporting or disclosure controls and procedures or to remediate any material weakness, could result in a material misstatement of our consolidated financial statements that would require a restatement or other materially deficient disclosures. Therefore, 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 provisions related to internal control over financial reporting 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, such as 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 and 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 level.

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 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.

We have and may further expand our business through acquisitions of new product lines or businesses, which expose us to various risks, including difficulties in integrating acquisitions. Our recent acquisitions pose 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 Adamas Acquisition and USWM Acquisition, may involve a number of risks, the occurrence of which could adversely affect our business, reputation, financial condition, and operating results, including:

- Dilutive issuances of equity securities;
- Incurrence of additional debt and contingent liabilities;
- Increased amortization of expenses related to intangible assets;
- Difficulties in the integration of the operations, technologies, services, and products of the acquired companies;
- Diversion of management's attention from our other business activities;
- Assumption of debt and liabilities of the target company including 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 despite the existence of representations, warranties, and indemnities in any definitive agreement; and an inability to recover or manage such liabilities and costs;

- Possibility of incurring significant restructuring charges and amortization expense;
- Potential impairment to assets 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;
- 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.

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, represents a contractual right to receive a contingent payment of $0.50 per share in cash, 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 represents a contractual right to receive a contingent payment of $0.50 per share in cash, is payable upon achieving net sales of GOCOVRI of $225 million in any four consecutive quarters between closing and the end of 2025.

As part of 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.

In addition, the assets acquired from the acquisitions, which included intangible assets, were recorded at their estimated fair value at the applicable 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 applicable 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 applicable 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.

As part of the Adamas Acquisition and the USWM Acquisition, we acquired substantial intangible assets, including goodwill. We may not realize all the economic benefits from the acquisition, which could cause an impairment of goodwill or other intangibles. We review our intangible assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. For example, during the year ended December 31, 2023, the Company recognized impairment charges of $20.2 million mainly due to the partial write-off of the carrying value of some of its acquired intangible assets, primarily XADAGO. The primary factors that led to the impairment determinations were the following: (1) the performance of the commercial products; (2) forthcoming loss of exclusivity of XADAGO in December 2027, or earlier under certain circumstances, due to settlement agreements with third party generic companies; and (3) the change in the Company's future outlook of the brands. 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 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, 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 when it approved an application for drug cartridges for use with the APOKYN 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. In addition, the Company also has an indefinite-lived intangible asset associated with SPN-830. 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. Any adverse action by the FDA can potentially impact our estimated fair value of the IPR&D intangible asset. 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 other intangible assets is determined, negatively affecting our results of operations and equity book value, the effect of which could be material.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales and use or other tax laws or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws and regulations could be interpreted, modified or applied adversely to us. These events could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest and other costs for past amounts deemed to be due. New laws, or laws that are changed, modified or newly interpreted or applied, also could increase our compliance, operating and other costs, as well as the costs of our products. Further, the Tax Act enacted many significant changes to the U.S. tax laws, some of which were further modified by the Coronavirus Aid, Relief, and Economic Security Act, and may be modified in the future by the current of a future presidential administration. Among other changes, the Tax Act amended the Code to require that certain research and experimental expenditures be capitalized and amortized over five years if incurred in the United States or fifteen years if incurred in foreign jurisdictions for tax years beginning after December 31, 2021. Although the U.S. Congress has considered legislation that would defer, modify, or repeal the capitalization and amortization requirement, there is no assurance that such changes will be made. If the requirement is not deferred, repealed or otherwise modified, it may increase our cash taxes and effective tax rate. In addition, it is uncertain if and to what extent various states will conform to current federal law, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net operating losses, and other

deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets and could increase our future tax expense.

Our Credit Line is secured by a portfolio of marketable securities and we may be required to post additional collateral.

During the first quarter of 2023, we entered into the Credit Line, an uncommitted demand secured credit line with a financial institution for up to $150.0 million. The Credit Line, if the Company borrows against it, will be secured primarily by our portfolio of marketable securities, which is primarily comprised of corporate and U.S. government agency and municipal debt securities and may fluctuate in value. To the extent the value of the collateral decreases below the required collateral maintenance requirements we may be required to promptly post additional collateral. If we are unable to promptly post additional collateral, or reduce the level of borrowings pursuant to the Credit Line, the lender has the right, in its discretion, to liquidate, transfer, withdraw or sell all or any part of the collateral and apply the proceeds to repay the borrowings. The prices realized by the lender in a liquidation may be lower than the prices that would be realized if such securities were sold under ordinary circumstances or held to maturity.

Changes in interest rates could adversely affect the profitability of the Company by increasing our interest expense.

Borrowings pursuant to the Credit Line may be at variable or fixed rates. Although as of December 31, 2023 the Company does not have any borrowings from the Credit Line, it might do so in the future. To the extent the Company borrows funds pursuant to the Credit Line on a variable rate basis, the Company's debt obligation thereunder would be subject to changes in short-term interest rates. If interest rates were to increase, it would increase the Company's borrowing cost and it could reduce the Company's overall profitability.

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.

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. 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, 2023, we had retained earnings of approximately $482.6 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 new product candidates.

While we operated profitably in 2023, we cannot be certain that we will continue to 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.

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, 2023, we had outstanding 54,723,356 shares of common stock, of which approximately 2,331,839 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, 2023, we had outstanding options to purchase 6,583,822 shares of common stock that, if exercised, would result in these additional shares becoming available for sale. 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 2,086,766 and 686,105 shares of our common stock are reserved for future issuance under the 2021 Equity Incentive Plan and the 2012 Employee Stock Purchase Plan, respectively.

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 may significantly decrease. In addition, our issuance of additional shares of common stock will dilute the ownership interests of our existing common stockholders.

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 but not limited to:

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

- Changes in third-party coverage and reimbursement policies for our products and/or product candidates; and
- Discussion by us of our stock price in the financial or scientific press or 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, 2023, we had issued options to purchase 6,583,822 shares of common stock outstanding, with exercise prices ranging from $7.63 to $58.15 per share and a weighted average exercise price of $29.20 per share, as well as 300,141 unvested restricted stock units and 271,630 performance stock units. Upon the

vesting of each of these options, the holder may exercise his or her options, and following 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.

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.

In 2018 we incurred $402.5 million of indebtedness as a result of the sale of 0.625% Convertible Senior Notes, which matured on April 1, 2023 (2023 Notes) at which time the Company paid the total principal amount and the outstanding interest due. During the first quarter of 2023, we entered into the Credit Line, an uncommitted demand secured credit line with a financial institution for up to $150.0 million. In the future, we may incur indebtedness, including by drawing funds from the Credit Line, to meet financing needs or otherwise refinance existing indebtedness. 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; 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 any indebtedness we incur.

Our Credit Line is an uncommitted debt facility that may be terminated by the lender at any time.

Our Credit Line is an uncommitted debt facility and, accordingly, the lender may not provide funding to us when we request a borrowing thereunder. Additionally, the terms of the Credit Line permit the lender to terminate the Credit Line and demand full or partial payment of amounts borrowed thereunder at any time. Although we believe that our existing financing sources, including the Credit Line, are adequate for our current operations, reductions in our available credit, or the inability to draw on the Credit Line, could have an adverse effect on our business, financial condition and results of operations.

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.

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 costs to us as well as ongoing 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.

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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As a result of the COVID-19 pandemic, economic conditions and other geopolitical events, in recent years the global credit and financial markets have experienced extreme volatility and disruptions, which has included periods of severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, and increases in inflation and uncertainty about economic stability. The financial markets, global economy and supply chains have and may continue to be adversely affected by pandemics, economic conditions and current or anticipated geopolitical events, including the impact of military conflicts, sanctions imposed in response to such conflicts, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in supply chains, credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, inflationary economic environment or continued unpredictable and unstable market conditions, including disruption to enrollment within our ongoing clinical trials and our ability to purchase necessary supplies on acceptable terms, if at all, and increased costs in compensation levels to recruit and retain qualified personnel and to carry out ongoing and future clinical trials. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, suppliers or other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

Cybersecurity

Our business depends on information technology systems and networks, which we protect from cyber threats that could harm our data, operations, and reputation. We have invested in security measures designed to safeguard the data of our customers and employees, prevent, detect, and respond to cyberattacks, and comply with data privacy requirements.

Cybersecurity Governance

Our approach to cybersecurity begins with our responsibility for strong governance and controls. Security begins at the top of our organization, where Company leadership consistently communicates the requirements for vigilance and compliance throughout the organization, and then leads by example. We use a risk-based and layered approach to prevent, detect, and respond to cyberattacks, and leverage external partnerships for threat intelligence.

Our management is responsible for risk identification, risk management and risk mitigation strategies associated to cybersecurity related information technology risks, including fully documenting our cybersecurity policies and procedures and cybersecurity risk management program as well as implementing a cybersecurity risk management program and ensuring compliance with our cybersecurity policies and procedures. Our Senior Vice President of Quality, GMP Operations, and Information Technology leads our Information Technology team, which includes experienced and information security professionals and has expertise in various aspects of cybersecurity, such as network security, data protection, incident response,

threat intelligence, and security awareness. Our Information Technology Team's expertise is supplemented by external consultants who provide specialized services and independent assessments of our cybersecurity posture and capabilities.

Management has appointed a Cybersecurity Incident Response Team (the "CSIRT") which is operationally responsible for coordinating, executing, and managing cybersecurity incident response activities. The CSIRT is comprised of experienced information security personnel from our Information Technology team. The CSIRT's responsibilities include, among other things, incident identification and escalation to designated members of management. Among the designated members of management who are required to be notified are our Chief Executive Officer and our Chief Financial Officer.

Our Board of Directors has appointed its Audit Committee as its primary body to oversee management's risk identification, risk management and risk mitigation strategies related to cybersecurity related information technology risks. Members of our management who have responsibility for designing and implementing our risk management processes are required to meet periodically with the Audit Committee regarding our policies, processes, procedures and any significant development related to the identification, management and mitigation of cybersecurity risks. The Audit Committee's primary oversight of management's cybersecurity risk management efforts is supplemented by our full Board, which is required to receive, on an annual basis an update from management on any significant developments related to the identification, management and mitigation of cybersecurity risks.

Cybersecurity Risk Identification and Management

As part of management's initiative to enhance our information security program, during 2023 our program underwent an internal audit, which was supported by an international firm experienced in auditing such programs. The results of the audit are being used by management to supplement previously planned enhancements. Management, with the assistance of third-party experts, is developing and implementing governance-related enhancements to its cybersecurity risk management program. A significant aspect of that process involves fully documenting policies, standards and procedures and developing others, including personnel training requirements, threat monitoring, detection, and containment standards, risk assessment processes, standards for third-party penetration testing, and standards for third-party vendor security requirements. Management expects that the program will continue to adapt and incorporate new techniques and procedures in an effort to combat evolving and novel cybersecurity threats.

Our current cybersecurity risk management program includes the following key elements:

- *Cybersecurity risk mitigation:* We utilize various measures, tools and controls to prevent, detect, and mitigate cyberattacks, such as firewalls, antivirus software, encryption, authentication, backup, and recovery. We also adopt a defense-in-depth approach that layers multiple security mechanisms across our information systems and networks, such as perimeter, endpoint, application, and data security. We monitor and test our security measures and controls, and we update and enhance them as needed to address new and emerging cyber threats and vulnerabilities.

  We also rely on specialized services or tools from third-party vendors and software companies including network monitoring, threat, incident and breach identification and data security and backup services. For third-party service providers whose software or personnel have access to our systems, we review their security audit reports prior to the commencement of their services.

- *Cybersecurity risk response:* The Company's Executive Management, which is led by our CEO and includes leaders from across the Company's departments, is responsible for providing the necessary resources, support, and authority for the CSIRT to carry out their responsibilities effectively. Our Executive Management team is accountable for making critical decisions in response to an incident. The CSIRT is operationally responsible for coordinating, executing, and managing incident response activities. Both our Executive Management team and CSIRT receive regular training on information security topics.

- *Cybersecurity education and training:* We provide regular and mandatory cybersecurity education and training to our employees, contractors, and other authorized users of our information systems and networks, to raise their awareness and understanding of cyber risks and their responsibilities for

protecting our information systems and data. We also conduct periodic phishing and social engineering campaigns to test and reinforce the cybersecurity behavior and culture of our users. We also ensure our suppliers and other business partners, meet our cybersecurity expectations and requirements.

We are committed to maintaining and improving our cybersecurity risk management program as our business and the cybersecurity threat environment evolves.

Because no cybersecurity program can ensure an incident will not occur, we have established business continuity, contingency and recovery plans to be used if we experience a cybersecurity incident, and obtained cyber insurance coverage to mitigate the potential losses and liabilities arising from cyber incidents.

Cybersecurity Incidents

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. After verifying redundant off-site data backups had not been compromised by the ransomware attack, the backups were utilized to restore the data encrypted by the criminal groups. 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. In response to the 2021 ransomware attack, we accelerated previously planned information technology investments in ways designed to improve our information security and technology infrastructure. We have incurred costs since 2021 and expect to continue to incur costs as we continue to invest in our information security and technology infrastructure.

Despite our security measures, our information technology and infrastructure may be vulnerable to cybersecurity incidents in the future, and our insurance may be inadequate to mitigate the potential losses and liabilities arising from such an incident. For additional information regarding cybersecurity risks we face, see Item 1A. Risk Factors—*Cybersecurity incidents may adversely impact our financial condition, results of operations, and reputation. Security breaches and other disruptions could compromise our information and expose us to liability which would cause our business and reputation to suffer.*

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®

I. Supernus Pharmaceuticals, Inc. v. Apotex Inc., et al., C.A. No. 20-cv-7870 (MAS)(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. The Court lifted the stay on July 1, 2022. Pursuant to the Court's January 27, 2022, and July 1, 2022, Orders, the 30-month Stay was extended by 152 days from November 14, 2022, to April 15, 2023. On August 1, 2022, the Court issued an Order consolidating this lawsuit with another pending lawsuit against Apotex, C.A. No. 22-cv-322 (D.N.J.), discussed in Section II, below. The Court issued a revised Scheduling Order on December 20, 2022, that further extends the 30-month stay. The Company entered into a settlement agreement with Apotex, and on June 27, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of New Jersey. The agreement has been submitted to the applicable governmental agencies.

II. Supernus Pharmaceuticals, Inc. v. Apotex Inc., et al., C.A. No. 22-cv-322 (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 U.S. Patent No. 11,166,960 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 action, C.A. No. 20-cv-7870 (D.N.J.), the Court issued an Order staying all litigation proceedings and administratively terminated that related action. That Order further indicated that this action, i.e., C.A. No. 22-cv-322 (D.N.J.), will also be stayed. The Court lifted the stay of both actions on July 1, 2022. Pursuant to the Court's January 27, 2022, and July 1, 2022, Orders, the 30-month Stay was extended by 152 days from November 14, 2022, to April 15, 2023. On August 1, 2022, the Court issued an Order consolidating this lawsuit with another pending lawsuit against Apotex, C.A. No. 20-cv-7870 (D.N.J.), discussed in Section I, above, and administratively terminated C.A. No. 22-cv-322 (D.N.J.). In related action C.A. No. 20-cv-7870 (D.N.J.), the Court issued a revised Scheduling Order on December 20, 2022, that further extends the 30-month stay. The Company entered into a settlement agreement with Apotex, and on June 27, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of New Jersey. The agreement has been submitted to the applicable governmental agencies.

