Risk Factors Comparison 2025-02-25 to 2024-02-27 Form: 10-K

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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. PageRisks Related to Our Industry and Business • We are dependent on the commercial success of our products in the U. S. 29 • If generics or other versions of our products including generics containing ~~oxcarbazepine. topiramate, apomorphine hydrochloride, amantadine,~~ **one or more of the active pharmaceutical ingredients present in** ~~or~~ **our products** ~~viloxazine hydrochloride,~~ are approved and successfully commercialized, our business could be materially harmed. ~~30~~ **31** • 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. 31 • 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. **33** ~~32 ITEM 1A. RISK FACTORS.~~ • 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. 33 • 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. ~~34~~ **35** • If we do not obtain marketing exclusivity for our product candidates, our business may suffer. 36 • If our competitors develop or market alternatives for the treatment of our target indications, our commercial opportunities will be reduced or eliminated. ~~36~~ **37** • We depend on collaborators to work with us to develop, manufacture and commercialize 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. ~~38~~ **39** • Our failure to successfully develop and market our product candidates would impair our ability to grow. 40 • 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. 41 • 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. ~~41~~ **42** • Healthcare reform measures could hinder or prevent the commercial success of our products or product candidates. ~~43~~ **44** • 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. ~~45~~ **46 ITEM 1A. RISK FACTORS.** • 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. 47 • We could be involved in **additional** lawsuits to protect or enforce our patents, which could be expensive, time consuming, distracting, and ultimately unsuccessful. ~~49~~ **50** • Limitations on our patent rights relating to our products and product candidates may limit our ability to prevent third parties from competing with us. ~~50~~ **51** • We face potential litigation and product liability exposures. If successful claims are brought against us, we may incur substantial liabilities. ~~51~~ **52** • 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. ~~52~~ **53** • 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. ~~55Risks~~ **56Risks** Related to Our Finances and Capital Requirements • Our operating results may fluctuate significantly. ~~55~~ **56** • Our ability to use our net operating loss carryforwards and other tax attributes may be limited or may expire prior to utilization. ~~55~~ **57** • 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. 58 • Any impairment in the value of our intangible assets, including goodwill, would negatively affect our operating results and total capitalization. ~~59 • Our Credit Line is secured by a portfolio of marketable securities and we may be required to post additional collateral. 60 Risks~~ **60Risks** 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. 61 • 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. 62General 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. ~~63~~ **64** • Our insurance coverage may not be sufficient to cover our legal claims or other losses that we may incur in the future. 64 • Our operations rely on sophisticated

information technology, systems, and infrastructure, a disruption of which could harm our operations. ~~64~~ **65** 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 **38** ~~24 %, 21~~ %, 20 %, **16 %,** and ~~13~~ **12** % of our total net revenues for the year ended December 31, ~~2023~~ **2024** , 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~~ **such** 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 ® **and Oxteller XR ®** began in January 2023 and **September 2024, respectively.** ~~those~~ **Those** competitive products have significantly impacted the sales of Trokendi XR and ~~have had~~ **Oxtellar XR, resulting in** 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~~ **products containing one or more of the active pharmaceutical ingredients present in our products** 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 **and license** agreements with third parties **, which** ~~permitting~~ ---- **permit** the sale of ~~a~~ generic ~~version~~ **versions** of Trokendi **XR and Oxtellar** XR on January ~~1,~~ 2023 **and September 2024, respectively** . Sales of generic versions of Trokendi XR ~~®~~ **and Oxtellar XR** began in 2023 **and 2024, respectively** . 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~~ **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, **in 2019,** Acorda Therapeutics, Inc. launched Inbrija **(acquired by Merz Pharmaceuticals, LLC in July 2024)** , 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 **(later withdrawn from the U. S. in June 2023)** . In February 2022, the FDA approved the first generic **containing** ~~of APOKYN (~~ apomorphine hydrochloride ~~injection)~~ to treat hypomobility" ~~off~~ **OFF** " episodes (" end- of- dose wearing off" and unpredictable" ~~on~~ **ON** / ~~off~~ **OFF** " episodes) associated with advanced Parkinson' s Disease. This approval ~~is~~ **was** for ~~an application of~~ the drug cartridges only, which **according to the FDA' s press release** are ~~compatible for~~ **to be** ~~use~~ **used** with the APOKYN pen, the brand- name pen injector **, as the generic manufacturer did not seek approval of its own pen** . 