Risk Factors Comparison 2024-02-22 to 2023-02-23 Form: 10-K

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Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as all other information included in this Annual Report on Form 10- K, including our financial statements, the notes thereto and the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and investors could lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock. Risk Factors Summary Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following principal risk factors that make an investment in our company speculative or risky. You are encouraged to carefully review our full discussion of the material risk factors relevant to an investment in our business, which follows the brief bulleted list of our principal risk factors set forth below: ● Our ability to maintain profitability is dependent upon our ability to continue successfully commercializing our products and any products ~~and future product candidates, if approved, that~~ we may ~~develop or~~ acquire in the future; ● We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations; ● **Adverse developments affecting the financial services industry could adversely affect our business, financial condition, or results of operations; ●** If we cannot continue successfully commercializing our products **and any products that we may acquire in the future** , our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline; ● Despite receiving approval by the FDA, additional data may emerge that could change the FDA' s position on the product labeling of any of our products, including our abuse- deterrent claims with respect to Xtampza ER, and our ability to market our products successfully may be adversely affected; ● Xtampza ER, the Nucynta Products, and Belbuca are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products; ● Failure to comply with ongoing governmental regulations for marketing our products, and in particular any failure to promote Xtampza ER' s abuse deterrent labeling in compliance with FDA regulations, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions; ● Unfavorable outcomes in intellectual property litigation could be costly and potentially limit our ability to commercialize our products; ● If we are unable to obtain or maintain intellectual property rights for our technologies, products or any ~~future product~~ **products** ~~candidates which~~ we may ~~develop~~ **acquire** , we may lose valuable assets or be unable to compete effectively in our market; ● We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets; ● Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements; ● If we are unable to utilize our own sales and marketing capabilities successfully or enter into strategic alliances with marketing collaborators, we may not continue to be successful in commercializing our products and may be unable to generate sufficient product revenue; ● If the medical community, patients, and healthcare payors do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer; ● Our products contain ~~, and our future product candidates may contain,~~ controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies; ● Current and future legislation may increase the difficulty and cost for us to continue to commercialize our products and may reduce the prices we are able to obtain for our products; ● Our products may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain; ● Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory and enforcement efforts to combat abuse, could decrease the potential market for our products and may adversely impact external investor perceptions of our business; ● If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline; ● If the third- party manufacturers of our products fail to devote sufficient time and resources to these products, or their performance is substandard, and / or we encounter challenges with our dedicated manufacturing suite at our third- party manufacturer' s site for the manufacturing of Xtampza ER, our costs may be higher than expected and could have a material adverse effect on our business; ● Because we currently rely on a sole supplier or limited ~~numbers~~ - **number** of suppliers to manufacture the active pharmaceutical ingredient of our products, any production problems with any of these suppliers could have a material adverse effect on us; ● We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors or their distribution network is disrupted, our financial condition and results of operations may be adversely affected; ● Our products could be subject to post- marketing requirements, which requirements may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control; ● We may not realize all of the anticipated benefits from future acquisitions, and we may be unable to successfully integrate future acquisitions; ● Our business ~~has been, and~~ may ~~continue to~~ be ~~,~~ adversely affected by certain events or circumstances outside our control, including **macroeconomic conditions** ~~the effects of the COVID- 19 pandemic~~ and geopolitical turmoil; ● Litigation or regulatory action regarding opioid medications could negatively affect our business; ● We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products more successfully than we do; ● Commercial sales of our products ~~, and clinical trials of any future product candidates we may develop or acquire,~~ may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all; ● Our relationships with customers and payors are subject to applicable anti- kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings; and ● The price of our common stock may be volatile and you may lose all or part of your investment. ~~23Risks~~ -- **Risks** Related to Our Financial Position and Capital NeedsOur ability to maintain profitability is dependent upon our ability to continue successfully commercializing our products and any products ~~and future product candidates, if approved,~~ that we may ~~develop or~~ acquire in the future. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results. Our ability to maintain profitability depends upon our ability to realize the full commercial potential of our products and to commercialize successfully any other products ~~and future product candidates, if approved,~~ that we may ~~develop,~~ in- license or acquire in the future. Our ability to generate revenue from our current or future products depends on a number of factors, including our ability to: ● realize a commercially viable price for our products; ● manufacture commercial quantities of our products at acceptable cost levels; ● sustain a commercial organization capable of sales, marketing and distribution for the products we sell; ● obtain coverage and adequate reimbursement from third parties, including government payors; **● acquire new products, or develop new indications or line extensions for existing products, in the event that revenues from our existing products are impacted by price controls, loss of intellectual property exclusivity or competition;** and ● comply with existing and changing laws and regulations that apply to the pharmaceutical industry, including opioid manufacturers, and to our products specifically, including FDA post- marketing requirements. **23** If we fail to maintain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2022~~ **2023** , we had a U. S. federal net operating loss (" NOL ") carryforward of approximately $ ~~229~~ **137** . ~~8~~ **5** million and state NOL carryovers of approximately $ ~~252~~ **202** . ~~6~~ **4** million. The U. S. federal and state NOL carryforwards expire at various dates through 2037. Federal NOLs and certain state NOLs incurred in 2018 and onward have an indefinite expiration under the Tax Cuts and Jobs Act of 2017 and applicable state statutes. We also had U. S. federal tax credits of approximately $ ~~4~~ **1** . ~~2~~ **0** million, and state tax credits of approximately $ 0. ~~8~~ **7** million. These tax attributes are generally subject to a limited carryover / carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (" IRC 382 "). In 2021, we completed a study to assess the impact of ownership changes, if any, on our ability to use our NOL and tax credit carryovers as defined under IRC 382 (the " IRC 382 Study "). As a result of the study, we concluded that there were ownership changes that occurred during the years 2006, 2012 and 2015 that would be subject to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use pre- ownership change federal NOL carryovers and pre- ownership change federal tax credit carryovers, which may potentially limit our ability to reduce our future federal income tax liability by using these losses. As part of the BDSI acquisition, we acquired an estimated $ 234. 