III. Supernus Pharmaceuticals, Inc. v. RiconPharma LLC, et al., C.A. No. 21-cv-12133 (MEF)(MAH) (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. On November 22, 2022, the Court issued an Order consolidating for all purposes this lawsuit with another pending lawsuit against Ricon, C.A. No. 22-cv-6340 (D.N.J.), discussed in Section IV, below. The Court issued a revised Scheduling Order on June 27, 2023, that provides a Joint Final Pretrial Order deadline of July 12, 2024. The Company entered into a settlement agreement with Ricon, and on August 21, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of New Jersey. The agreement has been submitted to the applicable government agencies.

IV. Supernus Pharmaceuticals, Inc. v. RiconPharma LLC, et al., C.A. No. 22-cv-6340 (KM)(MAH) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug maker RiconPharma, LLC ("Ricon") dated October 7, 2022, 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 October 28, 2022, the Company filed a lawsuit against Ricon 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 Ricon infringed U.S. Patent No. 11,166,960 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 November 22, 2022, the Court issued an Order consolidating for all purposes this lawsuit with another pending lawsuit against Ricon, C.A. No. 21-cv-12133 (D.N.J.), discussed in Section III, above. The Court further ordered that this action—C.A. No. 22-cv-6340 (D.N.J.)—be administratively terminated.

V. Supernus Pharmaceuticals, Inc. v. Ajanta Pharma Limited, C.A. No. 22-cv-1431 (GBW) (D. Del.)

The Company received a Paragraph IV Notice Letter from generic drug maker Ajanta Pharma Limited ("Ajanta") dated September 19, 2022, directed to ten 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; 10,220,042; and 11,166,960 generally cover once-a-day oxcarbazepine formulations and methods of treating seizures using those formulations. The FDA Orange Book lists all ten of the Company's Oxtellar XR® patents as expiring on April 13, 2027. On October 28, 2022, the Company filed a lawsuit against Ajanta alleging infringement of the Company's ten Oxtellar XR® patents. The Complaint—filed in the U.S. District Court for the District of Delaware—alleges, inter alia, that Ajanta 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 October 28, 2022, 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 January 3, 2023, 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. On January 24, 2023, the Company filed its Reply, denying the substantive allegations of Ajanta's Counterclaims. The Court issued a Scheduling Order on July 13, 2023, that sets a trial date of February 10, 2025. The Company entered into a settlement agreement with Ajanta, and on January 18, 2024, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of Delaware. The agreement has been submitted to the applicable governmental agencies.

Trokendi XR®

VI. Supernus Pharmaceuticals, Inc. v. Ajanta Pharma Limited, et al., C.A. No. 21-cv-6964 (GC)(DEA) (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 with the lawsuit against Torrent, discussed in Section VII, below. The consolidation order extended the 30-month stay preventing the FDA from approving Ajanta's ANDA to December 16, 2023. The Company entered into a settlement agreement with Ajanta, and on April 4, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of New Jersey. The agreement has been submitted to the applicable governmental agencies.

VII. Supernus Pharmaceuticals, Inc. v. Torrent Pharmaceuticals Ltd., et al., C.A. No. 21-cv-14268 (GC)(DEA) (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 VI, above. The Court held a bench trial between July 31, 2023, and August 3, 2023. Closing arguments for the trial were held on October 4, 2023. On December 12, 2023, the Court issued an

Order enjoining Torrent from launching its generic drug product through January 31, 2024, or until the Court's trial decision issues, whichever is sooner. On January 30, 2024, the Court issued a Trial Opinion and Order, deciding in Supernus's favor that the patent claims that Supernus asserted at trial against Torrent are both valid and infringed. The parties submitted a proposed final Judgment on February 20, 2024.

VIII. 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 May 11, 2023, the Company and Lupin filed a Stipulation and [Proposed] Order to Amend Scheduling Order, that proposed an extension of the 30-month stay to March 30, 2024, but also stated that "the parties do not object to the Court exercising its discretion to further extend the expiration of the 30-month stay beyond the Proposed Date of March 30, 2024 as the Court deems appropriate." The Company entered into a settlement agreement with Lupin, and on November 13, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of Delaware. The agreement has been submitted to the applicable governmental agencies.

IX. Supernus Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc., et al., C.A. No. 21-cv-17104 (GC)(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. On April 29, 2022, the Court issued a scheduling order. The Company entered into a settlement agreement with Zydus, and on January 6, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of New Jersey. The agreement has been submitted to the applicable governmental agencies.

X. Supernus Pharmaceuticals, Inc. v. Alkem Laboratories Ltd., C.A. No. 22-cv-3511 (EEB)(SRH) (N.D. Ill.)

The Company received a Paragraph IV Notice Letter from generic drug maker Alkem Laboratories Ltd. dated May 25, 2022, 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 6, 2022, the Company filed a lawsuit against Alkem Laboratories Ltd. ("Alkem") alleging infringement of the Company's Trokendi XR® Orange Book patents. The Complaint—filed in the U.S. District Court for the Northern District of Illinois—alleges, inter alia, that Alkem 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 6, 2022, Complaint within 45 days of receiving Alkem's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Alkem's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On October 3, 2022, Alkem answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. The Company entered into a settlement agreement with Alkem, and on March 20, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the Northern District of Illinois. The agreement has been submitted to the applicable governmental agencies.

XI. Supernus Pharmaceuticals, Inc. v. Dr. Reddy's Laboratories, Ltd., et al., C.A. No. 22-cv-4705 (GC)(JBD) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug makers Dr, Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. dated June 9, 2022, 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 22, 2022, the Company filed a lawsuit against Dr, Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. ("DRL") 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 DRL 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 22, 2022, Complaint within 45 days of receiving DRL's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving DRL's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On October 7, 2022, DRL answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity.

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[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.

The Company entered into a settlement agreement with DRL, and on June 28, 2023, a stipulation of dismissal without prejudice was entered by the U.S. District Court for the District of New Jersey. The agreement has been submitted to the applicable governmental agencies.

XII. Supernus Pharmaceuticals, Inc. v. Ascent Pharmaceuticals Inc., et al., C.A. No. 23-cv-4015 (GC)(DEA) (D.N.J.)

The Company received a Paragraph IV Notice Letter from generic drug maker Ascent Pharmaceuticals Inc. dated June 15, 2023, 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 26, 2023, the Company filed a lawsuit against Ascent Pharmaceuticals Inc., Camber Pharmaceuticals, Inc., and Hetero Labs Ltd. (collectively, "Ascent") 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 Ascent 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 26, 2023, Complaint within 45 days of receiving Ascent's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Ascent's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On September 28, 2023, the Court entered a stipulation of dismissal without prejudice as to only defendants Camber and Hetero, which included stipulations that, among other things: (i) Ascent Pharma will not contest personal jurisdiction or venue in this District for this Action; (ii) Camber and Hetero will be bound by any injunction in this Action to the extent it concerns the Ascent ANDA; and (iii) Ascent Pharma will collect and produce any relevant discovery that is in the possession, custody, or control of Camber and Hetero. On October 11, 2023, Ascent Pharma answered the Complaint and denied the substantive allegations of the Complaint, asserting affirmative defenses that include non-infringement and invalidity. On November 21, 2023, the Court issued a scheduling order that provides for a Pretrial Conference in July 2025 and a bench trial in July/August 2025. Pretrial discovery is ongoing as of the date of this letter.

XIII. Supernus Pharmaceuticals, Inc. v. Ascent Pharmaceuticals Inc., et al., C.A. No. 23-cv-5720 (E.D.N.Y.)

The Company received a Paragraph IV Notice Letter from generic drug maker Ascent Pharmaceuticals Inc. dated June 15, 2023, 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, 2023, the Company filed a lawsuit against Ascent Pharmaceuticals Inc., Camber Pharmaceuticals, Inc., and Hetero Labs Ltd. (collectively, "Ascent") alleging infringement of the Company's Trokendi XR® Orange Book patents. The Complaint—filed in the U.S. District Court for the Eastern District of New York—alleges, inter alia, that Ascent 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, 2023, Complaint within 45 days of receiving Ascent's Paragraph IV certification notice entitles Supernus to an automatic stay preventing the FDA from approving Ascent's ANDA for 30 months from the date of the Company's receipt of the Paragraph IV Notice Letter. On October 25, 2023, Supernus filed a notice of voluntary dismissal of the Complaint without prejudice. The Court dismissed the case without prejudice on October 30, 2023. The October 30, 2023, dismissal does not impact the co-pending matter against Ascent, C.A. No. 23-cv-4015 (D.N.J.), discussed in Section XII, above.

APOKYN®

XIV. Sage Chemical, Inc., et al. v. Supernus Pharmaceuticals, Inc., et al., C.A. No. 22-cv-1302 (CJB) (D. Del.)

On October 3, 2022, Sage Chemical, Inc. and TruPharma, LLC filed a lawsuit in the United States District Court for the District of Delaware alleging that Supernus Pharmaceuticals, Inc., Britannia Pharmaceuticals Limited ("Britannia"), and US WorldMeds Partners, LLC ("US WorldMeds") violated state and federal antitrust law in connection with APOKYN® (apomorphine HCl). On October 16, 2022, Plaintiffs amended their complaint to add additional defendants MDD US Enterprises, LLC, MDD US Operations, LLC (each a subsidiary of Supernus Pharmaceuticals, Inc.), USWM, LLC ("USWM"), Paul Breckinridge Jones, Sr., Herbert Lee Warren, Jr., Henry Van Den Berg, and Kristin L. Gullo. On January 10, 2023, Defendants filed an Omnibus Motion to Dismiss the Amended Complaint seeking dismissal of each of Plaintiffs' claims and the lawsuit in its entirety and US WorldMeds with USWM, Britannia, and the group of individual defendants each filed separate motions to dismiss. As of April 12, 2023, briefing on those motions is now complete. Those motions remain pending. On April 10, 2023, the Court issued a scheduling order that provides for a Pretrial Conference on March 7, 2025, and a jury trial beginning on March 24, 2025. Pretrial discovery is ongoing as of the date of this filing.

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®, the Company'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 was under the 5-year FDA exclusivity period that expired 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 generic versions 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' receipt of the Paragraph IV Notice Letters. On March 22, 2022, defendant Optimus Pharma Pvt Ltd was dismissed from the case without prejudice. Between January 5, 2023, and November 22, 2023, Plaintiffs entered into settlement agreements with all remaining defendants. The settlement agreements have been submitted to the applicable governmental agencies. The case is closed.

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 to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv), 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 Forest and 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 prices 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 motions to dismiss the complaint. The appeal was heard by the United States Court of Appeals for the Ninth Circuit (Case No. 21-80005). Argument was held on January 10, 2022. On August 25, 2022, the Ninth Circuit sided with the defendants by reversing the District Court's public disclosure bar rulings and remanding the case back to the District Court to decide certain issues in the first instance. On October 11, 2022, the plaintiff filed a petition for rehearing with the Ninth Circuit, which was denied. On December 23, 2022, defendants filed renewed motions to dismiss directed to the remaining unresolved issue. On March 20, 2023, the district court entered an order and final judgment dismissing with prejudice the FCA claim while declining to exercise supplemental jurisdiction over the state false claims act claims which were dismissed without prejudice. On April 19, 2023, the plaintiff appealed the District Court's dismissal of the Federal False Claims Act claim. The appeal remains pending in the United States Court of Appeals for the Ninth Circuit.

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. On January 13, 2023, the Court granted in part and denied in part Defendants' Motion to Dismiss. All claims against Adamas have been dismissed with prejudice, but claims against one of the individual defendants, who may have certain rights to indemnification, remain. On February 27, 2023, plaintiffs advised the Court that plaintiffs would proceed only on the remaining claim against one of the individual defendants. The individual defendant filed an answer denying the claim on April 28, 2023. On September 21, 2023, the parties reached an agreement in principle to settle the Zaidi litigation, subject to court approval. On October 31, 2023, the Court granted the parties' stipulation staying all proceedings and vacating all existing deadlines. The deadline for plaintiff to file a motion for preliminary approval of the class action settlement, or for the parties to submit a joint report updating the court of settlement status, is March 1, 2024.

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 former directors and officers as defendants. This lawsuit alleged certain of Adamas's former directors and officers breached fiduciary duties and violated the Securities Exchange Act of 1934. Adamas was 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 former directors and officers as defendants. This lawsuit contained the same allegations, claims, and defendants as the first derivative action. Adamas is named as a nominal defendant only. In both actions, Plaintiffs sought unspecified monetary damages and other relief. These actions were consolidated. On May 16, 2023 the court entered an order dismissing the consolidated actions, without prejudice. The consolidated cases were closed on June 7, 2023.

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 29, 2023, the closing price of our common stock on the NASDAQ Global Market was $28.94 per share. As of December 31, 2023, we had 15 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

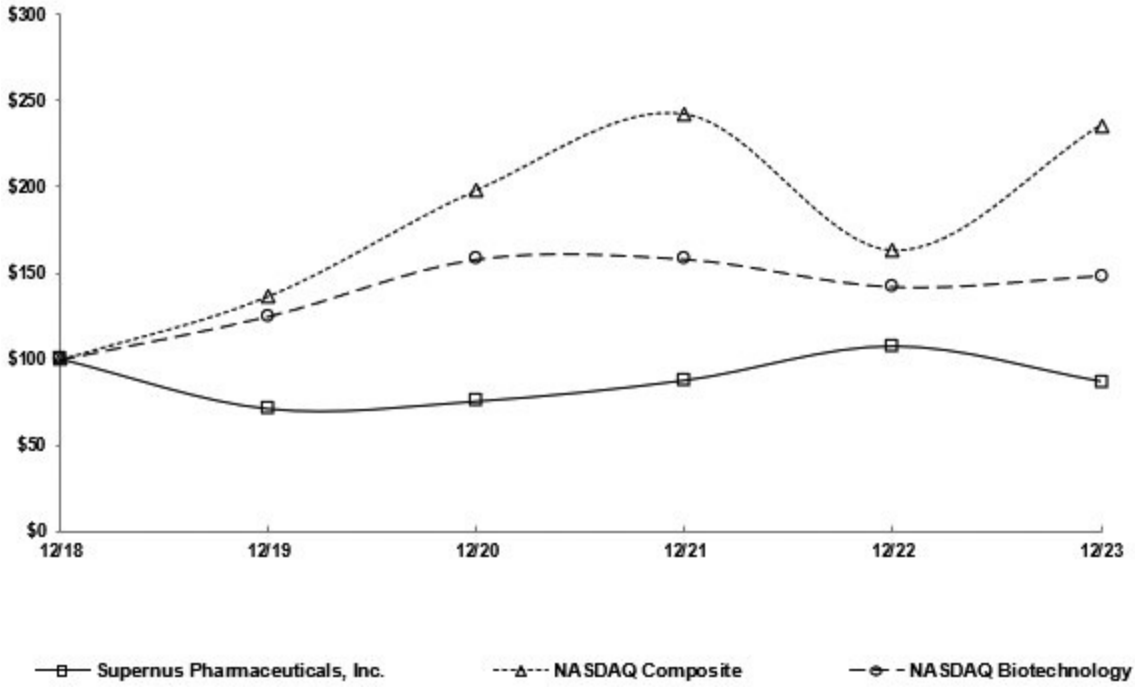
We have never declared or paid any cash dividends on our capital stock, and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance operations. Any future determination 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.