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~~ **To the extent** any third party is successful in obtaining approval to manufacture and market a generic or its own version of ~~safinamide~~ **a product containing one or more of the active pharmaceutical ingredients present in our products** in the U. S., we may not be able to prospectively realize revenues from **such products** ~~XADAGO. Third parties in the future may receive approval to manufacture and market their own versions of viloxazine hydrochloride~~ . Accordingly, **our** ~~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. 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 **ONAPGO (formerly known as** 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 **, as has occurred in the past,** 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, **where certain of our products are sold by third parties pursuant to license agreements with us,** 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~~ **Inflation Reduction Act** of 2022, discussed in greater detail below, we expect these challenges to continue and to potentially intensify ~~in~~ **during** ~~2024~~ **2025** ~~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. 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 **GOCOVRI and** 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~~ **2024** and collectively accounted for more than ~~75~~ **77** % of our total product revenue in ~~2023~~ **2024** . 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~~ **an** 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. 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~~ **In February 2025,** the **FDA approved ONAPGO (** ~~development of an infusion- pump delivery system containing~~ apomorphine **hydrochloride) injection** (**formerly** 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~~ , **as** ~~we received a Complete Response Letter (" CRL") from~~ the **first** ~~FDA regarding the NDA for SPN- 830 requesting additional information~~ and **only subcutaneous apomorphine** ~~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~~ **treatment of motor fluctuations in adults with advanced PD. See Item 1. Business** for **further information** ~~SPN- 830 and assigned PDUFA target action date in early April 2024~~ . 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~~ **suppliers** , 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, **resulting** ~~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 **ONAPGO (formerly known as** 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. 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, **as we have observed with Trokendi XR and Oxtellar XR,** competition from generic equivalents ~~would~~ adversely, materially, and permanently impact our revenues, profitability, and cash flows from those products **and may** ~~. 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~~ . 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 **a** product ~~candidates~~ **candidate** that may compete with **ONAPGO (formerly** SPN- 830 **). Also, AbbVie has developed and received FDA approval in October 2024 to market a subcutaneous 24- hour infusion of levodopa- based therapy for the treatment of motor fluctuations in adults with advanced Parkinson disease (PD)** . 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, **ONAPGO, Oxtellar XR,** Trokendi XR, ~~Oxtellar XR~~ and MYOBLOC, were approved on the basis of post-approval commitments. We **have** ~~received approval for Qelbree from the FDA, based on certain~~ post- marketing commitments ~~,~~ **for Qelbree** 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 **also** have **post- marketing commitment to conduct a new leachable study for ONAPGO, which was approved by the FDA in February 2025. We also have post- marketing commitments for Oxtellar XR and MYOBLOC. Although we have initiated work on some of these post- marketing commitments, we have not been able to accomplish them. We were released from the majority of our** post- marketing commitments for Trokendi XR **in 2024** ~~, 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. 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~~ **February** ~~2020~~ **2025**, ~~we submitted~~ the ~~NDA for~~ **FDA approved ONAPGO (apomorphine hydrochloride) injection, formerly known as** 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~~ **as** ~~not sufficiently complete to permit a substantive review. In~~ the **first** ~~letter, the FDA requested certain documents~~ and **only subcutaneous** ~~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 **adults with advanced PD** ~~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. 