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, 2018, and ending December 31, 2023.

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

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



* $100 invested on 12/31/2018 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

Performance Graph Data

	Supernus Pharmaceuticals, Inc.	NASDAQ Composite Index	NASDAQ Biotechnology Index
December 31, 2018	100.00	100.00	100.00
December 31, 2019	71.40	136.69	125.11
December 31, 2020	75.74	198.10	158.17
December 31, 2021	87.78	242.03	158.20
December 31, 2022	107.38	163.28	142.19
December 31, 2023	87.12	236.17	148.72

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.*

Unless the content requires otherwise, the words "Supernus," "we," "our" and "the Company" refer to Supernus Pharmaceuticals, Inc. and/or one or more of its subsidiaries, as the case may be. These terms are used solely for the convenience of the reader. Supernus *Pharmaceuticals, Inc. and each of its subsidiaries are distinct legal entities. For example, MDD US Operations, LLC, a wholly-owned indirect subsidiary of Supernus Pharmaceuticals, Inc., is the exclusive licensee and distributor of APOKYN in the United States and its territories. Adamas Operations, LLC, a wholly-owned indirect subsidiary of Supernus Pharmaceuticals, Inc., wholly owns the patents and patent applications related to GOCOVRI and Osmolex ER and has a license agreement with Supernus Pharmaceuticals, Inc., granting Supernus Pharmaceuticals, Inc. rights to market and sell GOCOVRI and Osmolex ER.*

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. 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.

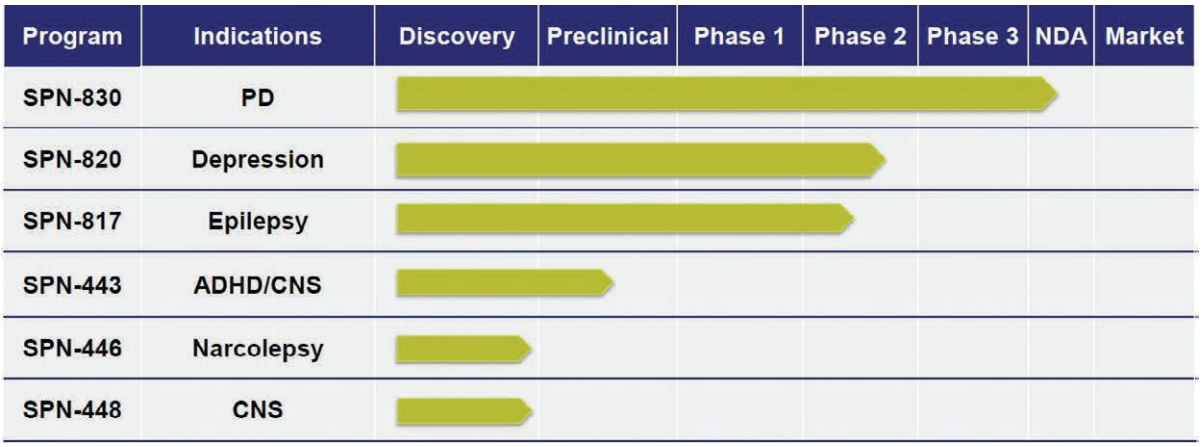
Commercial Products

- Qelbree® (viloxazine) extended-release capsules is a novel non-stimulant product indicated for the treatment of ADHD in adults and pediatric patients 6 years and older. The United States Food and Drug Administration (FDA) approved Qelbree for the treatment of ADHD in pediatric patients 6 to 17 years of age in April 2021, and in adult patients in April 2022. The Company launched Qelbree for pediatric patients in May 2021 and for adult patients in May 2022 in the United States (U.S.).
- 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 with PD experiencing "off" episodes.
- Oxtellar XR® (oxcarbazepine) is indicated as therapy for the treatment of partial onset seizures in patients 6 years of age and older. It is also the first once-daily extended-release oxcarbazepine product indicated for the treatment of epilepsy in the U.S. market.
- Trokendi XR® (topiramate) is the first once-daily extended-release topiramate product indicated for the treatment of epilepsy in patients 6 years of age and older in the U.S. market. It is also indicated for the prophylaxis of migraine headache in adults and adolescents 12 years and older.
- APOKYN® (apomorphine hydrochloride injection) is a product indicated for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced PD.
- XADAGO® (safinamide) is a once-daily product indicated as adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes.

- MYOBLOC® (rimabotulinumtoxinB injection) is a product indicated for the treatment of cervical dystonia and chronic sialorrhea in adults. It is the only botulinum toxin type B available on the market.
- Osmolex ER® (amantadine) extended-release tablets is for the treatment of PD and drug-induced extrapyramidal reactions in adult patients. In December 2023, the Company submitted to the FDA a notification of discontinuance to withdraw Osmolex ER from distribution, stating that manufacturing has been discontinued and distribution of the product will cease by April 1, 2024.

Research and Development

We are committed to the development of innovative product candidates in neurology and psychiatry, including the following:



SPN-830 (apomorphine infusion device)

SPN-830 is a late-stage drug/device combination product candidate for the continuous treatment of motor fluctuations ("off" episodes) in PD patients that are not adequately controlled with oral levodopa and one or more adjunct PD medications. 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 slow infusion may also limit some of the side effects of a bolus injection of apomorphine.

In December 2021, we resubmitted the (New Drug Application) NDA to the FDA. In February 2022, we received a notice from the FDA that the resubmission of the NDA for SPN-830 was considered as a Standard Review and was assigned a PDUFA target action date in early October 2022. In October 2022, the FDA issued a Complete Response Letter (CRL) regarding the NDA for SPN-830. The CRL requires additional information and analysis related to the infusion device and drug product across several areas of the NDA including, but not limited to, labeling, product quality and manufacturing, device performance and risk analysis. In addition, the FDA mentions that approval of the NDA requires inspections that could not be completed in a timely manner due to COVID-19 travel restrictions. The CRL does not request additional efficacy and safety clinical studies. The FDA has made an initial determination that the amendment to the Company's application in response to the CRL will be subject to a Class 2, or six-month, review timeline. In April 2023, the Company met with the FDA to discuss the CRL. In October 2023, the Company resubmitted the NDA for SPN-830. Refer to discussion under the Operational Highlights section below for further regulatory update. In November 2023, the FDA accepted the resubmission of the NDA for SPN-830. The resubmission is now considered filed, with a user fee goal date (PDUFA date) of April 5, 2024.

SPN-820—Novel first-in-class molecule that increases mTORC1 mediated synaptic function for depression

SPN-820 is a first-in-class, orally active small molecule that increases the brain mechanistic target of rapamycin complex 1 (mTORC1) mediated synaptic function intracellularly. SPN-820 does not bind to or modulate any cell surface receptors and therefore is unlikely to have abuse potential given lack of binding to targets

implicated in drug abuse. In addition, unlike leucine, it is not incorporated into proteins during protein synthesis, and therefore, it is more available at the target site in the brain than leucine.

SPN-817—Novel first-in-class highly selective AChE inhibitor for epilepsy

SPN-817 represents a novel mechanism of action (MOA) for an anticonvulsant. SPN-817 is a novel synthetic form of huperzine A, a first in class, highly selective acetylcholinesterase (AChE) inhibitor, with pharmacological activities in CNS conditions such as focal 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 epilepsy. SPN-817 is in clinical development and has received Orphan Drug designation for several epilepsy indications from the FDA.

Operational Highlights

Qelbree—Novel non-stimulant for ADHD Update

- Total IQVIA prescriptions were 617,192 for full year 2023, an increase of 91% compared to full year 2022.
- The Company initiated a Phase IV open-label study to assess the efficacy of Qelbree over the course of 14 weeks of treatment in approximately 500 adults with ADHD and mood symptoms. The primary outcome measure is change from baseline in the Adult ADHD Investigator Symptom Rating Scale (AISRS).

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

- As previously disclosed, the FDA accepted the resubmission of the New Drug Application for SPN-830 for continuous treatment of motor fluctuations ("off" episodes) in Parkinson's disease (PD) and set a user fee goal date (PDUFA date) of April 5, 2024.
- Assuming FDA approval, the Company expects to launch SPN-830 in the second half of 2024.

SPN-820—Novel first-in-class activator of mTORC1 for the treatment of depression

- The Phase IIb multi-center randomized double-blind placebo-controlled parallel design study of SPN-820 in adults with treatment-resistant depression is ongoing. The study will examine the efficacy and safety of SPN-820 over a course of five weeks of treatment in approximately 268 patients in up to 50 clinical sites. The primary outcome measure is the change from baseline to end of treatment period on the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score. Approximately 118 patients have been enrolled in the trials, to date. Topline data from the Phase IIb trial is expected in the first half of 2025.
- The Company has initiated a Phase II open-label study in approximately 40 subjects with major depressive disorder (MDD). The primary objective of the study is to assess efficacy in MDD, as well as onset of efficacy.

SPN-817—Novel first-in-class selective acetylcholinesterase (AChE) inhibitor for the treatment of epilepsy

- An open-label Phase IIa clinical study of SPN-817 for treatment-resistant seizures is ongoing. The study is examining the safety and tolerability of SPN-817 as adjunctive therapy in adult patients with treatment-resistant seizures, as well as assessing efficacy. The Company expects to report interim results from approximately half of the target randomized patients in May 2024, and topline results from the Phase IIa study in the second half of 2024.
- The Company now expects to initiate a Phase IIb randomized, double-blind, placebo-controlled study in approximately 436 patients with treatment-resistant focal seizures in the second half of 2024. The primary endpoint is change from baseline in focal seizure frequency per 28 days. Topline results from the Phase IIb study are expected in 2026.

SPN-443—Novel stimulant for the treatment of ADHD/CNS

- The Company plans to initiate a Phase I single dose study in healthy adults in 2024 following submission of an Investigational New Drug (IND) application. The primary objective of the study is to assess safety and tolerability.

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; and
- Impairment of Indefinite-Lived Intangible Assets
- Impairment of Definite-Lived Intangible Assets

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, including rebates and returns. 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. While sales rebates have been relatively predictable based on historical experience such that there have not been material changes in estimates in prior periods, there have been critical estimates associated with rebates and returns that may result in significant variability as further discussed below.

Returns

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, changes in the current wholesaler prices, 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 January 1, 2023. The Company is actively monitoring returns activity in light of the loss of exclusivity and actual and possible further future sales decline based on timing of generic entry. The recent 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. Historically, we have experienced changes in estimates in return reserve calculations, but those adjustments have not been material to net earnings. However, given the extensive number of inputs and assumptions, described above, future changes in our return reserves could be material. The Company has also entered into settlement and license agreements with third parties, permitting sale of a generic version of Oxtellar XR beginning in September 2024, or sooner under certain conditions. Similarly, the Company is actively monitoring returns activity in light of the upcoming loss of exclusivity of Oxtellar XR.

Rebates

Rebates are discounts which we pay 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 us with managed care providers. Both types of rebates vary over time. 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.

Specifically, 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. Historically, adjustments to rebate accruals have not been material to net earnings, but there continues to be an extensive time lag related to certain programs that could result in variability in future periods.

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

Impairment of Indefinite-Lived Intangible Assets

In 2020, the Company acquired the right to further develop and commercialize SPN-830 (apomorphine infusion device), a late-stage product candidate (IPR&D intangible asset). The In Process Research and Development (IPR&D) intangible asset represents the estimate of the fair value of acquired technology which has not yet reached technological feasibility. The primary basis for determining the technological feasibility is obtaining specific regulatory approvals. IPR&D is accounted for as an indefinite-lived intangible asset until completion or abandonment of the IPR&D project. Upon completion of the development project, the IPR&D will be amortized over its estimated useful life. We review intangible assets with indefinite lives for impairment annually or more often if impairment indicators 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. If the Company is unable to conclude that the indefinite-lived 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. 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, and 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 October 2022, the FDA issued a CRL regarding the NDA for SPN-830. In October 2023, we resubmitted the NDA for SPN-830. In November 2023, the FDA accepted the resubmission of the NDA for SPN-830. The resubmission is now considered filed, with a user fee goal date (PDUFA date) of April 5, 2024. 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, 2023. 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. If the IPR&D project is abandoned or regulatory approvals are not obtained, we may have a full or partial impairment charge related to the IPR&D, calculated as the excess carrying value of the IPR&D assets over the estimated fair value.

Impairment of Definite-Lived Intangible Assets

Management assesses the potential impairment of our finite-lived intangibles whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The carrying amount of the definite-lived intangible assets, net was $475.9 million as of December 31, 2023. Changes that could prompt such an assessment may include significant or adverse changes in the legal and regulatory environment, the introduction or advancement of competitive products and product candidates, changes in market demand, declining revenue and/or other events that indicate it is more likely than not that fair value is less than its carrying value. If a review of the definite-lived intangibles indicates that the carrying value of certain of these assets is more than the estimated undiscounted future cash flows, an impairment charge is made, as required, to adjust the carrying value to the estimated fair value. Evaluating for impairment requires judgment, including evaluating current economic and competitive circumstances, estimating future cash flows, future growth rates and future profitability. The primary inputs and assumptions used in the model included timing and projections of estimated future revenues and cash flows, loss of exclusivity, and discount rate. If the carrying amount of the asset exceeds its fair value, the Company writes down the 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. The use of different assumptions could increase or decrease the estimated fair value of assets and could therefore affect any impairment measurement. The Company recognized impairment charges of $20.2 million in 2023 mainly due to the partial write-off of the carrying value of some of its acquired intangible assets, primarily XADAGO. The primary factors that led to the impairment determinations were the following: (1) the performance of the commercial products; (2) forthcoming loss of exclusivity of XADAGO in December 2027, or earlier under certain circumstances, due to settlement agreements with third party generic companies; and (3) the change in the Company's future outlook of the brands.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2023, compared to the year ended December 31, 2022. Our Annual Report on Form 10-K for the year ended December 31, 2022, includes a discussion and analysis of our financial condition and results of operations for the year ended December 31, 2021, in *Part II, Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations*.