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 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~~ **Orphan** ~~drug~~ **Drug** ~~designation~~ **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~~ **Orphan** ~~drug~~ **Drug** ~~designation~~ **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~~ **Drug** ~~designation~~ **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~~ **Orphan** ~~drug~~ **Drug** ~~designation~~ **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~~ **Orphan** ~~drug~~ **Drug** ~~designation~~ **Designation** for SPN- 817 for the treatment of Dravet Syndrome and Lennox- Gaustaut Syndrome **and for ONAPGO for the treatment of motor fluctuations in adults with advanced PD** , and we intend to expand our designation for alternative uses where applicable, we may not receive the benefits associated with ~~orphan~~ **Orphan** ~~drug~~ **Drug** ~~designation~~ **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. 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~~ **continuing** 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 **(MDRP)** for drugs that are inhaled, infused, instilled, implanted, or injected. **During** ~~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 ~~;~~**. On May 26, 2023, CMS issued a proposed rule seeking to implement policies in the MDRP related to the new legislative requirements in the Medicaid Services Investment and Accountability Act of 2019 to address, among other things, drug misclassification and drug pricing and product data misreporting by manufacturers** • 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~~ **had** 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~~ **effective January 1,** 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. **As a result of** ARPA ~~may push~~ certain pharmaceutical manufacturers ~~to~~ **may** 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, **then** 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 **. On June 28, 2024, the Supreme Court overruled their landmark 1984 decision in Chevron v. Natural Resources Defense Council, which gave rise to the doctrine known as the Chevron doctrine. The Supreme Court' s ruling sharply reduced the power of federal agencies to interpret the laws they administer and ruled that courts should rely on their own interpretation of ambiguous laws. This ruling could have a significant impact on the health care industry, which is heavily regulated by multiple federal agencies and subject to frequent federal rulemaking regarding such topics as reimbursement, health care operations, patient safety, and patient privacy. There was enormous growth and visibility for artificial intelligence (AI) systems and tools in 2023, leading to increased calls for regulation and oversight. On October 30, 2023, the Biden Administration issued an Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI, which addressed the use of AI in health care and the safety and integrity of data stored and generated by AI health care technology systems and directed HHS to establish an AI Task Force that must, within 365 days of its creation, develop policies and specific frameworks addressing the use of AI and AI- enabled technologies in the health sector, including research, drug and device safety, and health care delivery and financing** . 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. 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. **Specifically, the guidance described that, until November 27, 2024, the FDA did not intend to take action to enforce requirements for the interoperable, electronic, package level product tracing under section 582 (g) (1) of the FDCA Act that went into effect on November 27, 2023. The FDA issued an additional guidance document in October 2024 noting that companies in the pharmaceutical distribution supply chain who have initiated their systems and processes and established electronic DSCSA data connections with their trading partners may need additional time beyond November 27, 2024 to strengthen capabilities to mitigate data issues associated with electronic DSCSA transaction information and transaction statements to ensure uninterrupted product distribution. The October 2024 guidance specifies that the FDA is responding to such need by issuing exemptions to accommodate the additional time needed by such trading partners beyond November 27, 2024, but such exemptions apply only to trading partners who have initiated their systems and processes and established electronic DSCSA data connections with their trading partners prior to November 27, 2024. The guidance also provides that such exemptions will extend beyond November 27, 2024, for different lengths of time depending on the category of the trading partner (i. e., manufacturers and repackagers, wholesale distributors, dispensers with 26 or more full time employees). As of January 31, 2025, the Trump Administration has not made any updates to, or rescinded, the October 2024 guidance document.** • 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 **was** ~~is scheduled to be~~ announced ~~by September 1~~ **on August 14** , 2024, with the first year of maximum price applicability to begin in calendar year 2026 **. There are currently ten drugs subject to government pricing under the IRA** .