Revenues

Revenues consist primarily of net product sales of our commercial products in the U.S., supplemented by royalty and licensing revenues from our collaborative licensing arrangements. The following table provides information regarding our revenues during the years ended December 31, 2023 and 2022 (dollars in thousands):

	Years Ended December 31,		Change	
	2023	2022	Amount	Percent
Net product sales				
Qelbree	$140,192	$ 61,322	$ 78,870	129%
GOCOVRI	119,637	104,421	15,216	15%
Oxtellar XR	113,404	115,345	(1,941)	(2)%
Trokendi XR	94,336	261,221	(166,885)	(64)%
APOKYN	75,083	75,305	(222)	—%
Other[(1)]	31,281	31,818	(537)	(2)%
Total net product sales	$573,933	$649,432	$ (75,499)	(12)%
Royalty and licensing revenues	33,588	17,806	15,782	89%
Total revenues	$607,521	$667,238	$ (59,717)	(9)%

(1) Includes net product sales of MYOBLOC, XADAGO and Osmolex ER.

Net Product Sales

Net product sales decreased by $75.5 million from $649.4 million in 2022 to $573.9 million in 2023. The decrease in net product sales was primarily due to the decline in net product sales of Trokendi XR which was partially offset by the increase in net product sales from Qelbree and GOCOVRI.

Qelbree net product sales increased from $61.3 million in 2022 to $140.2 million in 2023 primarily due to favorable unit prescription volume growth, the price increase taken during the year, and improvements in gross-to-net. The Company launched Qelbree for pediatric patients in May 2021 and for adult patients in May 2022 in the U.S. Trokendi XR net product sales decreased from $261.2 million in 2022 to $94.3 million in 2023 due to the loss of exclusivity with generics entering the market in January 2023.

Sales deductions and related accruals

We record accrued product returns and accrued product rebates as current liabilities in *Accrued product returns and rebates,* on our consolidated balance sheets. We record sales discounts as a reduction against *Accounts receivable, net* on the consolidated balance sheets. Both amounts are generally affected by changes in gross product sales, changes in 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, 2023 and 2022 (dollars in thousands):

	Accrued Product Returns and Rebates			
	Product Returns	Product Rebates	Allowance for Sales Discounts	Total
Balance at December 31, 2022	$ 45,008	$ 106,657	$ 12,995	$ 164,660
Provision				
Provision for sales in current year	22,928	406,329	65,896	495,153
Adjustments relating to prior year sales	(213)	1,672	31	1,490
Total provision	22,715	408,001	65,927	496,643

	Accrued Product Returns and Rebates			
	Product Returns	Product Rebates	Allowance for Sales Discounts	Total
Less: Actual payments/credits	(10,433)	(417,674)	(68,203)	(496,310)
Balance at December 31, 2023	$ 57,290	$ 96,984	$ 10,719	$ 164,993
Balance at December 31, 2021	$ 35,127	$ 97,597	$ 13,537	$ 146,261
Adamas Acquisition liabilities assumed				
Provision				
Provision for sales in current year	22,129	437,323	76,079	535,531
Adjustments relating to prior year sales	(3,866)	(155)	(3)	(4,024)
Total provision	18,263	437,168	76,076	531,507
Less: Actual payments/credits	(8,382)	(428,108)	(76,618)	(513,108)
Balance at December 31, 2022	$ 45,008	$ 106,657	$ 12,995	$ 164,660

Accrued product returns and rebates

The accrued product returns balance increased from $45.0 million as of December 31, 2022 to $57.3 million as of December 31, 2023 due to timing of related return activity, and an increase in provision for product returns primarily for Qelbree.

The accrued product rebates balance decreased from $106.7 million as of December 31, 2022 to $97.0 million as of December 31, 2023 due to lower gross sales primarily related to the loss of exclusivity on Trokendi XR, and timing of payments.

Provision for returns and rebates

The provision for product returns increased from $18.3 million in 2022 to $22.7 million in 2023. The increase was primarily attributable to an increase in volume of products sold with the launch of Qelbree for adults in 2022, partially offset by lower sales of Trokendi XR.

The provision for product rebates decreased from $437.2 million in 2022 to $408.0 million in 2023. The decrease was primarily attributable to lower Trokendi XR sales partially offset by higher Qelbree sales.

Allowance for sales discounts

The provision for sales discounts decreased from $76.1 million in 2022 to $65.9 million in 2023 primarily attributable to lower Trokendi XR sales.

Adjustments related to prior year sales

Adjustments related to prior year sales in 2023 of $1.5 million was less than 1% of both net product sales and total provision for the year ended December 31, 2023. Adjustments related to prior year sales in 2022 of $4.0 million was less than 1% of both net product sales and total provision for the year ended December 31, 2022.

Royalty and Licensing Revenues

Royalty and licensing revenues increased by approximately $15.8 million, or 89% in 2023 compared to 2022, primarily due to royalties on generic Trokendi XR. The Company entered into settlement agreements on Trokendi XR that allowed third party generics to enter the market beginning January 1, 2023 and required them to pay royalties to the Company. Noncash royalty revenue decreased from $9.8 million in 2022 to $4.0 million in 2023 due to full ownership of the royalty rights from its royalty agreement with United Therapeutics reverting back to the Company in the second quarter of 2023.

Cost of Goods Sold

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

			Change	
	2023	2022	Amount	Percent
Cost of goods sold	$83,779	$87,221	$(3,442)	(4)%

Cost of goods sold includes the cost of royalties; cost of materials, including active pharmaceutical ingredients (API); and cost to manufacture, including tableting, packaging, personnel, overhead, stability testing, and distribution.

Cost of goods sold decreased from $87.2 million in 2022 to $83.8 million in 2023. The decrease was primarily due to lower Trokendi XR costs in 2023 due to loss of patent exclusivity for Trokendi XR in January 2023 and a higher GOCOVRI inventory reserve in 2022 offset by Qelbree costs in 2023.

Research and Development Expense

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

			Change	
	2023	2022	Amount	Percent
Research and development expense	$91,593	$74,552	$17,041	23%

R&D expenses increased from $74.6 million in 2022 to $91.6 million in 2023. The increase was primarily due to increased clinical program costs on SPN-817 and SPN-820 and increased manufacturing costs of our product candidates.

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	
	2023	2022	Amount	Percent
Selling and marketing expense	$229,186	$267,788	$(38,602)	(14)%
General and administrative expense	107,175	109,433	(2,258)	(2)%
Total	$336,361	$377,221	$(40,860)	(11)%

Selling and Marketing Expense

Selling and marketing expenses decreased from $267.8 million in 2022 to $229.2 million in 2023. The decrease was primarily attributable to activities to support the launch of Qelbree to the adult population in 2022.

General and Administrative Expense

General and administrative expenses decreased from $109.4 million in 2022 to $107.2 million in 2023. The decrease was primarily due to higher professional and consulting costs in 2022, mainly to support finance and information technology operations, which was partially offset by higher legal costs and share-based compensation expense in 2023.

Amortization of Intangible Assets

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

			Change	
	2023	2022	Amount	Percent
Amortization of intangible assets	$82,385	$82,630	$(245)	0%

Amortization of intangible assets was materially consistent year-over-year.

Intangible Asset Impairment Charges

The following table provides information regarding the intangible asset impairment charges during the periods indicated (dollars in thousands):

			Change	
	2023	2022	Amount	Percent
Intangible asset impairment charges	$20,189	$ —	$20,189	100%

In the fourth quarter of 2023, the Company recognized impairment charges of $20.2 million mainly due to the partial write-off of the carrying value of some of its acquired intangible assets, primarily XADAGO. The primary factors that led to the impairment determinations were the following: (1) the performance of the commercial products; (2) forthcoming loss of exclusivity of XADAGO in December 2027, or earlier under certain circumstances, due to settlement agreements in the fourth quarter of 2023 with third party generic companies; and (3) the change in the Company's future outlook of the brands.

Contingent Consideration Gain

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

			Change	
	2023	2022	Amount	Percent
Contingent consideration gain	$(1,517)	$(510)	$(1,007)	197%

Contingent consideration gain recorded for the years ended December 31, 2023 and December 31, 2022 of $1.5 million and $0.5 million, respectively. The change of $1.0 million was primarily driven by the gain recognized due to the passage of time related to the Adamas contingent consideration, offset by the expense recognized from the accretion to the payout amount related to the USWM contingent consideration milestone achieved in the first quarter of 2022.

Other Income (Expense)

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

			Change	
	2023	2022	Amount	Percent
Interest income & other income, net	$10,453	$21,689	$(11,236)	(52)%
Interest expense	(1,321)	(2,542)	(1,221)	48%
Noncash interest expense on nonrecourse liability related to sale of future royalties	(562)	(2,416)	(1,854)	77%
Noncash interest expense on debt	(532)	(2,112)	(1,580)	75%
Total	$ 8,038	$14,619	$ (6,581)	(45)%

Interest and other income, net includes primarily interest earned from cash, cash equivalents, and marketable securities holdings. Interest and other income, net decreased from $21.7 million in 2022 to $10.5 million in 2023. The decrease in interest and other income, net was primarily due to $12.9 million recorded in 2022 in connection with the gain associated with the Navitor investment. The decrease in interest expense and noncash interest expense on debt of $2.8 million was due to the 2023 Notes being fully repaid on April 1, 2023. The decrease in noncash interest expense of $1.9 million was due to the nonrecourse royalty liability related to the HC Royalty agreement being fully amortized as of June 30, 2023.

Income Tax Expense

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

			2023 vs 2022 Change	
	2023	2022	Dollar	Percent
Income tax expense	$1,453	$ 32	$1,421	**
Effective tax rate	52.5%	0.1%		

** Indicates calculation result is equal to or greater than 100%

Income tax expense was $1.5 million and $32.0 thousand for the years ended December 31, 2023 and December 31, 2022, respectively. The income tax expense and effective tax rate in 2023 was primarily driven by near break-even pre-tax book income. The income tax expense and effective tax rate in 2022 was primarily driven by tax benefits associated with the Adamas legal entities reorganization in the first quarter of 2022.

Net Earnings

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

			Change	
	2023	2022	Amount	Percent
Net earnings	$1,316	$60,711	$(59,395)	(98)%

The decrease in net earnings was primarily due to the lower revenues in 2023 with the loss of exclusivity of Trokendi XR and the intangible asset impairment charges in the fourth quarter of 2023, partially offset by lower operating expenses.

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
	2023	2022	Amount
Net cash provided by (used in):			
Operating activities	$ 111,085	$ 116,826	$ (5,741)
Investing activities	268,729	(216,663)	485,392
Financing activities	(397,880)	(10,477)	(387,403)
Net change in cash and cash equivalents	$ (18,066)	$(110,314)	$ 92,248

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 $111.1 million in 2023 compared to $116.8 million in 2022. The year over year change was primarily driven by a decrease in working capital which reflects the timing impacts of cash collections on receivables and settlement of payables, lower inventory purchases in 2023 compared to 2022, and a decrease in operating earnings offset by an increase in non-cash items.

Investing Activities

Net cash provided by investing activities was $268.7 million in 2023 compared to $216.7 million used in 2022. The year over year change is primarily due to the proceeds from the maturities of investments in marketable securities which were used to pay off the 2023 Notes.

Financing Activities

Net cash used in financing activities was $397.9 million in 2023 compared to $10.5 million used in the same period in 2022. The increase in cash flows used by financing activities is primarily due to the payment of the total principal amount and accrued interest due on the 2023 Notes. On March 30, 2023, the Company transferred funds totaling $403.8 million to the Trustee (Wilmington Trust) related to the repayment of the 2023 Notes which was reported as restricted cash in the first quarter of 2023. On April 1, 2023, the Company paid the total principal amount of $402.5 million under the 2023 Notes and the remaining outstanding interest due of $1.3 million with the restricted cash. This increase was slightly offset by the payment of $22.9 million for a contingent consideration milestone associated with the USWM Acquisition during the same period in 2022.

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, 2023
Cash and cash equivalents	$ 75,054
Marketable securities	179,820
Long term marketable securities	16,617
Total	$271,491

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 continued market and payor pressures for our commercial products; the unfavorable impact of the loss of patent exclusivity for Trokendi XR in January 2023; the potential unfavorable impact of the forthcoming loss of exclusivity of Oxtellar XR and XADAGO; funding for research and development of our product candidates; and the additional funding to launch SPN-830, if approved by the FDA.

The Company believes its balances of cash, cash equivalents and unrestricted marketable securities, which totaled $271.5 million as of December 31, 2023, 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.

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, 2023, we have fixed lease payment obligations of $48.6 million, with $9.9 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.

Milestone Payment Obligations from Acquisitions

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. 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 2024.

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. There are certain additional payments which could be incurred by the Company that are contingent upon Navitor Inc. achieving defined milestones. These milestone payments include an additional license or acquisition fee depending on whether the Company ultimately licenses or acquires NV-5138, and subsequent clinical, regulatory and sales milestone payments. The Company has an option to acquire or license NV-5138 (SPN-820), for which additional payments would be required.

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. 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, regulatory, and developmental milestones per contractual agreements.

- 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, 2023, we had unrestricted cash and cash equivalents, marketable securities, and long term marketable securities of $271.5 million.

We fully repaid the outstanding principal and interest on the 2023 Notes in April 2023. We borrowed funds pursuant to our Credit Line in connection with the payment of the 2023 Notes. We fully repaid the outstanding debt under the Credit Line in June 2023. In the future, we may borrow funds under the Credit Line. Variable rate borrowing, which may occur under the Credit Line, exposes us to interest rate risk as increases in interest rates would increase our borrowing costs.

Any borrowed funds pursuant to our Credit Line are subject to a collateral maintenance requirement. The Credit Line is secured primarily by our portfolio of marketable securities, which is primarily comprised of corporate and U.S. government agency and municipal debt securities and may fluctuate in value. The fluctuations may be driven by, among other things, changes in interest rates, economic conditions, and other financial conditions as well as idiosyncratic factors related to a security's issuer. To the extent a fluctuation in value results in the value of the collateral decreasing below the required collateral maintenance requirements we may be required to promptly post additional collateral. Additionally, our Credit Line is an uncommitted facility that may be terminated by the lender at any time. During periods of rapidly changing interest rates, economic conditions or other financial conditions, the Credit Line may be terminated by the lender and/or the lender may declare that all borrowings thereunder are immediately due.

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; and corporate and municipal debt 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 may contract with clinical research organizations (CROs) and investigational sites globally. Currently, we have ongoing clinical trials being conducted outside the U.S. We do not hedge our foreign currency exchange rate risk. Transactions denominated in currencies other than the U.S. dollar are recorded based on

exchange rates at the time such transactions arise. As of December 31, 2023, and December 31, 2022, 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, 2023, and 2022 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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, 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, 2023, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 27, 2024 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit 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 $57,290 (dollars in thousands) as of December 31, 2023. 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, Oxtellar XR and Qelbree product returns, and specifically the assessment of the expected long-term return rates, as a critical audit matter. The assessment of the expected long-term return rates included a comparison to actual returns experience and involved a high degree of auditor judgment due to the significant passage of time between product sale and the time at which the Company issues credit for expired product.