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~~ **On November 17,** 2023, CMS released ~~a draft~~ **final program** guidance **to pharmaceutical manufacturers** and ~~request~~ **Part D plan sponsors** for **implementing** ~~comment regarding~~ the ~~new~~ **Medicare** 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 **. Beginning in 2025, all Medicare prescription drug plans (Medicare Part D plans) — including both standalone Medicare prescription drug plans and Medicare Advantage plans with prescription drug coverage — will be required to offer enrollees the option to pay out- of- pocket prescription drug costs in the form of capped monthly installment payments instead of all at once at the pharmacy** . 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. 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; • **Effective April 26, 2024, HHS modified certain provisions of the HIPAA Privacy Rule to prohibit the use or disclosure of protected health information by a covered health care provider, health plan, or health care clearing house, or their business associate, to: (i) conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, where such health care is lawful under the circumstances in which it is provided; or (ii) identify any person for the purpose of conducting such investigation or imposing such liability; •** 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. Competitors may infringe our patents. To counter infringement or

unauthorized use, **in the past** we **have been, and in the future we** may **again** 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. 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. 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 **applicable laws** ~~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 **to 674 employees in 2024** . 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. 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~~ **such as** 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 **, or other disruptions** 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 **, or other incident** 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 **may** ~~accelerated~~ **accelerate** 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. **Since** ~~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 **with us** . Other members of the senior management team have executive retention agreements **with us** , 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. **Any** ~~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, **or** 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. 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. 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~~ **our** ~~product~~ **products**, 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~~ **dependence** 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 **, borrowings** 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 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~~ **2024**, we had U. S. ~~Federal~~ **federal** net operating loss carryforwards of approximately $ ~~374~~ **340**. ~~0~~ **6** 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. **In** ~~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 **in the future**, 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. 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. **As ONAPGO (apomorphine hydrochloride) injection, formerly known as SPN-**

830, received FDA approval in February 2025, certain milestones related to the FDA approval of the SPN- 830 NDA were paid in February 2025, and we expect certain of the remaining regulatory and commercial milestone activities to become due and paid in 2025. 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. As part of **prior** ~~the Adamas Acquisition~~ **acquisitions** ~~and the USWM Acquisition~~ , we acquired substantial intangible assets, including goodwill. We may not realize all the economic benefits from ~~the acquisition~~ **acquisitions** , 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~~ **Factors** that **may** ~~led~~ **lead** to ~~the~~ **an** impairment ~~determinations~~ **determination include** ~~were the following~~ : (1) the performance of ~~the~~ **an acquired** commercial products; (2) ~~forthcoming~~ **anticipated** loss of exclusivity of **an acquired commercial product** ~~XADAGO in December 2027, or earlier under certain circumstances, due to settlement agreements with third party generic companies~~ ; and (3) ~~the change~~ **changes** in the Company' s future outlook of ~~the brands~~ **acquired products** . 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~~ **OFF** " episodes (" end- of- dose wearing off" and unpredictable" ~~on~~ **ON** / ~~off~~ **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, **as of December 31, 2024,** the Company also ~~has~~ **had** an indefinite- lived intangible asset associated with SPN- 830. **In February 2025, the FDA approved ONAPGO (apomorphine hydrochloride) injection, formerly known as SPN- 830, as the first and only subcutaneous apomorphine infusion device for the treatment of motor fluctuations in adults with advanced PD.** 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~~ **or** 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. ~~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~~ **marketing** our current products and **developing our** 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 **financing** 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~~ **2024** , we had retained earnings of approximately $ ~~482~~ **556** . ~~6~~ **4** 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~~ **2024** , 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. 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~~ **2024** , we had outstanding ~~54~~ **55** , ~~723~~ **743** , ~~356~~ **095** shares of common stock, of which approximately 2, ~~331~~ **242** , ~~839~~ **033** 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~~ **2024** , we had outstanding options to purchase 6, ~~583~~ **719** , ~~822~~ **073** 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~~ **4** , ~~086~~ **609** , ~~766~~ **727** and ~~686~~ **584** , ~~105~~ **192** shares of our common stock are reserved for future **grant** 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. 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~~ **2024**, we had issued options to purchase 6, ~~583~~ **719**, ~~822~~ **073** shares of common stock outstanding, with exercise prices ranging from $ ~~7~~ **9**. ~~63~~ **13** to $ 58. 15 per share and a weighted average exercise price of $ ~~29~~ **30**. ~~20~~ **44** per share, as well as ~~300~~ **378**, ~~141~~ **165** unvested restricted stock units and ~~271~~ **324**, ~~630~~ **685** 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. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or in lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, causing damage to our business. We 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. 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, **cyberattacks,** 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 **products and** 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.