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

/s/ KPMG LLP

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

Baltimore, Maryland
February 27, 2024

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, 2023, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, 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, 2023 and 2022, 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, 2023, and the related notes (collectively, the consolidated financial statements), and our report dated February 27, 2024 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ KPMG LLP

Baltimore, Maryland
February 27, 2024

Supernus Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 75,054	$ 93,120
Marketable securities	179,820	368,214
Accounts receivable, net	144,155	165,497
Inventories, net	77,408	91,541
Prepaid expenses and other current assets	16,676	15,779
Total current assets	493,113	734,151
Long term marketable securities	16,617	93,896
Property and equipment, net	13,530	15,173
Intangible assets, net	599,889	702,463
Goodwill	117,019	117,019
Other assets	37,505	39,806
Total assets	$1,277,673	$1,702,508
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 79,569	$ 96,342
Accrued product returns and rebates	154,274	151,665
Contingent consideration, current portion	52,070	21,120
Convertible notes, net	—	401,968
Other current liabilities	4,283	16,863
Total current liabilities	290,196	687,958
Contingent consideration, long term	1,380	33,847
Operating lease liabilities, long term	33,196	35,998
Deferred income tax liabilities, net	24,963	49,809
Other liabilities	6,422	8,692
Total liabilities	356,157	816,304
Stockholders' equity		
Common stock, $0.001 par value; 130,000,000 shares authorized; 54,723,356 and 54,253,796 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	55	54
Additional paid-in capital	439,493	408,115
Accumulated other comprehensive (loss) earnings, net of tax	(593)	(3,210)
Retained earnings	482,561	481,245
Total stockholders' equity	921,516	886,204
Total liabilities and stockholders' equity	$1,277,673	$1,702,508

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Earnings

(in thousands, except share and per share data)

	Years Ended December 31,		
	2023	**2022**	**2021**
Revenues			
Net product sales	$ 573,933	$ 649,432	$ 567,504
Royalty and licensing revenues	33,588	17,806	12,271
Total revenues	607,521	667,238	579,775
Costs and expenses			
Cost of goods sold[(a)]	83,779	87,221	75,061
Research and development	91,593	74,552	90,467
Selling, general and administrative	336,361	377,221	304,759
Amortization of intangible assets	82,385	82,630	29,989
Intangible asset impairment charges	20,189	—	—
Contingent consideration gain	(1,517)	(510)	(6,530)
Total costs and expenses	612,790	621,114	493,746
Operating earnings (loss)	(5,269)	46,124	86,029
Other income (expense)			
Interest and other income, net	10,453	21,689	10,569
Interest expense	(2,415)	(7,070)	(23,423)
Total other income (expense)	8,038	14,619	(12,854)
Earnings before income taxes	2,769	60,743	73,175
Income tax expense	1,453	32	19,751
Net earnings	$ 1,316	$ 60,711	$ 53,424
Earnings per share			
Basic	$ 0.02	$ 1.13	$ 1.01
Diluted	$ 0.02	$ 1.04	$ 0.98
Weighted-average shares outstanding			
Basic	54,536,281	53,665,143	53,099,330
Diluted	55,506,828	61,679,800	54,356,744

[(a)] Excludes amortization of intangible assets.

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Earnings

(in thousands)

	Years Ended December 31,		
	2023	**2022**	**2021**
Net earnings	$1,316	$60,711	$53,424
Other comprehensive gain (loss):			
Unrealized gain (loss) on marketable securities, net of tax	2,617	(4,749)	(7,436)
Other comprehensive gain (loss)	2,617	(4,749)	(7,436)
Comprehensive earnings	$3,933	$55,962	$45,988

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Changes in Stockholders' Equity

Years Ended December 31, 2021, 2022 and 2023

(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, 2020	52,868,482	$53	$409,332	$ 8,975	$326,498	$744,858
Share-based compensation expense related to employee stock purchase plan and share-based awards	—	—	17,910	—	—	17,910
Issuance of common stock related to employee stock purchase plan and share-based awards	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
Cumulative effect of adoption of ASU 2020-06	—	—	(56,212)	—	40,612	(15,600)
Balance, January 1, 2022	53,256,094	53	378,125	1,539	420,534	800,251
Share-based compensation expense related to employee stock purchase plan and share-based awards	—	—	17,568	—	—	17,568
Issuance of common stock related to employee stock purchase plan and share-based awards	997,702	1	12,422	—	—	12,423
Net earnings	—	—	—	—	60,711	60,711
Unrealized loss on marketable securities, net of tax	—	—	—	(4,749)	—	(4,749)
Balance, December 31, 2022	54,253,796	54	408,115	(3,210)	481,245	886,204
Share-based compensation expense related to employee stock purchase plan and share-based awards	—	—	26,759	—	—	26,759
Issuance of common stock related to employee stock purchase plan and share-based awards, net of taxes withheld	469,560	1	4,619	—	—	4,620
Net earnings	—	—	—	—	1,316	1,316
Unrealized gain on marketable securities, net of tax	—	—	—	2,617	—	2,617
Balance, December 31, 2023	54,723,356	$55	$439,493	$ (593)	$482,561	$921,516

See accompanying notes.

Supernus Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2023	2022	2021
Cash flows from operating activities			
Net earnings	$ 1,316	$ 60,711	$ 53,424
Adjustments to reconcile net earnings to net cash provided by operating activities:			
Depreciation and amortization	84,859	85,543	32,595
Navitor investment R&D expense (see Note 4)	—	—	15,000
Other income from Navitor (see Note 4)	—	(12,888)	—
Intangible asset impairment charges	20,189	—	—
Amortization of deferred financing costs and debt discount	532	2,112	17,501
Share-based compensation expense	26,759	17,568	17,910
Realized gains from sales of marketable securities	—	(14)	(347)
Amortization of premium/discount on marketable securities	(122)	3,233	418
Changes in fair value of contingent consideration	(1,517)	(510)	(6,530)
Other noncash adjustments, net	13,920	11,638	(1,420)
Deferred income tax benefit	(25,714)	(26,324)	(4,994)
Changes in operating assets and liabilities:			
Accounts receivable	18,765	(16,366)	3,867
Inventories	6,110	(17,858)	(14,580)
Prepaid expenses and other assets	(334)	12,303	(8,398)
Accrued product returns and rebates	2,609	18,941	4,502
Accounts payable and other liabilities	(36,287)	(19,163)	18,179
Contingent consideration	—	(2,100)	—
Net cash provided by operating activities	111,085	116,826	127,127
Cash flows from investing activities			
Sales and maturities of marketable securities	370,901	190,739	530,509
Purchases of marketable securities	(101,621)	(406,990)	(311,573)
Acquisition of USWM, net of cash acquired	—	—	(950)
Acquisition of Adamas, net of cash acquired	—	—	(310,742)
Distribution from Navitor	—	—	12,888
Purchase of property and equipment and deferred legal fees paid	(551)	(412)	(2,045)
Net cash provided by (used in) investing activities	268,729	(216,663)	(81,913)
Cash flows from financing activities			
Proceeds from issuance of common stock	6,610	12,423	7,095
Employee taxes paid related to net share settlement of equity awards	(1,990)	—	—
Proceeds from Line of Credit	93,000	—	—
Payments on Line of Credit	(93,000)	—	—
Payment on convertible notes	(402,500)	—	—
Proceeds from governmental loan and grant	—	—	800
Repayment of acquired Adamas loan	—	—	(138,315)
Payment of contingent consideration	—	(22,900)	—
Net cash used in financing activities	(397,880)	(10,477)	(130,420)
Net change in cash and cash equivalents	(18,066)	(110,314)	(85,206)
Cash and cash equivalents at beginning of year	93,120	203,434	288,640
Cash and cash equivalents at end of year	$ 75,054	$ 93,120	$ 203,434
Supplemental cash flow information:			
Cash paid for interest on debt	$ 1,946	$ 2,516	$ 2,516
Cash paid for operating leases	$ 17,112	$ 12,883	$ 11,908
Cash paid for income taxes	$ 36,602	$ 16,200	$ 25,190
Noncash investing and financing activity:			
Contingent consideration liability related to acquisitions	$ —	$ —	$ 10,307
Property and equipment additions from utilization of tenant improvement allowance	$ —	$ 580	$ 25

See accompanying notes.

1. Business Organization

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: Qelbree®, GOCOVRI®, Oxtellar XR®, Trokendi XR®, APOKYN®, XADAGO®, MYOBLOC®, and Osmolex ER®. In addition, SPN-830 (apomorphine infusion device) is a late-stage drug/device combination product candidate for the continuous treatment of motor fluctuations ("off" episodes) in PD patients that are not adequately controlled with oral levodopa and one or more adjunct PD medications.

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 deferred income tax assets (liability) summary under Note 11, *Income Tax Expense,* have been reclassified to conform to the current year presentation. The reclassifications did not affect the consolidated balance sheets, statements of 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. and its wholly-owned subsidiaries. These are collectively referred to herein as "Supernus" or "the Company." All material 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 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.

2. Summary of Significant Accounting Policies (Continued)

Use of Estimates

The Company bases its estimates on: historical experience; 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.

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.

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.

Business Combinations and Contingent Consideration

The Company determines whether an acquisition should be accounted for as a business combination or as an asset acquisition. If the acquired set of activities and assets does not meet the definition of a business, as defined by U.S. GAAP, 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

2. Summary of Significant Accounting Policies (Continued)

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.

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.

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. 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 may require 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 6, *Contingent Consideration.*

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

2. Summary of Significant Accounting Policies (Continued)

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 customers representing more than 10% of the Company's total gross product sales, and the percentage of the Company's accounts receivables, net from each:

	Percentage of Gross Product Sales			Percentage of Accounts Receivable, net	
	2023	2022	2021	2023	2022
Customer A	28%	26%	28%	38%	37%
Customer B	23%	28%	29%	30%	34%
Customer C	25%	26%	29%	16%	15%
Customer D	12%	10%	1%	7%	6%
	88%	90%	87%	91%	92%

Refer to Note 3, *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 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.

Intangible Assets

Intangible assets consist of definite-lived intangible assets: acquired developed technology and product rights, 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.

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 lease assets, and definite-lived intangible assets. The Company assesses the recoverability of its long-lived assets with definite lives whenever

2. Summary of Significant Accounting Policies (Continued)

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

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

2. Summary of Significant Accounting Policies (Continued)

Interest Expense

Interest expense includes 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, *Interest Expense*). The Company amortizes the deferred financing costs and debt discount over the term of the debt, using the effective interest method. Interest expense also includes stated interest in connection with the Company's debt instruments.

Revenue Recognition

The Company determines revenue recognition for our contractual arrangements with customers based on the following five steps: (1) identify each contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to our performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfy the relevant performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. 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, 2023, or 2022.

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 customers take control of its products, including title and ownership. Customer orders are generally fulfilled within a few days of order receipt, resulting in minimal order backlog.

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." Sales deductions are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of sale using the most likely value method. The Company includes these estimated amounts in the transaction price to the extent it is probable that a significant reversal will not occur.

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. 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.

2. Summary of Significant Accounting Policies (Continued)

Sales Deductions

The Company records product sales net of rebates, returns and discounts.

- *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. Rebates are owed when our customer dispenses our product to a patient; i.e., filling a prescription. 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.
- *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.
- *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.

Licensing Revenue

License and Collaboration Arrangements

At contract inception, the Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (ASC 808) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those

2. Summary of Significant Accounting Policies (Continued)

that are more reflective of a vendor-customer relationship and therefore within the scope of ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the five-step model under ASC 606 noted above.

The Company's agreements with third parties generally involve the right to use the Company's intellectual property as a functional license. Certain agreements include an up-front license fee and ongoing milestone payments upon the achievement of specific events, and may also require minimum royalty payments based on in-country sales of products developed from the applicable intellectual property.

In determining when to recognize the revenue under a collaboration agreement, the Company assesses whether the license is distinct, which depends upon whether the customer can benefit from the license and whether the license is separate from other performance obligations in the agreement. If the license is distinct, the Company must further assess whether the customer has a right to access or a right to use the license depending on whether the functionality of the license is expected to substantively change over time. If the license is not expected to substantively change, the revenue is recognized at the point in time when the license is provided. Generally, the Company recognizes revenues from non-refundable up-front fees allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Revenue recognition from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Generally, milestone payments under the Company's collaboration agreements with third parties are non-refundable. The Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. This can involve management's judgment that includes assessing factors that are outside of the Company's influence, such as: likelihood of regulatory success; availability of third party information; and expected duration of time until achievement of event. These factors are evaluated based on the specific facts and circumstances. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price.

Milestone payments based on a non-sales metric such as a development-based milestone (e.g. obtaining regulatory approval) represent variable consideration and would be included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience, the specific facts and circumstances, and the significance a third-party has on the outcome. Milestone payments that are not within the control of the Company, such as approval from regulatory authorities or where attainment of the specified event is dependent on the development activities of a third-party, are fully constrained and are not included in the transaction price until the period in which those regulatory approvals are obtained, or the specified event occurs due to the inherent uncertainty with the approval process.

For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales are incurred or the performance obligation to which the sales relate has been satisfied as noted below.

Royalty Revenues

Royalty revenues include cash royalty amounts received from third parties pursuant to settlement agreements and agreements with collaboration partners for the right to use the Company's intellectual property as a functional license. These agreements may include sales-based royalties on the licensed intellectual property to which the royalties relate and milestone payments based on the level of sales (collectively, "sales-based

2. Summary of Significant Accounting Policies (Continued)

royalties"). For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). If it is probable that a significant revenue reversal will not occur, the Company will estimate the royalty revenues using the most likely amount method. Certain of the Company's royalty revenues are recognized by the Company based on information supplied to the Company by its licensees and require estimates to be made. Sales-based royalties are recorded based on estimated net sales of the underlying product. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known, which is generally within the following quarter. The difference between the Company's actual and estimated royalty revenues has not been material to date.

Royalty revenues also includes noncash royalty revenues for amounts earned pursuant to its royalty agreement with United Therapeutics Corporation (United Therapeutics) and is based on estimated product sales of Orenitram by United Therapeutics (see Note 3, *Disaggregated Revenues*). 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). Pursuant to this agreement, the Company recorded a nonrecourse liability related to this transaction and amortizes this liability as noncash royalty revenues. 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, *Interest Expense*). This interest rate is determined based on projections of HC Royalty's rate of return. During the second quarter of 2023, full ownership of the royalty rights has reverted back to the Company as the cumulative payment threshold has been reached (see Note 3, *Disaggregated Revenues* and Note 15, *Commitments and Contingencies*).

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

Cost of Goods Sold

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

Research and Development Expenses

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

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

If the actual timing of the performance of services or the level of effort varies from our estimate, the Company adjusts its accrued expenses, or its deferred advance payments, accordingly. If the Company

2. Summary of Significant Accounting Policies (Continued)

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, 2023, and 2022, 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 granted to employees generally vest over four equivalent annual installments, starting on the first anniversary of the grant. RSUs granted to directors generally vest over a one year term.

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.

2. Summary of Significant Accounting Policies (Continued)

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 television, print media, digital marketing, marketing programs and speaker programs. The cost of the Company's advertising efforts are expensed as incurred.

The Company incurred approximately $99.7 million, $131.7 million, and $86.0 million in advertising expense for the years ended December 31, 2023, 2022, and 2021, 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

2. Summary of Significant Accounting Policies (Continued)

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.

Recently Issued Accounting Pronouncements

Accounting Pronouncements Not Yet Adopted

ASU 2023-07, *Improvements to Reportable Segment Disclosures (Topic 280)*—The new standard, issued in November 2023, improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses that are regularly provided to the chief operating decision maker. ASU 2023-07 also clarifies that entities with a single reportable segment are subject to both new and existing reporting requirements under Topic 280. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, on a retrospective basis, with early adoption permitted. The Company plans to adopt the guidance for the fiscal year ending December 31, 2024. We expect ASU 2023-07 to require additional disclosures in the notes to our consolidated financial statements. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

ASU 2023-09, *Improvements to Income Tax Disclosures* (Topic 740)—The new standard, issued in December 2023, requires entities to disclose additional information with respect to the effective tax rate reconciliation and to disclose the disaggregation by jurisdiction of income tax expense and income taxes paid. The standard is effective with annual periods beginning after December 15, 2024, with early adoption permitted. The standard is to be applied on a prospective basis, although optional retrospective application is permitted. The Company plans to adopt the guidance for the fiscal year ending December 31, 2025. We expect ASU 2023-09 to require additional disclosures in the notes to our consolidated financial statements. The Company is currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

3. Disaggregated Revenues

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

	Years Ended December 31,		
	2023	2022	2021
Net product sales			
Qelbree	$140,192	$ 61,322	$ 9,879
GOCOVRI	119,637	104,421	9,778
Oxtellar XR	113,404	115,345	110,708
Trokendi XR	94,336	261,221	304,817
APOKYN	75,083	75,305	99,233
Other[(1)]	31,281	31,818	33,089
Total net product sales	$573,933	$649,432	$567,504
Royalty and licensing revenues	33,588	17,806	12,271
Total revenues	$607,521	$667,238	$579,775

(1) Includes net product sales of MYOBLOC, XADAGO and Osmolex ER.

3. Disaggregated Revenues (Continued)

The Company recognized noncash royalty revenues of $4.0 million, $9.8 million, and $9.4 million for the years ended December 31, 2023, 2022, and 2021, respectively, pursuant to the Company's agreement with HC Royalty (see Note 2, *Summary of Significant Accounting Policies*).

Adjustments related to prior year sales in 2023, 2022, and 2021 have amounted to less than 1% of net product sales for each of the respective periods.

The following table shows the percentage of net product sales to total net product sales:

	Percentage of Net Product Sales Years Ended December 31,		
	2023	2022	2021
Qelbree	24%	9%	2%
GOCOVRI	21%	16%	2%
Oxtellar XR	20%	18%	19%
Trokendi XR	16%	40%	54%
APOKYN	13%	12%	17%
Other[1]	6%	5%	6%
Total	100%	100%	100%

(1) Includes net product sales of MYOBLOC, XADAGO and Osmolex ER.

4. Investments

Marketable Securities

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

	December 31, 2023	December 31, 2022
Corporate, U.S. government agency and municipal debt securities		
Amortized cost	$197,153	$466,333
Gross unrealized gains	5	14
Gross unrealized losses	(721)	(4,237)
Total fair value	$196,437	$462,110

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

	December 31, 2023
Less than 1 year	$179,820
1 year to 2 years	16,617
Total	$196,437

There was no impairment on any available-for-sale marketable securities as of December 31, 2023 and December 31, 2022.

4. Investments (Continued)

Investment in Navitor

In April 2020, the Company entered into a development agreement (the Development Agreement) with Navitor Pharmaceuticals, Inc. (Navitor Inc.). The Company can terminate the Development Agreement upon 30 days' notice. 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) for treatment-resistant depression. The Company will bear all of the Phase I and Phase II development costs incurred by either party, up to a maximum of $50 million. There are certain additional payments which could be incurred by the Company that are contingent upon Navitor Inc. achieving defined milestones. These milestone payments include an additional license or acquisition fee depending on whether the Company ultimately licenses or acquires NV-5138, and subsequent clinical, regulatory and sales milestone payments. The Company has an option to acquire or license NV-5138 (SPN-820), for which additional payments would be required.

In addition to entering into the Development Agreement in April 2020, the Company acquired Series D Preferred Shares of Navitor Inc. (the "Navitor Shares") for $15 million, representing an approximately 13% ownership position in Navitor Inc. As part of a legal restructuring in March 2021, the Company's Navitor Shares were exchanged for membership interests in Navitor Pharmaceutics LLC, which became the sole shareholder of Navitor Inc. The Company has determined that although Navitor LLC is a VIE, the Company does not consolidate the results of this VIE into its financial results because the Company lacks the power to direct the activities that most significantly impact Navitor's economic performance.

The Company records its share of the results of Navitor LLC, a private company, on a quarter lag as the financial information of Navitor LLC is not available on a sufficiently timely basis for the Company to apply the equity method of accounting. In December 2021, Navitor LLC sold one of its subsidiaries and distributed cash to its members in accordance with each member's share of the proceeds from the sale. The Company received $12.9 million in December 2021 from Navitor LLC in connection with this sale. As the Company's policy is to record its share of the results in its 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. In the first quarter of 2022, the Company determined its estimated share of Navitor LLC's year-end 2021 earnings and recorded a gain of $12.9 million in *Interest and other income, net* in the consolidated statement of earnings.

The maximum exposure to losses related to Navitor LLC is approximately $50 million 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.

Subsequent to the Development Agreement entered into in 2020, no additional equity investment has been made or financing has been provided to Navitor Inc. or Navitor LLC.

5. Fair Value of Financial Instruments

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

The Company reports the fair value of assets and liabilities using a three level measurement hierarchy that prioritizes the inputs used to measure fair value. The fair value hierarchy consists of the following three levels:

- Level 1—Valuations based on unadjusted quoted prices in active markets that are accessible at measurement date for identical assets.
- Level 2—Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and model-based valuations in which all significant inputs are observable in the market, either directly or indirectly (e.g., interest rates; yield curves).

5. Fair Value of Financial Instruments (Continued)

- Level 3—Valuations using significant inputs that are unobservable in the market and inputs that reflect the Company's own assumptions. These are based on the best information available, including the Company's own data.

The fair value of the restricted marketable securities which are classified as Level 2 financial assets are recorded in *Other assets* on the consolidated balance sheets. There have been no transfers of assets or liabilities into or out of Level 3 of the fair value hierarchy.

Financial Assets and Liabilities Recorded at Fair Value on a Recurring Basis

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

		Fair Value Measurements at December 31, 2023		
	Total Fair Value at December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs that Reflect the Company's own Assumptions (Level 3)
Assets:				
Cash and cash equivalents				
Cash	$ 35,957	$35,957	$ —	$ —
Money market funds	39,097	39,097	—	—
Marketable securities				
Corporate, U.S. government agency and municipal debt securities	179,820	—	179,820	—
Long term marketable securities				
Corporate and municipal debt securities	16,617	—	16,617	—
Other noncurrent assets				
Marketable securities—restricted (SERP)	568	16	552	—
Total assets at fair value	$272,059	$75,070	$196,989	$ —
Liabilities:				
Contingent consideration	$ 53,450	$ —	$ —	$53,450
Total liabilities at fair value	$ 53,450	$ —	$ —	$53,450

5. Fair Value of Financial Instruments (Continued)

		Fair Value Measurements at December 31, 2022		
	Total Fair Value at December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs that Reflect the Company's own Assumptions (Level 3)
Assets:				
Cash and cash equivalents				
Cash	$ 52,181	$52,181	$ —	$ —
Money market funds	40,939	40,939	—	—
Marketable securities				
Corporate, U.S. government agency and municipal debt securities	368,214	—	368,214	—
Long term marketable securities				
Corporate and municipal debt securities	93,896	—	93,896	—
Other noncurrent assets				
Marketable securities—restricted (SERP)	496	11	485	—
Total assets at fair value	$555,726	$93,131	$462,595	$ —
Liabilities:				
Contingent consideration	$ 54,967	$ —	$ —	$54,967
Total liabilities at fair value	$ 54,967	$ —	$ —	$54,967

Other Financial Instruments

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 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, 2022	
	Carrying Value	Fair Value (Level 2)
Convertible notes, net	$401,968	$395,959

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

6. Contingent Consideration

The following table provides the current and long-term portions related to the contingent consideration for the USWM Acquisition and Adamas Acquisition (dollars in thousands):

	December 31, 2023	December 31, 2022
Reported under the following captions in the consolidated balance sheets:		
Contingent consideration, current portion	$52,070	$21,120
Contingent consideration, long-term	1,380	33,847
Total	$53,450	$54,967

The Company's contingent consideration liabilities are related to the USWM Acquisition in 2020 (as defined below) and the Adamas Acquisition in 2021. The contingent consideration liabilities are measured at fair value on a recurring basis using either a Monte Carlo simulation or the income approach. 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. The change in fair value is reported on the consolidated statement of earnings in *Contingent consideration (gain) expense*.

USWM Contingent Consideration

On June 9, 2020 (the USWM Closing Date), the Company completed its acquisition of all the outstanding equity of USWM Enterprises, LLC (USWM Enterprises) (USWM Acquisition). The USWM Acquisition included potential additional contingent consideration payments for regulatory and development milestones and sales-based milestones. As of December 31, 2023, the remaining potential contingent consideration payments include the following:

- Regulatory and developmental milestones:
- The potential $55 million in regulatory and development milestones is comprised of (1) $25 million related to the FDA's approval of the SPN-830 NDA and (2) $30 million related to the subsequent commercial product launch.
- The $30 million sales-based milestone that was due upon the achievement of certain U.S. net product sales of APOKYN in 2023 was not achieved.

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, and the estimated amount and timing of projected revenues from the acquired USWM products.

Adamas Contingent Consideration

On November 24, 2021 (the Adamas Closing Date), the Company completed its acquisition of all the outstanding equity of Adamas (Adamas Acquisition). The Adamas Acquisition included payment of two non-tradable contingent value rights (CVRs) each of which represents the contractual right to receive a contingent payment upon the achievement of the applicable aggregate worldwide net product sales of GOCOVRI.

Each CVR 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 between the Company and American Stock Transfer & Trust Company, LLC, as

6. Contingent Consideration (Continued)

rights agent, as further defined in the 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. The possible outcomes for the contingent consideration range from $0 to $50.9 million on an undiscounted basis.

The key assumptions considered in estimating the fair value of the Adamas sales-based milestones include the estimated revenue projections, volatility, estimated discount rates and risk-free interest rate.

Change in the Fair Value of Contingent Consideration

The following table provides a reconciliation of the beginning and ending balances related to the contingent consideration liabilities for the USWM Acquisition and Adamas Acquisition (dollars in thousands):

	USWM Acquisition	Adamas 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	70,170	10,307	80,477
Milestone payments	(25,000)	—	(25,000)
Change in fair value recognized in earnings	1,100	(1,610)	(510)
Balance at December 31, 2022	$ 46,270	$ 8,697	$ 54,967
Change in fair value recognized in earnings	130	(1,647)	(1,517)
Balance at December 31, 2023	$ 46,400	$ 7,050	$ 53,450

The Company recorded the following changes in fair value of the contingent consideration liability for the USWM milestones:

- For the year ended December 31, 2023, the Company recorded $0.1 million expense which was primarily driven by the passage of time, as well as the change in timing of milestone achievement and estimated discount rate in the first quarter of 2023.
- For the year ended December 31, 2022, the Company recorded a $1.1 million expense which was primarily driven by the passage of time and the accretion to the payout amount related to the milestone achieved in the first quarter of 2022.
- For the year ended December 31, 2021, the Company recorded a $6.5 million gain which 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 paid $25 million of the USWM contingent consideration in the first quarter of 2022 of which $22.9 million represents the acquisition date fair value of the contingent consideration liability and was reported under cash flows from financing activities. The remaining $2.1 million represents the excess of the acquisition date fair value and was reported under cash flows from operating activities. The amount

6. Contingent Consideration (Continued)

paid was for the milestone that was due upon the FDA acceptance of the SPN-830 NDA for review, which was achieved in the first quarter of 2022.

The Company recorded the following changes in fair value of the contingent consideration liabilities for the Adamas CVRs:

- For the year ended December 31, 2023, the Company recorded a $1.6 million gain which was primarily driven by the passage of time.
- For the year ended December 31, 2022, the Company recorded a $1.6 million gain primarily due to changes in market data and revenue projections.

7. Goodwill and Intangible Assets, Net

Goodwill

The following table sets forth the gross carrying amounts of goodwill (dollars in thousands):

	December 31, 2023	December 31, 2022
Goodwill	$117,019	$117,019

There were no goodwill impairment charges recognized in 2023 or 2022.

Intangible Assets, Net

The following table sets forth the gross carrying amounts and related accumulated amortization of intangibles assets (dollars in thousands):

	Remaining Weighted-Average Amortization Period (Years)	December 31, 2023			December 31, 2022		
		Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net	Carrying Amount, Gross	Accumulated Amortization	Carrying Amount, Net
Acquired in-process research and development		$124,000	$ —	$124,000	$124,000	$ —	$124,000
Intangible assets subject to amortization:							
Acquired developed technology and product rights	6.84	661,311	(190,395)	470,916	681,500	(113,061)	568,439
Capitalized patent defense costs	0.67	43,820	(38,847)	4,973	43,820	(33,796)	10,024
Total intangible assets	6.78	$829,131	$(229,242)	$599,889	$849,320	$(146,857)	$702,463

Patent defense costs are deferred legal fees incurred in conjunction with defending patents for Oxtellar XR and Trokendi XR. U.S. patents covering Trokendi XR and Oxtellar XR will expire no earlier than 2027. In regards to Trokendi XR, the Company entered into settlement agreements that allowed third parties to enter the market by January 1, 2023. In regards to Oxtellar XR, the Company entered into settlement and license agreements that allows third parties to enter the market in September 2024, or sooner under certain conditions.

7. Goodwill and Intangible Assets, Net (Continued)

In regards to XADAGO, the Company entered into settlement and license agreements that allows third parties to enter the market in December 2027, or sooner under certain conditions.

In the fourth quarter of 2023, the Company recognized impairment charges of $20.2 million mainly due to the partial write-off of the carrying value of some of its acquired intangible assets, primarily XADAGO. The primary factors that led to the impairment determinations were the following: (1) the performance of the commercial products; (2) forthcoming loss of exclusivity of XADAGO; and (3) the change in the Company's future outlook of the brands. The Company recognized as impairment loss the difference between the estimated fair values and carrying values of these intangible assets. The Company used the discounted cash flow income approach to estimate the fair values of each of these intangible assets. The primary inputs and assumptions used in the model included timing and projections of estimated future revenues and cash flows, loss of exclusivity, and discount rate. The fair value measurement is classified as Level 3 within the fair value hierarchy as defined in ASC 820, *Fair Value Measurement*, due to the unobservable inputs used. The impairment loss is reported as *Intangible asset impairment charges* in the consolidated statements of earnings.

Amortization expense for intangible assets was approximately $82.4 million, $82.6 million, and $30.0 million for the years ended December 31, 2023, 2022, and 2021, respectively.

The following table sets forth the anticipated annual amortization expense for definite-lived intangible assets. Actual amortization expense to be reported in future periods could differ from these estimates as a result of acquisitions, divestitures, and asset impairments, among other factors (dollars in thousands):

Year:	Estimated Amortization Expense
2024	$ 77,977
2025	70,876
2026	70,876
2027	70,745
2028	69,301
Thereafter	116,114

8. Debt

The 0.625% Convertible Senior Notes Due 2023 (2023 Notes), which were 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 matured on April 1, 2023. On March 30, 2023, the Company transferred funds totaling $403.8 million to the Trustee (Wilmington Trust) related to the repayment of the 2023 Notes which was reported as restricted cash in the first quarter of 2023. On April 1, 2023, the Company paid the total principal amount due of $402.5 million under the 2023 Notes and the remaining outstanding interest due of $1.3 million with the restricted cash.

Contemporaneous with the issuance of the 2023 Notes, the Company also entered into separate privately negotiated convertible note hedge transactions (collectively, the Convertible Note Hedge Transactions) with each of the call spread counterparties. The Company issued 402,500 convertible note hedge options.

The Convertible Note Hedge Transactions were 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. As of March 31, 2023, the Convertible Note Hedges have expired.

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

8. Debt (Continued)

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 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 had 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, exceeded the strike price of the warrants. The warrants expired unexercised on November 22, 2023.

As of December 31, 2022, the liability component of the 2023 Notes consists of the following (dollars in thousands):

	December 31, 2022
2023 Notes	$402,500
Unamortized debt discount and deferred financing costs	(532)
Total carrying value	$401,968

The Company 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,* on January 1, 2022 using the modified retrospective method of transition resulting in an increase in the carrying amount of the debt by $20.6 million as of the adoption date. No 2023 Notes were ever converted.

Uncommitted Demand Secured Line of Credit

On February 8, 2023, the Company entered into a credit line agreement with UBS. The Credit Line provides for a revolving line of credit of up to $150 million, which can be drawn at any time. Any fixed rate borrowing will bear interest at a fixed interest rate, equal to the sum of (i) the UBS Fixed Funding Rate (as defined in the Credit Line) plus (ii) the applicable Percentage Spread established in the Credit Line. Any variable rate borrowing will bear interest at a variable interest rate, equal to the sum of (i) the UBS Variable Rate (as defined in the Credit Line) plus (ii) the applicable Percentage Spread established in the Credit Line.

The Credit Line is secured by a first priority lien and security interest in certain of the Company's assets, including each account of the Company at UBS Financial Services Inc. (the "Collateral Account"), and other such collateral (collectively, the "Collateral"), as further defined in the Credit Line. The Company may be required to post additional collateral if the value of the Collateral declines below the required collateral maintenance requirements.

Upon certain customary events of default, all amounts due under the Credit Line will become immediately due and payable without demand, and UBS has the right, in its discretion, to liquidate, transfer, withdraw or sell all or any part of the Collateral and apply the proceeds to repay any borrowings pursuant to the Credit Line.

The Company has the right to repay any variable rate advance under the Credit Line at any time, in whole or in part, without penalty. The Company may repay any fixed rate advance in whole, but may not repay any fixed rate advance in part. In its discretion and without cause, UBS has the right at any time to demand full or partial payment of amounts borrowed pursuant to the Credit Line and terminate the Credit Line.

8. Debt (Continued)

On March 30, 2023, the Company borrowed $93.0 million under the Credit Line, which bore a variable interest rate. The funds from this borrowing were used to repay outstanding indebtedness under the 2023 Notes as discussed above under the Convertible Senior Notes Due 2023. As of June 30, 2023, the Company repaid the total principal balance of $93.0 million under the Credit Line and the interest incurred on the Credit Line of $0.7 million. As of December 31, 2023, there was no outstanding debt under the Credit Line.

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 to, 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, 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 1,700,000 shares of the Company's common stock. The Company records compensation expense related to its ESPP.

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

	Years Ended December 31,		
	2023	2022	2021
Research and development	$ 4,743	$ 2,922	$ 2,403
Selling, general and administrative	22,016	14,646	15,507
Total	$26,759	$17,568	$17,910

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 & SARs	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	5,774,076	$24.15	5.95	$41,530
Granted	1,103,635	$32.12		
Exercised	(817,919)	$12.77		
Forfeited	(262,223)	$30.42		
Outstanding, December 31, 2022	5,797,569	$26.99	6.11	$53,650
Granted	1,204,643	$37.78		
Exercised	(258,154)	$16.70		
Forfeited	(160,236)	$33.48		
Outstanding, December 31, 2023	6,583,822	$29.20	5.90	$23,668
As of December 31, 2023				
Vested and expected to vest	6,583,822	$29.20	5.90	$23,668
Exercisable	4,110,537	$26.58	4.43	$22,305

The weighted-average grant date fair value of options granted for the years ended December 31, 2023, 2022, and 2021 were $21.3 million, $18.1 million, and $16.3 million per share, respectively.

The aggregate intrinsic value of shares exercised for the years ended December 31, 2023, 2022, and 2021 were $5.1 million, $16.3 million, and $2.8 million, respectively. Proceeds from the options exercised for the years ended December 31, 2023, 2022, and 2021 were $4.3 million, $10.4 million, and $4.9 million, respectively.

The total fair value of the underlying common stock related to shares that vested during the years ended December 31, 2023, 2022, and 2021 were approximately $14.8 million, $13.9 million, and $13.9 million, respectively.

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,		
	2023	2022	2021
Fair value of common stock	$27.66 - $38.60	$28.93 - $35.23	$25.09 - $30.45
Expected volatility	56.87% - 58.22%	58.71% - 60.15%	60.62% - 61.8%
Dividend yield	0%	0%	0%
Expected term	5.60 years - 7.03 years	5.58 years - 6.72 years	5.63 years - 6.56 years
Risk-free interest rate	3.27% - 4.33%	1.87% - 3.70%	0.72% - 1.3%

As of December 31, 2023, the total unrecognized compensation expense was approximately $34.1 million. The Company expects to prospectively recognize these expenses over a weighted-average period of 2.7 years.

9. Share-Based Payments (Continued)

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 31, 2021	21,110	$29.61		
Granted	134,460	$32.17		
Vested	(21,110)	$29.61	$ 69.5	$ 625.1
Forfeited	(2,500)	$32.20		
Nonvested, December 31, 2022	131,960	$32.17		
Granted	227,980	$38.60		
Vested	(47,049)	$32.18	$1,814.3	$1,514.0
Forfeited	(12,750)	$35.68		
Nonvested, December 31, 2023	300,141	$36.90		

As of December 31, 2023, the total unrecognized compensation expense was $8.0 million. The Company expects to prospectively recognize these expenses over a weighted-average period of 2.9 years.

Performance Stock Units

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

	Performance-Based PSUs		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, 2021	53,500	$29.82	35,625	$26.34	89,125	$28.43
Granted	155,000	$28.93	—	$ —	155,000	$28.93
Vested	(22,250)	$29.69	(15,625)	$23.41	(37,875)	$27.10
Forfeited	(4,500)	$29.94	—	$ —	(4,500)	$29.94
Nonvested, December 31, 2022	181,750	$29.07	20,000	$28.63	201,750	$29.03
Granted	205,000	$34.00	—	$ —	205,000	$34.00
Vested	(132,120)	$30.72	—	$ —	(132,120)	$30.72
Forfeited	(3,000)	$28.93	—	$ —	(3,000)	$28.93
Nonvested, December 31, 2023	251,630	$32.22	20,000	$28.63	271,630	$31.96

The total fair value of PSUs that vested during the years ended December 31, 2023, 2022, and 2021 were $4.1 million, $1.0 million, and $1.2 million, respectively. The total intrinsic value of PSUs vested during the years ended December 31, 2023, 2022, and 2021 were $0.5 million, $0.2 million, and $0.0 million, respectively.

9. Share-Based Payments (Continued)

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 of achievement of the performance target is certified. As of December 31, 2023, the total unrecognized compensation expense was $4.2 million. The Company expects to prospectively recognize these expenses over a weighted-average period of 1.2 years.

Market-Based Awards

The market-based PSU awards are subject to achievement of market-based performance targets in order to vest. The Company used a Monte-Carlo Simulation to determine the fair value and expected term of the awards as of grant date. There was no unrecognized compensation expense as of December 31, 2023. 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, employee stock purchase plan (ESPP) awards, and the 2023 Notes, as determined per the if-converted method for the years ended December 31, 2023 and December 31, 2022 in connection with the adoption of ASU 2020-06, and the treasury stock method for the year ended December 31, 2021.

The following table sets forth the computation of basic and diluted EPS for the years ended December 31, 2023, 2022 and 2021 (dollars in thousands, except share and per share amounts):

	Years Ended December 31,		
	2023	2022	2021
Numerator:			
Net earnings	$ 1,316	$ 60,711	$ 53,424
After-tax interest expense for 2023 Notes	—	3,556	—
Numerator for dilutive earnings per share	$ 1,316	$ 64,267	$ 53,424
Denominator:			
Weighted average shares outstanding, basic	54,536,281	53,665,143	53,099,330
Effect of dilutive securities:			
Stock options, RSUs and SARs	970,547	1,230,721	1,257,414
Convertible Notes	—	6,783,936	—
Weighted average shares outstanding, diluted	55,506,828	61,679,800	54,356,744
Earnings per share, basic	$ 0.02	$ 1.13	$ 1.01
Earnings per share, diluted	$ 0.02	$ 1.04	$ 0.98

Effect of Convertible Notes and Related Convertible Note Hedges and Warrants

The Company adopted ASU 2020-06 on January 1, 2022 using the modified retrospective method of transition. ASU 2020-06 requires the application of the if-converted method for calculating diluted EPS, whereas the Company previously calculated diluted EPS under the treasury stock method. As a result of the adoption of ASU 2020-06, the 6.8 million in dilutive shares associated with the conversion of the 2023 Notes were included in the calculation of diluted EPS for the year ended December 31, 2022 because their

10. Earnings per Share (Continued)

inclusion would be dilutive. For the year ended December 31, 2021, the Company calculated diluted earnings per share using the treasury stock method wherein the shares associated with the conversion of the 2023 Notes were excluded as the Company assumed the 2023 Notes would be settled entirely or partly in cash.

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, *Debt*. 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 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 warrants because the average price of the Company's common stock was less than the strike price of the warrants of $80.91 per share. Prior to actual conversion, the Convertible Note Hedge Transactions are not considered in calculating diluted EPS, as their impact would be anti-dilutive.

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

	Years Ended December 31,		
	2023	2022	2021
Stock options, RSUs, PSUs	543,140	373,728	1,275,114
2023 Notes	1,691,337	—	—

11. Income Tax Expense

The summary of the income tax expense for the years ended December 31, 2023, 2022, and 2021 is as follows (dollars in thousands):

	Years Ended December 31,		
	2023	2022	2021
Current			
Federal	$ 20,772	$ 17,515	$16,606
State	6,395	8,846	8,196
Deferred			
Federal	(21,351)	(6,802)	(1,651)
State	(4,363)	(19,527)	(3,400)
Total income tax expense	$ 1,453	$ 32	$19,751

11. Income Tax Expense (Continued)

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

	Years Ended December 31,		
	2023	2022	2021
Income tax expense computed at U.S. federal statutory income tax rate	$ 581	$12,756	$15,367
State income taxes	(330)	(3,198)	3,088
Permanent items	3,028	399	1,465
Research and development credits	(1,117)	237	(1,016)
Uncertain income tax position	(2,529)	(1,992)	(314)
Change in valuation allowance	1,267	(8,626)	250
Other	553	456	911
Income tax expense	$ 1,453	$ 32	$19,751

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

	As of December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 101,325	$ 112,516
Accrued product returns and rebates	22,150	23,300
Accrued compensation and stock based compensation	15,613	15,422
Capitalized research and development	29,953	13,926
Operating lease liability	10,374	10,821
Other	12,755	18,486
Total deferred tax assets	192,170	194,471
Less: valuation allowance	(60,866)	(59,598)
Total deferred tax asset, net of valuation allowance	131,304	134,873
Deferred tax liabilities:		
Intangibles	(144,327)	(171,113)
Operating lease assets	(7,251)	(7,338)
Other	(4,689)	(6,231)
Total deferred tax liabilities	(156,267)	(184,682)
Net deferred tax liabilities	$ (24,963)	$ (49,809)

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

11. Income Tax Expense (Continued)

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.

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

	Years Ended December 31,		
	2023	2022	2021
Beginning balance	$59,598	$70,529	$ 582
Acquisition Accounting[(1)]	—	(2,305)	69,697
Additions	1,268	435	250
Deductions	—	(9,061)	—
Ending balance	$60,866	$59,598	$70,529

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

The Company recorded a valuation allowance addition of $1.3 million for the year ended December 31, 2023. 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 carryforwards in several jurisdictions. Due to changes in the Company's ownership, the utilization of net operating loss 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, 2023, the U.S. federal and state NOL carryforwards amounted to approximately $374.0 million and $489.9 million, respectively, which will expire in various years beginning in 2031. For the year ended December 31, 2023, the Company utilized federal NOLs of approximately $42.6 million and state NOLs of approximately $25.7 million.

The Company is no longer subject to U.S. Federal income tax examinations for years prior to 2020. Operating loss or tax credit carryforwards generated prior to 2020 may be subject to tax audit adjustment.

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

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

11. Income Tax Expense (Continued)

	Years Ended December 31,		
	2023	2022	2021
Balance as of January 1	$ 4,323	$ 6,100	$5,881
Gross increases related to current year tax positions	112	32	898
Gross increases related to prior year tax positions	9	—	—
Gross decreases related to prior year tax positions	—	(39)	(363)
Lapse of statute of limitations	(2,295)	$(1,770)	(316)
Balance as of December 31	$ 2,149	$ 4,323	$6,100

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.

12. Leases

Office Space and Fleet Vehicle Leases

The Company has operating leases for its headquarters lease, certain other office space, 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 vehicles and headquarters leases.

The Company's headquarters lease commenced on February 1, 2019 (the Commencement Date) and will continue until April 30, 2034, unless earlier terminated in accordance with the terms of the lease. The lease includes options to extend the lease for up to 10 years.

As part of the Adamas Acquisition, the Company acquired a lease for office space. Adamas' 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

The Company has a contract manufacturing agreement with Merz Pharma GmbH & Co. KGaA (Merz), for the manufacture and supply of rimabotulinumtoxinB finished products (Merz Agreement). 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 MYOBLOC 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.

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 classifies and accounts for the embedded lease as an operating lease.

12. Leases (Continued)

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

	Balance Sheet Classification	December 31, 2023	December 31, 2022
Assets			
Operating lease assets	Other assets	$28,994	$28,904
Total lease assets		28,994	28,904
Liabilities			
Accounts payable and accrued liabilities			
Operating lease liabilities, current portion	Accounts payable and accrued liabilities	8,331	6,791
Lease liabilities, long-term			
Operating lease liabilities, long-term	Operating lease liabilities, long-term	33,196	35,998
Total lease liabilities		$41,527	$42,789

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

	December 31, 2023	December 31, 2022
Operating lease cost:		
Fixed lease cost	$ 8,258	$ 8,239
Variable lease cost	5,998	4,608
Total	$14,256	$12,847

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

	December 31, 2023	December 31, 2022	December 31, 2021
Cash paid for operating leases	$17,112	$12,883	$11,908
Lease assets and tenant receivable obtained for new operating leases	7,170	1,867	10,868

Weighted average lease term, and weighted average discount rate for operating leases as of December 31, 2023, are as follows:

Operating leases	
Weighted-average remaining lease term (years)	7.3
Weighted-average discount rate	4.5%

12. Leases (Continued)

Future minimum lease payments under noncancellable operating leases as of December 31, 2023, are as follows (dollars in thousands):

	Operating Leases
Year ending December 31:	
2024	$ 9,854
2025	8,579
2026	5,493
2027	4,633
2028	3,004
Thereafter	17,067
Total future minimum lease payments	48,630
Less: Imputed interest[(1)]	(7,103)
Present value of lease liabilities	$41,527

(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, 2023, and December 31, 2022, the Company has reduced accounts receivable by approximately $10.7 million and $13.0 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.

Inventories, net

Inventories consist of the following (dollars in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$16,274	$24,820
Work in process	31,212	31,710
Finished goods	29,922	35,011
Total	$77,408	$91,541

The Company recorded inventory write-offs of $8.0 million and $10.4 million for the years ended December 31, 2023 and 2022, respectively.

13. Composition of Other Balance Sheet Items (Continued)

Property and Equipment, net

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

	December 31, 2023	December 31, 2022
Lab equipment and furniture	$ 13,069	$ 12,127
Leasehold improvements	14,023	14,023
Software	883	883
Computer equipment	960	983
Construction-in-progress	—	206
	28,935	28,222
Less accumulated depreciation and amortization	(15,405)	(13,049)
Total	$ 13,530	$ 15,173

Depreciation and amortization expense on property and equipment was approximately $2.5 million, $3.0 million, and $2.6 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Accounts Payable and Accrued Liabilities

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

	December 31, 2023	December 31, 2022
Accounts payable	$ 1,964	$10,543
Accrued compensation, benefits, & related accruals	20,722	16,963
Accrued manufacturing expenses	11,652	15,216
Accrued sales & marketing	11,666	16,783
Accrued R&D expenses	10,530	7,490
Operating lease liabilities, current portion[(1)]	8,331	6,791
Accrued royalties[(2)]	7,918	12,022
Other accrued expenses	6,786	10,534
Total	$79,569	$96,342

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

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

Accrued Product Returns and Rebates

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

	December 31, 2023	December 31, 2022
Accrued product rebates	$ 96,984	$106,657
Accrued product returns	57,290	45,008
Total	$154,274	$151,665

14. Interest Expense

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

	Years Ended December 31,		
	2023	2022	2021
Interest expense	$(1,321)	$(2,542)	$ (2,195)
Noncash interest expense on nonrecourse liability related to sale of future royalties	(562)	(2,416)	(3,727)
Noncash interest expense on debt	(532)	(2,112)	(17,501)
Total	$(2,415)	$(7,070)	$(23,423)

Noncash interest expense on debt is related to amortization of deferred financing costs on the 2023 Notes. The Company fully amortized the deferred financing costs on the 2023 Notes in the first quarter of 2023. (see Note 8, *Debt*).

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. The Company recorded a nonrecourse liability related to this transaction and amortizes this liability as noncash royalty revenues. Full ownership of the royalty rights has reverted back to the Company as the cumulative payment threshold has been reached as of June 30, 2023 (see Note 2, *Summary of Significant Accounting Policies—Royalty Revenues* and Note 3, *Disaggregated Revenues*).

As of December 31, 2022, the nonrecourse liability related to sale of future royalties was $6.0 million and was included in *Other current liabilities* as reported on the consolidated balance sheet.

USWM Enterprises Commitments Assumed

As part of the USWM Acquisition, the Company assumed the remaining commitments of USWM Enterprises and its subsidiaries, which are discussed below.

The Company assumed 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. Refer to Note 12, *Leases* for further discussion related to the Merz Agreement in connection with the MYOBLOC annual minimum purchase requirement.

15. Commitments and Contingencies (Continued)

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 which was effective in April 2019. 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, the Company 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, the Company will continue to maintain a broad array of processes, policies and procedures necessary to comply with the CIA through March 2024.

Data Breach-related Contingency

On November 24, 2021, the Company announced that it was 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 its internal investigation, the Company believes the criminal ransomware groups ("criminal groups") copied certain data from the Company's systems, encrypted certain data on the Company's systems, and then deployed malware designed to impede access to the Company's systems. Thereafter the criminal groups 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. In the fourth quarter of 2021, the Company had successfully recovered the impacted files and took 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. The Company continues to monitor the situation.

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. The Company does 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 (the District Court) (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

15. Commitments and Contingencies (Continued)

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' patents in question were licensed exclusively to Forest Laboratories Holdings Limited. 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. On August 25, 2022, the Ninth Circuit sided with the defendants by reversing the District Court's public disclosure bar rulings and remanding the case back to the District Court to decide certain issues in the first instance. On October 11, 2022, the plaintiff filed a petition for rehearing with the Ninth Circuit which was denied on November 3, 2022. On December 23, 2022, the defendants filed renewed motions to dismiss directed to the remaining unresolved issue. On March 20, 2023, the District Court entered an order and final judgement dismissing with prejudice the FCA claim while declining to exercise supplemental jurisdiction over the state false claims act claims which were dismissed without prejudice. On April 19, 2023, the plaintiff appealed the District Court's dismissal of the Federal False Claims Act claim. The appeal remains pending in the United States Court of Appeals for the Ninth Circuit.

APOKYN Litigation

On October 3, 2022, Sage Chemical, Inc. and TruPharma, LLC filed a lawsuit in the United States District Court for the District of Delaware (Case No.22-cv-1302) alleging that Supernus Pharmaceuticals, Inc., Britannia Pharmaceuticals Limited, and US WorldMeds Partners, LLC violated state and federal antitrust law in connection with APOKYN. On January 10, 2023, the Company filed motions to dismiss all claims and the lawsuit in its entirety. As of April 12, 2023, briefing on those motions is now complete. Those motions remain pending. On April 10, 2023, the Court issued a scheduling order that provides for a Pretrial Conference on March 7, 2025, and a jury trial beginning on March 24, 2025. Pretrial discovery is ongoing. The Company intends to defend itself vigorously. However, the Company can offer no assurances that it will be successful in a litigation.

Apotex Settlement and License Agreement

The Company entered into settlement and license agreements dated June 21, 2023 with Apotex Inc. The agreements settled ongoing patent litigation regarding Apotex ANDA filings seeking approval to market a generic version of the Company's 150mg, 300mg, and 600mg strength Oxtellar XR (extended-release oxcarbazepine) tablets in September 2024, or sooner under certain conditions.

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, 2023, the end of the period covered by this report. Based on that evaluation, under the supervision and with the participation of our management, including our CEO and CFO, we concluded that our disclosure controls and procedures were effective as of December 31, 2023.

Management's 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, 2023 based on criteria related to internal control over financial reporting described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO 2013 Framework).

Based on management's assessment using the criteria set forth above, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2023.

Our independent registered public accounting firm KPMG LLP, who audited our consolidated financial statements included in this Annual Report on Form 10-K, issued an opinion on the effectiveness of the Company's internal control over financial reporting. KPMG LLP's report is included in this Annual Report on Form 10-K.

Remediation of Previously Disclosed Material Weakness in Internal Control over Financial Reporting

As previously disclosed in "Item 4. Controls and Procedures" in our Quarterly Report on Form 10-Q as of March 31, 2023, we remediated the material weaknesses in our internal control over financial reporting that were reported in Item 9A. Controls and Procedures" in our Annual Report on Form 10-K as of December 31, 2022. These material weaknesses were due to 1) the lack of qualified resources and an adequate risk assessment over the design and effective operation of controls in our inventory and cost of goods sold processes and 2) the lack of an adequate risk assessment over the design and effective operation of controls that would affect our estimation of accrued product rebates.

Management took several steps to remediate the previously disclosed material weaknesses including the following:

1) For the inventory and cost of goods sold processes, we hired new inventory personnel during the fourth quarter of 2022, performed risk assessment procedures, and redesigned certain controls and procedures.

2) For our estimation of accrued commercial product rebates, we performed additional risk assessment procedures and redesigned controls as necessary.

As of March 31, 2023, Management completed their remediation efforts described above and has concluded through testing, that the controls are operating effectively, and the material weaknesses in our internal controls over financial reporting have been remediated.

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, 2023. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 that occurred during the quarter ended December 31, 2023, that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Insider Trading Arrangements and Policies.

There were no insider trading arrangements adopted or terminated during the quarter.

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 2024 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2023.

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 2024 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2023.

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 2024 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2023.

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, 2023:

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	6,583,822	$29.20	2,086,766
Equity compensation plans not approved by security holders	—	—	—
Total	6,583,822	$29.20	2,086,766

(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 2024 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2023.

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 2024 Annual Meeting to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2023.

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, 2023 and 2022 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).
10.1*+	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).
10.2*+	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).
10.3†*	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).
10.4†*	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).
10.5†*	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).
10.6†*	Purchase and Sale Agreement, dated as of June 9, 2006, by and between the Registrant and Rune Healthcare Limited.
10.7*	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.

Exhibit Number	Description
10.8*+	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).
10.9*+	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).
10.10*+	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).
10.11*+	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).
10.12†*	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).
10.13†*	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).
10.14*	Royalty Interest Acquisition Agreement, dated July 1, 2014, by and between Supernus Pharmaceuticals, Inc. and HealthCare Royalty Partners III, L.P. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on July 8, 2014, File No. 001-35518).
10.15*	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).
10.16**	Form of Executive Retention Agreement.
10.17*+	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).
10.18*+	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).
10.19†*	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).
10.20*+	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).
10.21*+	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).

Exhibit Number	Description
10.22†*	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).
10.23†*	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).
10.24†*	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).
10.25*+	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).
10.26*	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).
10.27*	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).
10.28*	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).
10.29††#*	Development and Option Agreement, dated April 21, 2020, by and between Navitor Pharmaceuticals, Inc. and Supernus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Form 10-Q filed on August 17, 2020, File No. 001-35518).
10.30††#*	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).
10.31††*	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).
10.32††#*	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).
10.33††*	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).
10.34††+*	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).

Exhibit Number	Description
10.35††*	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).
10.36††*	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).
10.37+*	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).
10.38**	Form of Time-Based Incentive Stock Option Agreement, for awards issued after 2023 under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan.
10.39+*	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).
10.40**	Form of Non-Statutory Time-Based Stock Option Agreement, for awards issued after 2023 under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan.
10.41+*	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).
10.42**	Form of Restricted Stock Unit Award Agreement, for awards issued after 2023 under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan.
10.43+*	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).
10.44**	Form of Performance Share Unit Award Agreement, for awards issued after 2023 under the Supernus Pharmaceuticals, Inc. 2021 Equity Incentive Plan.
10.45††*	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).
10.46††*	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).
10.47††	Settlement Agreement, dated as of December 31, 2022, by and between Supernus Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited. (incorporated by reference to Exhibit 10.71 to the Form 10-K filed on March 9, 2023, File No. 001-35518).
10.48††**	Settlement Agreement, dated as of June 21, 2023, by and between Supernus Pharmaceuticals, Inc. with Apotex Inc. and Apotex Corp.
10.49††*	Credit Line Agreement between UBS Bank USA and Supernus Pharmaceuticals, Inc. dated as of February 8, 2023 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on February 14, 2023, File No. 001-35518).
14 *	Code of Ethics (incorporated by reference to Exhibit 14 to the Company's Annual Report on Form 10-K for the period ended December 31, 2012, filed on March 15, 2013, File No. 001-35518).

Exhibit Number	Description
19**	Policy Statement on Securities Trades by Directors, Officers, and Employees.
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
97**	Incentive Compensation Recoupment Policy.
101**	The following financial information from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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, 2023, 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: February 27, 2024

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

Signature	Title	Date
/s/ JACK A. KHATTAR	President and Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2024
/s/ TIMOTHY C. DEC	Senior Vice-President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2024
/s/ CHARLES W. NEWHALL, III.	Director and Chairman of the Board	February 27, 2024
CARROLEE BARLOW, M.D., PH.D.	Director	February 27, 2024
/s/ GEORGES GEMAYEL, PH.D.	Director	February 27, 2024
/s/ FREDERICK M. HUDSON	Director	February 27, 2024
/s/ BETHANY SENSENIG	Director	February 27, 2024
/s/ JOHN M. SIEBERT, PH.D.	Director	February 27, 2024

EXHIBIT 21

SIGNIFICANT 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, LLC	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 statements (Nos.333-181479, 333-201049, 333-216135, 333-239459, and 333-257392) on Form S-8 of our reports dated February 27, 2024, with respect to the consolidated financial statements of Supernus Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Baltimore, Maryland
February 27, 2024

EXHIBIT 31.1

CERTIFICATION

I, Jack A. Khattar, certify that:

1. I have reviewed this Annual Report on Form 10-K of Supernus Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2024

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: February 27, 2024

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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jack A. Khattar, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2024

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, 2023 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: February 27, 2024

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.
Former Chief Medical Officer of EScape Bio and Chief Executive Officer of Parkinson's Institute and Clinical Center

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.
Director Disc Medicine Inc.

Bethany Sensenig
Chief Financial Officer of Radius Health

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, Information Technology and Regulatory Affairs

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 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 14, 2024 at 10:00 A.M. EDT. The virtual only meeting may be accessed at meetnow.global/M424FWX.

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