7 million of federal NOL carryovers which are generally subject to a limited carryover / carryback period and are also subject to the annual limitations that may be imposed under IRC 382. We performed an IRC 382 study following the BDSI Acquisition in 2022 and concluded that there were ownership changes that occurred during the years 2006 and 2022 that would be subject to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use pre- ownership change federal NOL carryovers and pre- ownership change federal tax credit carryovers, which may potentially limit our ability to reduce our future federal income tax liability by using these losses. **As of December 31, 2023, remaining net operating losses of $ 124. 3 million are subject to limitation.** Refer to Note ~~17~~ **18** , Income Taxes, to our consolidated financial statements included in Part IV of this Annual Report on Form 10- K for more information. We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations. In March 2022, we entered into a $ 650. 0 million secured term loan (the " 2022 Term Loan ") pursuant to our Amended and Restated Loan Agreement with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (as amended from time to time, the " 2022 Loan Agreement "), of which $ ~~575~~ **412** . ~~0~~ **5** million in principal was outstanding as of December 31, ~~2022~~ **2023** . In addition, we have $ 26. 4 million in 2. 625 % Convertible Senior Notes due in 2026 (the " 2026 Convertible Notes ") and $ 241. 5 million in 2. 875 % Convertible Senior Notes due 2029 (the " 2029 ~~Conertible~~ **Convertible** Notes " and, together with the 2026 Convertible Notes, the " Convertible Notes "). We may ~~24also~~ -- **also** incur additional indebtedness to meet future financing needs. Our existing and future levels of indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, and among other things: ● requiring the dedication of a substantial portion of our cash ~~flow~~ **flows** from operations to service our indebtedness, which will reduce the amount of cash available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes; ● limiting our ability to obtain additional financing; ● limiting our flexibility to plan for, or react to, changes in our business; ● exposing us to the risk of increased interest rates as certain of our borrowings, including the 2022 Term Loan, are at variable rates of interest; ● diluting the interests of our existing shareholders as a result of issuing shares of our common stock upon conversion of the ~~convertible~~ **Convertible** ~~notes~~ **Notes** ; ● placing us at a possible competitive disadvantage with competitors that are less leveraged than we are or have better access to capital; and ● increasing our vulnerability to downturns in our business, our industry or the economy in general ~~, including any such downturn related to the impact of the COVID- 19 pandemic~~ . **24** Holders of our Convertible Notes, subject to a limited exception described in the notes, may require us to repurchase their notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the notes or pay the cash amounts due upon conversion. Applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the notes or pay the cash amounts due upon conversion, and any failure by us to repurchase notes or to pay the cash amounts due upon the conversion when required would constitute a default under the indenture. Additionally, the indentures governing the Convertible Notes and our 2022 Loan Agreement contain certain covenants and obligations applicable to us, including, without limitation, covenants that limit our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business, which could limit our ability to capitalize on business opportunities that may arise or otherwise place us at a competitive disadvantage relative to our competitors. Failure to comply with covenants in the indentures governing the Convertible Notes or in the 2022 Loan Agreement would constitute an event of default under those instruments, notwithstanding our ability to meet our debt service obligations. A default under the indentures or a fundamental change could also result in a default under one or more of the agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. In such event, we may not have sufficient funds to satisfy all amounts that would become due. The 2022 Loan Agreement includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the 2022 Loan Agreement and execution upon the collateral securing obligations under the 2022 Loan Agreement. In addition, because our assets are pledged as a security under the 2022 Loan Agreement, if we are not able to cure any default or repay outstanding borrowings, our assets would be subject to the risk of foreclosure by our lenders. Further, amounts outstanding under our 2022 Loan Agreement ~~bear~~ **historically bore** interest at a rate based on **the London Interbank Offered Rate ("** LIBOR **")** , ~~subject to~~ **and, effective July 1, 2023, bears interest at** a **rate** ~~LIBOR floor of 1. 20 %. LIBOR tends to fluctuate~~ based on ~~general short- term interest rates, rates set by the U. S. Federal Reserve and other~~ - **the** ~~central banks, the supply of and demand~~ **Secured Overnight Financing Rate (" SOFR ") subject to a SOFR** ~~for~~ **floor of 1. 2 %** ~~credit in the London interbank market and general economic conditions~~ . We have not hedged our interest rate exposure with respect to our floating rate debt. Accordingly, our interest expense for any period will fluctuate based on ~~LIBOR~~ **SOFR** and other variable interest rates, as applicable. To the extent the interest rates applicable to our floating rate debt increase, our interest expense will increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected. ~~The~~ **Adverse developments affecting the** ~~Financial~~ **financial** ~~Conduct Authority~~ **services industry, including events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition, or results of operations. Events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, in early 2023, several financial institutions closed and were taken into receivership by the Federal Deposit Insurance Corporation** (" ~~FCA~~ **FDIC** ") **. Although we assess our banking and customer relationships** ~~, the regulatory supervisor of USD LIBOR' s administrator (" IBA "), has~~ - **as** ~~announced~~ **we believe necessary or appropriate, our access to funding sources and** ~~the~~ **other credit arrangements in amounts adequate to finance or capitalize our current and projected** future ~~cessation or loss of representativeness of overnight / Spot Next~~ **business operations could be significantly impaired by factors that affect us** , **the financial services industry or economy in general** ~~1- month, 3- month, 6- month and 12- month USD LIBOR tenor settings~~ . ~~As a~~ **Further, investor concerns regarding domestic or international financial systems could** result **in less favorable commercial financing terms** , ~~most USD tenors of LIBOR will cease~~ **including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations** on **access** ~~December 31, 2023. Following 25such date, subject~~ to **credit** ~~an~~ **and liquidity sources, thereby making it more difficult** ~~earlier opt- in triggered by the collateral agent or~~ **for** us ~~, amounts outstanding under~~ **to acquire financing on acceptable terms** ~~our~~ - **or** ~~2022 Loan Agreement are expected to bear interest~~ at ~~a rate based~~ **all. Any decline in available funding or access to cash and liquidity resources could, among other risks, adversely impact our ability to meet our financial obligations, which could have material adverse impacts** on ~~the Secured Overnight Financing Rate (" SOFR "), a new index calculated by reference to short- term repurchase agreements backed by U. S. Treasury securities, in place of LIBOR. Currently, it is not possible to predict the effect of any discontinuance, modification or~~ **our liquidity and** ~~other reforms to LIBOR, or~~ **our business** ~~the establishment of alternative reference rates such as SOFR~~ , **financial condition** ~~or any other reference rate~~ , ~~will have on us or our~~ - **or** ~~borrowing costs~~ **results of operations** . **25** Risks Related to our ProductsIf we cannot continue successfully commercializing our products **and any products that we may acquire in the future** , our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline. Our business and future success are substantially dependent on our ability to continue successfully commercializing our products, including Xtampza ER, the Nucynta Products, Belbuca and Symproic **, and any products that we may acquire in the future** . Our ability to continue successfully commercializing our products will depend on many factors, including but not limited to: ● our ability to manufacture commercial quantities of our products at reasonable cost and with sufficient speed to meet commercial demand; ● our ability to execute sales and marketing strategies successfully and continually; ● our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of our products; ● with respect to Xtampza ER, the perceived availability and advantages, relative cost, relative safety and relative efficacy of other abuse- deterrent products and treatments with similar indications; ● our ability to defend successfully any challenges to our intellectual property or suits asserting patent infringement relating to our products; ● the availability and quality of coverage and adequate reimbursement for our products; ● a continued acceptable safety profile of our products **; ● our ability to acquire**

new products, or develop new indications or line extensions for existing products, in the event that revenues from our existing products are impacted by price controls, loss of intellectual property exclusivity or competition ; and ● our ability to comply with applicable legal and regulatory requirements, including any additional manufacturing or packaging requirements that may become applicable to certain opioid products. Many of these matters are beyond our control and are subject to other risks described elsewhere in this " Risk Factors " section. Accordingly, we cannot assure you that we will be able to continue successfully commercializing or to generate sufficient revenue from our products. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed. Despite receiving approval by the FDA, additional data may emerge that could change the FDA' s position on the product labeling of any of our products, including our abuse- deterrent claims with respect to Xtampza ER, and our ability to market our products successfully may be adversely affected. Xtampza ER was approved with label language describing abuse- deterrent properties of the formulation with respect to the nasal and IV routes of abuse, consistent with Guidance for Industry, " Abuse- Deterrent Opioids- Evaluation and Labeling. " In November 2017, the FDA approved ~~an~~ **a** sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin and a control (oxycodone hydrochloride immediate- release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim. The FDA can require changes to the product labeling for any of our products at any time which can impact our ability to generate product sales. In particular, if the FDA determines that our post- marketing data for Xtampza ER does not demonstrate that the abuse- deterrent properties result in reduction of abuse, or demonstrates a shift to routes of abuse that present a greater risk, the FDA may find that product labeling revisions are needed, and potentially require the removal of our abuse- deterrence claims, which would have a material adverse effect on our ability to continue successfully commercializing Xtampza ER. **26** ~~26Our~~ -- **Our** opioid products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products. The FDA has imposed a class- wide REMS on all IR, ER and long-acting opioid drug products (known as the Opioid Analgesic REMS). The FDA continually evaluates whether the REMS program is meeting its goal of ensuring that the benefit of these drugs continue to outweigh their risks, and whether the goals or elements of the program should be modified. As opioids, Xtampza ER, the Nucynta Products and Belbuca are subject to the Opioid Analgesic REMS. Any modification of the Opioid Analgesic REMS by the FDA to impose additional or more burdensome requirements could increase the costs associated with marketing these products and / or reduce the willingness of healthcare providers to prescribe these products, which would have a material adverse effect on our ability to continue to successfully commercialize and generate sufficient revenue from these products. Failure to comply with ongoing governmental regulations for marketing our products, and in particular any failure to promote Xtampza ER' s abuse deterrent labeling in compliance with FDA regulations, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions. In addition to scrutiny by the FDA, advertising and promotion of any pharmaceutical product marketed in the United States is heavily scrutinized by, among others, the Department of Justice, the Office of Inspector General for the U. S. Department of Health and Human Services, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by government agencies. In particular, Xtampza ER has FDA- approved product labeling that describes its abuse deterrent features, which allows us to promote those features and differentiate Xtampza ER from other opioid products containing the same active pharmaceutical ingredients. Because the FDA closely regulates promotional materials and other promotional activities, even though the FDA- approved product labeling includes a description of the abuse deterrent characteristics of Xtampza ER, the FDA may object to our marketing claims and product advertising campaigns. Engaging in off- label promotion of our products, including Xtampza ER, could subject us to false claims liability under federal and state statutes, and other litigation and / or investigations, and could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of our products, including Xtampza ER. Further, ~~after product approval, subsequent~~ discovery of serious and unanticipated adverse events associated with the product; the emergence of other problems with the product, manufacturer or facility; or our failure to make required regulatory submissions may result in adverse regulatory actions, including withdrawal of the product from the market or the requirement to add or strengthen label warnings about the product. The failure to obtain or maintain requisite governmental approvals or the imposition of additional or stronger warnings could delay or preclude us from ~~further developing, marketing or~~ realizing the full commercial potential of our products. Risks Related to Intellectual PropertyUnfavorable outcomes in intellectual property litigation could be costly and potentially limit our ability to commercialize our products. Our commercial success depends upon our ability to commercialize products without infringing the intellectual property rights of others. Our current or future products, or any uses of them, may now or in the future infringe third- party patents or other intellectual property rights. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, ~~27including~~ -- **including** by court order, to cease commercializing the infringing technology or product. In addition, in any such **27** proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post- grant review proceedings to patents in the United States, or litigation against our collaborators may be costly and time consuming and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. We expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non- infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation, including our pending litigation with Purdue, could compromise the validity and scope of our patents or other proprietary rights or hinder our ability to manufacture and market our products. If we are unable to obtain or maintain intellectual property rights for our technologies, products or any ~~future product~~ **products** ~~candidates which~~ we may ~~develop~~ **acquire** , we may lose valuable assets or be unable to compete effectively in our market. We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know- how, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights in the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets. We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets, including in connection with our pending litigation against generic competitors that have filed Paragraph IV Certifications relating to certain of our products. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope. This litigation is expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and products, we rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts in the United States may be less willing ~~28or~~ **or** unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor, or those with whom they communicate, from using **28** that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The United States Patent and Trademark Office (" USPTO ") requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, our competitive position would be adversely affected. Risks Related to the Commercialization of Our Products If we are unable to utilize our own sales and marketing capabilities successfully or enter into strategic alliances with marketing collaborators, we may not continue to be successful in commercializing our products and may be unable to generate sufficient product revenue. Our commercial organization continues to evolve and we cannot guarantee that we will continue to be successful in marketing our products. In addition, we compete with other pharmaceutical and biotechnology companies with extensive and well- funded sales and marketing operations to recruit, hire, train and retain sales and marketing personnel. If we are unable to continue to grow and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, including with respect to our recent acquisition of Belbuca and Symproic, we may not be able to generate sufficient product revenue and may not remain profitable. Factors that may inhibit our efforts to continue successfully commercializing our products in the United States include: ● our inability to recruit and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to reach adequate numbers of physicians who may prescribe our products; and ● unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization. If we are not successful in retaining sales and marketing personnel or in maintaining our sales and marketing infrastructure or if we do not preserve strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty in continuing to commercialize our products. **If** ~~Additionally, our sales, marketing and distribution capabilities may continue to be hindered as a result of the COVID- 19 outbreak. As the COVID- 19 pandemic unfolded, and governmental and societal reactions to it evolved, our business was impacted by several trends, including depressed pain patient office visits compared to pre- COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. Notwithstanding the fact that the Department of Health and Human Services is planning for the federal public health emergency for COVID- 19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term. We have, and will continue to, equip our personnel with the tools and resources needed to effectively continue their sales and marketing efforts in a manner that complies with all relevant regulations, whether in person or from a remote setting. We face the risk, however, that limitations on activities within the healthcare sector and on economic activity generally will impede our ability to continue successfully commercializing our products. 29If~~ the medical community, patients, and healthcare payors do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer. Physicians and others in the medical community, patients, and healthcare payors may not continue to accept and use our products, or accept and use any new products that we may ~~develop or~~ acquire. Acceptance and use of our products will depend on a number of factors including: ● approved indications, warnings and precautions language that may be less desirable than competitive products; ● perceptions of physicians and other healthcare community members of the safety and efficacy of our products; ● perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology; ● the availability of competitive products; ● the pricing and cost- effectiveness of our products relative to competing products; ● the potential and perceived advantages of our products over alternative treatments; ● the convenience and ease of administration to patients of our products; **29** ● actual and perceived availability and quality of coverage and reimbursement for our products from government or other third- party payors; ● negative publicity related to our products or negative or positive publicity related to our competitors' products; ● the prevalence and severity of adverse side effects; ● policy initiatives by FDA, HHS, DEA, or other federal or state agencies regarding opioids; ● our ability to comply with the Opioid Analgesic REMS; and ● the effectiveness of marketing and distribution efforts by us and any licensees and distributors. If our products fail to have an adequate level of acceptance by the medical community, patients, or healthcare payors, we will not be able to generate sufficient revenue to remain profitable. Since we expect to rely on sales generated by Xtampza ER, the Nucynta Products, Belbuca, and Symproic for substantially all of our revenues for the foreseeable future, the failure of these products to maintain market acceptance would harm our business prospects. Some of our products contain ~~, and our future product candidates may contain,~~ controlled substances, **and** the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies. Some of our products contain ~~, and our future product candidates may contain,~~ controlled substances that are subject to state and federal laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza ER' s active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as Schedule II controlled substances under the CSA and regulations of the DEA and the active ingredient in Belbuca, buprenorphine, is classified as a Schedule III controlled substance. A number of states also independently regulate these drugs, including oxycodone, tapentadol and buprenorphine, as controlled substances. We and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. For more information, ~~see~~ **refer to** the section in our Annual Report entitled " Business — Government Regulation — DEA and Opioid Regulation. " We may not be able to obtain sufficient quantities of these controlled substances in order to meet commercial demand. If commercial demand for Xtampza ER, or any of our other approved products, increases and we cannot meet such demand in a timely fashion because of our limited supply of its active pharmaceutical ingredient (in the case of Xtampza ER, oxycodone) then physicians may perceive such product as unavailable and may be less likely to prescribe it in the future. In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas (for Schedule I and II substances), recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with ~~development and~~ commercialization of our products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances. ~~30Failure~~ -- **Failure** to obtain and maintain required registrations or to comply with any applicable regulations could delay or preclude us from ~~developing~~ **manufacturing** and commercializing our products that contain controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of our products containing controlled substances. Current and future legislation may increase the difficulty and cost for us to continue to commercialize our products and may reduce the prices we are able to obtain for our products. In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system generally, and the manufacturing, distribution, and marketing of opioids in particular, that could ~~prevent or delay marketing approval of future product candidates, restrict or regulate post- approval activities or~~ affect our ability to **commercialize** ~~profitably sell~~ our products ~~for which we obtain marketing approval~~ . For example, several states, including New York, have imposed taxes or fees on the sale of opioids. Other states, and even the federal government, could impose similar taxes or fees, and such laws and proposals can vary in the tax and fee amounts imposed and the means of calculation. Liabilities for taxes or assessments under any such laws could have an adverse impact on our results of operations. **30** California and several other states have enacted legislation related to prescription drug pricing transparency and it is unclear the effect this legislation will have on our business. Laws intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing of our products may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may subject us to more stringent product labeling and post- marketing testing and other requirements. Our products may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain. The regulations that govern marketing approvals, pricing and reimbursement for new drug products can vary widely. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Pricing limitations may hinder our ability to recoup our investment in our products. Our ability to commercialize any product successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third- party payors determine which medications they will cover and establish reimbursement levels and tiers of preference based on the perceived value and innovation of a given product. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications and establishing administrative hurdles that incentivize use of generic and / or lower cost products first. Increasingly, third- party payors are requiring that drug companies provide them with discounts and rebates from list prices and are challenging the prices charged for medical products. We have agreed to provide such discounts and rebates to certain third-party payors. We expect increasing pressure to offer larger discounts and rebates. Additionally, a greater number of third- party payors may seek discounts and rebates in order to offer or maintain access for our products. We cannot be sure that high- quality coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory. ~~31Reimbursement~~ -- **Reimbursement** rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. In August 2022, the Inflation Reduction Act of 2022 was signed into law. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would ~~require~~ **subject** manufacturers **of some brand- name medications without generic or biosimilar competition** to ~~charge~~ **a price negotiation program that results in** a negotiated " maximum fair price " **(** ~~for certain selected drugs~~ or pay an excise tax for noncompliance **)** , the establishment of rebate payment requirements on manufacturers of ~~certain~~ drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and ~~requires~~ **revises the way** manufacturers ~~to~~ provide discounts on Part D drugs. The **IRA** ~~Inflation Reduction Act of 2022~~ also caps Medicare beneficiaries' annual out- of- pocket drug expenses **at $ 2, 000 per year, thereby eliminating the Medicare Part D coverage gap or " donut hole** . **"** Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the **IRA** ~~Inflation Reduction Act of 2022~~ . The **IRA** ~~Inflation Reduction Act of 2022~~ could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of the **IRA** ~~Inflation Reduction Act of 2022~~ on our business and the pharmaceutical industry in general is not yet known. **31** Our inability to expand and maintain coverage and profitable reimbursement rates from both government- funded and private payors for our products could have a material adverse effect on our operating results, our ability to raise capital needed to continue to commercialize our products and our overall financial condition. The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to continue to commercialize our products and affect the prices we may obtain. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our products, including implementing cost- containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act, and the Affordable Care Act has also been subject to challenges in the courts. ~~See~~ **Refer to** the section in our Annual Report entitled " Business — Government Regulation — Healthcare Reform. " Further changes to and under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private ~~payers~~ **payors** . The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue and maintain profitability. Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory and enforcement efforts to combat abuse, could decrease the potential market for our products and may adversely impact external investor perceptions of our business. Law enforcement and regulatory agencies may apply policies and guidelines that seek to limit the availability or use of opioids. Such efforts may inhibit our ability to continue to commercialize our products. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse- resistant formulations; the ability of people who abuse drugs to discover ~~32previously~~ -- **previously** unknown ways to abuse opioid drugs, including Xtampza ER, the Nucynta Products and Belbuca; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for our products, decrease the revenues we are able to generate from their sale and adversely impact external investor perceptions of our business. Similarly, to the extent opioid abuse becomes less prevalent or less urgent of a public health issue, regulators and third **-** party ~~payers~~ **payors** may not be willing to pay a premium for abuse-deterrent formulations of ~~opioid~~ **opioids** . Federal laws have been enacted to address the national epidemics of prescription opioid abuse and illicit opioid use, including the Comprehensive Addiction and Recovery Act and the Substance Use- Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. These laws are described in more detail in our Annual Report under the caption " Business — Government Regulation — DEA and Opioid Regulation. " If the FDA or other applicable regulatory authorities approve generic products with claims that compete with our products, our sales could decline. Once an NDA, including a Section 505 (b) (2) application, is approved, the product covered thereby becomes a " listed drug " which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to **32** create modified, non- infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices **. Additionally, under FDORA, FDA will assign therapeutic equivalence ratings for certain prescription drugs approved via the Section 505 (b) (2) NDA pathway with respect to other approved drug products and it is unclear how assignment of these ratings will impact the market opportunity for our products** . Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore, to obtain a return on the investments we have made in our products. In the past, we have initiated litigation with generic competitors that have filed Paragraph IV Certifications challenging certain of our patents. While we have entered into settlement agreements with certain competitors, we are currently pursuing litigation to defend against Paragraph IV Certifications related to Belbuca. ~~For more information, refer~~ **Refer** to Note ~~12~~ **13** , Commitments and Contingencies, to our consolidated financial statements included in Part IV of this Annual Report on Form 10- K. We believe that we will continue to be subject to ANDA- related litigation, which can be costly and distracting and has the potential to impact the long- term value of our products **. We may seek FDA pediatric exclusivity for some of our products. Pediatric exclusivity, if granted, adds six months of patent term and marketing exclusivity to existing exclusivity periods for all formulations, dosage forms, and indications for the active moiety, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. The regulatory exclusivity period for Nucynta IR in the United States has been extended through July 3, 2026, following the grant of New Patient Population exclusivity in pediatrics by the FDA in August 2023 based on data from pediatric trials which were submitted in response to the FDA' s Pediatric Written Request to evaluate the use of Nucynta as a treatment for pain in pediatric patients aged 6 years and older. If FDA deems these data to be responsive to its Written Request, the exclusivity of the entire Nucynta franchise could be extended an additional six months, to December 2025 for Nucynta ER and January 2027 for Nucynta IR. However, there is no guarantee that FDA will agree that the Written Request has been satisfied and that we will receive this additional exclusivity, or that we will maintain such exclusivity, if granted** . In November 2017, the FDA issued a final guidance to assist industry in the development of generic versions of approved opioids with abuse-deterrent formulations, including recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse- deterrent than its brand- name counterpart. In the second half of 2018, the FDA posted three revised product- specific guidances related to generic abuse- deterrent opioid formulations, including one guidance specifically relating to Xtampza ER, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of the FDA' s wider focus on assisting developers of generic abuse- deterrent formulations in navigating the regulatory path to market more quickly. Earlier market entry of generic abuse- deterrent formulations could have a material adverse effect on our business. Risks Related to Our Dependence on Third Parties If the third- party manufacturers of our products fail to devote sufficient time and resources to these products, or their performance is substandard, and / or we encounter challenges with our dedicated manufacturing suite at our third- party manufacturer' s site for the manufacturing of Xtampza ER, our costs may be higher than expected and could have a material adverse effect on our business. We do not own any manufacturing facilities in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility and do not have the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our products. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products, as well as other vendors to formulate, test, supply, store and distribute our products, and we control only certain aspects of their activities. In 2020, we completed the build- out of a dedicated manufacturing suite for Xtampza ER at a site operated by our contract manufacturing organization, Patheon, part of Thermo Fisher Scientific. This facility requires the maintenance of ~~33regulatory~~ -- **regulatory** approvals and other costs, all of which we absorb. We cannot guarantee that we will be able to continue to leverage the dedicated manufacturing suite in a profitable manner. If the demand for Xtampza ER and any future related products never meets our expectations and forecasts, or if we do not produce the output we plan, we may not be able to realize the return on investment we anticipated, which would have a negative impact on our financial condition and results of operations. **33** We have **also** ~~completed the activities required to transition~~ **transitioned** commercial manufacturing for Nucynta ER from Janssen to Patheon. While we were successful in our regulatory approval and validation activities, we could encounter issues in obtaining commercial supply from Patheon' s facility due to technical problems or challenges obtaining adequate and / or timely DEA procurement quota. Although we have identified alternate sources for these services, it would be time- consuming, and require us to incur additional ~~cost~~ **costs** , to qualify these sources. Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and Nucynta ER, exposes us to the following risks, any of which could impact commercialization of our products, result in higher costs, or deprive us of potential product revenues: ● Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products ~~including the COVID- 19 pandemic~~, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment; ● Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of our products and / or we could experience technical problems in the operation of our dedicated manufacturing suite; ● The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products, before we may use the alternative manufacturer to produce commercial supplies; ● It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully; and ● If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs. Failure to obtain the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture our products could adversely affect our ability to continue to commercialize our products, which could in turn adversely affect our results of operations and financial condition. Likewise, the inability of any of our sole or limited suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our products. In addition, DEA regulations, through the quota procurement process, limit the amount of DEA- controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to maintain an appreciable safety stock of finished drug product. Our reliance on third parties reduces our control over our ~~development~~ **manufacturing** and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require our products to be manufactured according to cGMP. Any failure by our third- party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to **inspection deficiencies,** a shortage of commercial product **, or potential products liability exposure for any noncompliant distributed products** . Such failure could also be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, ~~suspension of ongoing clinical trials,~~ refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution. ~~34Any~~ -- **Any** stock out, or failure to obtain sufficient supplies of any of our products, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture each of our products, could adversely affect our ability to commercialize such products, which could in turn adversely affect our results of operations and financial condition. **34** Because we currently rely on a sole supplier or limited number of suppliers to manufacture the active pharmaceutical ingredient of our products, any production problems with any of these suppliers could have a material adverse effect on us. We currently rely on a sole supplier or limited number of suppliers to manufacture the active pharmaceutical ingredients of our products. ~~For example, we presently depend upon a single supplier for the active pharmaceutical ingredient for the Nucynta Products (tapentadol) and Symproic, and two active pharmaceutical ingredient suppliers for Xtampza ER and Belbuca.~~ We contract with these suppliers for commercial supply to manufacture our products. Further, our suppliers for Xtampza ER and the Nucynta Products active pharmaceutical ingredients also supply our primary competitor in the extended- release oxycodone space, Purdue. Identifying alternate sources of active pharmaceutical ingredients for our products is generally time- consuming and costly. Any changes that our suppliers make to the respective drug substance raw materials, intermediates, or manufacturing processes would introduce technical and regulatory risks to our downstream drug product supply. If our suppliers were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs (including as a result of any disruptions in personnel or the global supply chain), we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business. Global supply chain disruptions and shortages may limit manufacturing and commercial supply of our products and have a material impact on our business. There are currently global supply chain disruptions and shortages caused by a variety of factors, including ~~the COVID- 19 pandemic and~~ geopolitical turmoil, such as the Ukrainian War **and current conflict in Israel and Gaza** . While we and our suppliers are still able to receive sufficient inventory of the key materials and components needed, we could experience pressure on our supply chain, including shipping delays, higher prices from suppliers, and reduced availability of materials, including excipients and packaging components. To date, supply chain pressure has not had a material impact on our results of operations. However, if these disruptions and shortages continue, we may in the future experience a material interruption to our supply chain. Such an interruption could have a material adverse impact on our business, including but not limited to, our ability to timely manufacture and distribute our products. Manufacturing issues may arise that could increase product and regulatory approval costs, delay commercialization or limit commercial supply. In our current commercial manufacturing operations, and as we scale up manufacturing of our products and conduct required stability testing, we may encounter product, packaging, equipment and process- related issues that may require refinement or resolution in order to **successfully** ~~proceed with our planned clinical trials, obtain regulatory approval for commercial~~ **commercialize our products** ~~marketing and build commercial supplies~~. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, failure to obtain or maintain approval or limitations in our commercial supply. We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors or their distribution network is disrupted, our financial condition and results of operations may be adversely affected. A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented greater than 90 % of our product shipments for the year ended December 31, ~~2022~~ **2023** . Our loss of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases or a significant disruption to transportation infrastructure or other means of distribution of our products ~~, including as a result of the COVID- 19 pandemic~~ , could have a material adverse effect on our business, results of operations, financial condition and prospects. The significance of each wholesale pharmaceutical distributor account to our business adversely impacts our ability to negotiate favorable commercial terms with each such distributor, and as a result, we may be forced to accept terms that adversely impact our results of operations. ~~35In~~ **In** addition, these wholesaler customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot guarantee that we can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period. **35 Certain** ~~In addition, due to unprecedented and significant disruptions in the processing~~ of ~~product returns by wholesale pharmaceutical distributors, as further disclosed in " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " we formally denied a significant portion of unprocessed product claims under our return policy. We subsequently received payment for only a portion of the denied claims and vigorously pursued collections of the full amount of these short- pay receivables. Although we were able to formally settle a portion of the unprocessed product claims and receive payment therefor, payment for a significant portion of the unprocessed product claims has not been and is not expected to be received. There can be no assurance that similar disruptions in the wholesaler distribution network will not occur in the future or~~ **our** ~~if they do, that we will be able to successfully manage such disruptions. Our~~ opioid products are subject to post- marketing requirements **or commitments** , which ~~requirements~~ may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control. ~~Our opioid~~ **For certain of our** products **, we** are subject to ~~a comprehensive regulatory scheme, including~~ post- marketing requirements ~~(" PMRs ")~~ to conduct epidemiological studies and clinical trials **, or, in some cases, to conduct post- marketing surveillance or observational studies to gather additional information about our products** . ~~We~~ **For our opioid products, we generally** intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium (" OPC "). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of the OPC and engage in decision- making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our opioid products. **Additionally, there may be certain PMRs or post- marketing commitments that we fulfill on our own for our products, including via the conduct of post- marketing surveillance or observational studies. If such studies lead to the discovery of adverse findings regarding the safety or benefit profiles of our products, then the FDA may choose to withdraw or otherwise restrict the approval of our products or the FDA or we may determine that labeling changes are warranted based on their finding.** Such withdrawal or restriction **or labeling changes for our products** would have an adverse impact on our business and financial condition. ~~We have historically relied on third parties to conduct our non- clinical and clinical trials, and may continue to rely upon third parties for any product candidates we develop or acquire in the future. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to maintain regulatory approval for our products and our business could suffer a material adverse effect. We have relied upon and plan to continue to rely upon contract research organizations (" CROs ") to monitor and manage data for any non- clinical and clinical programs that we may conduct in the future, including the OPC PMR studies discussed above. We rely on these parties for execution of our non- clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our~~

~~clinical trials must be conducted with product produced under cGMP requirements. While we have agreements governing the activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our products would have an adverse impact on our commercial efforts.~~ Risks Related to Our Business and StrategyWe may not realize all the anticipated benefits from our future acquisitions, and we may be unable to successfully integrate future acquisitions. Our growth strategy will, in part, rely on acquisitions. We must plan and manage acquisitions effectively to achieve revenue growth and maintain profitability in our evolving market. We may not realize all the anticipated benefits from our future acquisitions, such as increased earnings, cost savings and revenue enhancements, for various reasons, including difficulties integrating operations and personnel, higher than expected acquisition and operating costs or other ~~36difficulties~~ -- **difficulties** , inexperience with operating in new geographic regions, unknown liabilities, inaccurate reserve estimates and fluctuations in market prices. In addition, integrating acquired businesses and properties involves a number of special risks and unforeseen difficulties can arise in integrating operations and systems and in retaining and assimilating employees. These difficulties include, among other things: ● operating a larger organization; ● coordinating geographically disparate organizations, systems, and facilities; ● integrating corporate, technological, and administrative functions; ● diverting management' s attention from regular business concerns; ● diverting financial resources away from existing operations; ● increasing our indebtedness; and ● incurring potential environmental or regulatory liabilities and title problems. Any of these or other similar risks could lead to potential adverse short- term or long- term effects on our operating results. The process of integrating our operations could cause an interruption of, or loss of momentum in, the activities of our business. Members of our management may be required to devote considerable amounts of time to this integration process, which decreases the time they have to manage our business. If our management is not able to effectively manage the integration process, or if any business activities are interrupted as a result of the integration process, our business could suffer. Our business ~~has been, and we~~ may ~~in the future continue to~~ be ~~,~~ adversely affected by certain events or circumstances outside our control, including **macroeconomic conditions** ~~the COVID- 19 pandemic~~ and geopolitical turmoil. ~~Our business has been, and we may in the future continue to be, adversely affected by certain events~~ **Events** ~~or circumstances outside our control. For example, the COVID- 19 pandemic has, and may continue to have, a substantial impact on the delivery of healthcare services in the United States. As the COVID- 19 pandemic unfolded, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. We believe that the disruptions caused by COVID- 19 may continue and, despite the Department of Health and Human Services planning for the federal public health emergency for COVID- 19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term. These circumstances may result in reduced demand for our products and negatively impact our sales and results of operations. In addition, other events~~ or circumstances outside of our control, including macroeconomic conditions such as recession or depression, inflation, and declines in consumer- spending could result in reduced demand for our products. An economic downturn could result in business closures, higher levels of unemployment, or declines in consumer disposable income which **36** could have an impact on the number of patients seeking and receiving treatment for conditions that might otherwise result in the prescription of our products, as patients may make efforts to avoid or postpone seeking non- essential medical care to allocate their resources to other priorities or essential items. These circumstances, in addition to the impact of geopolitical turmoil, **such as the ongoing Ukrainian War and current conflict in Israel and Gaza (including any escalation or expansion),** social unrest, political instability **in the United States and elsewhere** , terrorism, cyberwarfare or other acts of war, may result in reduced demand for our products and negatively impact our sales, results of operations, and liquidity **. Security breaches and other disruptions to our, or our vendors', information technology systems may compromise our information and expose us to liability that could adversely impact our financial condition, operations, and reputation. We, our collaborators, third- party providers, distributors, customers and other contractors utilize information technology systems and networks (" Systems ") to transmit, store and otherwise process electronic data in connection with our business activities, including our supply chain processes, operations and communications including, in some cases, our business proprietary information, and Electronic Data Interchange (" EDI ") on purchase orders, invoices, chargebacks, among other things. Our Systems, along with those of the third parties whom we rely on to process confidential and sensitive data in a variety of contexts, are potentially vulnerable to a variety of evolving threats that may expose this data to unauthorized persons or otherwise compromise its integrity. These threats may include, but are not limited to, social- engineering attacks (including through phishing attacks), business email compromise, online and offline fraud, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks, access attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. We may expend significant resources to try to protect against these threats to our Systems. Certain data privacy and security laws, as well as industry best practice standards, may require us to implement and maintain security measures. While we have implemented security measures designed to protect our Systems and confidential and sensitive data, there can be no assurance that these measures will be effective. Threat actors and their techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. If we, or a third party upon whom we rely, experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund**

diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Further, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices . Litigation or regulatory action regarding opioid medications could negatively affect our business. Beginning in 2018, lawsuits alleging damages related to opioids have been filed naming us as a defendant along with other manufacturers of prescription opioid medications. These lawsuits, filed in multiple jurisdictions, are brought by various local governments as well as private claimants, against various manufacturers, distributors and retail pharmacies. These lawsuits generally ~~alleged~~ - **allege** that we had engaged in improper marketing practices related to Xtampza ER and the Nucynta Products. In March 2022, we entered into a Master Settlement Agreement resolving ~~all~~ 27 pending opioid-related lawsuits brought against us by cities, counties, and other subdivisions in the United States. As part of the Master Settlement Agreement, we paid $ 2. 75 million to the plaintiffs and the cases **were** ~~will be~~ dismissed, with prejudice **. In late March 2023, three new cases were filed in three federal courts, naming us as one of numerous defendants, from which we have been dismissed** . Certain governmental and regulatory agencies are focused on the abuse of opioid medications, a concern we share, and we have received Civil Investigative Demands or subpoenas from four state attorneys general investigating our sales and ~~37marketing~~ -- **marketing** of opioids and seeking documents relating to the manufacture, marketing and sale of opioid medications. In December 2021, we entered into an Assurance of Discontinuance with the Massachusetts Attorney General pursuant to which we provided certain assurances and agreed to pay certain of the Massachusetts Attorney General' s costs of investigation, in exchange for closure of the investigation and a release of claims pertaining to the subject matter of the investigation. We are cooperating fully in the open investigations. Managing litigation and responding to governmental investigations is costly and may involve a significant diversion of management attention. Such proceedings are **37** unpredictable and may develop over lengthy periods of time. An adverse resolution of any of these lawsuits or investigations may involve injunctive relief or substantial monetary penalties, either or both of which could have a material adverse effect on our reputation, business, results of operations and cash flows. We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products more successfully than we do. Competition in the pain and opioid market is intense. Our competitors include major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our products compete with oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Actavis, Endo, Mallinckrodt, Purdue, Teva, and others. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do. Our competitors have developed or may develop technologies that are, or may be, the basis for competitive products that are safer, more effective or less costly than our products. Moreover, oral medications, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available treatments for chronic pain, are widely accepted in the medical community and have a long history of use. These treatments will compete with our products and the established use of these competitive products may limit the potential for our products to receive widespread acceptance. Commercial sales of our products ~~,~~ and ~~clinical trials of~~ any ~~future product~~ **products** ~~candidates~~ we ~~develop or~~ acquire, may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all. We currently carry product liability insurance. Product liability claims may be brought against us by patients; ~~clinical trial participants;~~ healthcare providers; or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may cause us to incur significant costs to defend the litigation. Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings. Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of our products. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products ~~and any product candidates for which we may obtain marketing approval~~ . Even though we do not and will not control referrals of healthcare services or bill Medicare, Medicaid or other third- party payors directly, we may provide reimbursement guidance and support regarding our products to our customers and patients. Federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If a government authority were to conclude that we provided improper advice to our customers and / or encouraged the submission of false claims for reimbursement, we could face action by government authorities. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. ~~38We~~ **We** or the third parties upon whom we depend may be adversely affected by natural disasters and / or health epidemics, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemic ~~(such as the COVID- 19 pandemic)~~ or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as the manufacturing facilities of our third- party contract manufacturers, or that otherwise disrupted operations, it might **38** become difficult or, in certain cases, impossible for us to continue our business, and any disruption could last for a substantial period of time. The disaster recovery and business continuity plans we have in place, and the technology that we may rely upon to implement such plans, may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition and results of operation. Risks Related to Our Common StockThe price of our common stock may be volatile and you may lose all or part of your investment. The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors described in these " Risk Factors, " some of which are beyond our control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our business model, prospects or actual operating performance. The realization of any of these risks, or any of a broad range of other risks discussed in this report, could have a material adverse effect on the market price of our common stock. We are subject to anti- takeover provisions in our second amended and restated articles of incorporation and amended and restated bylaws and under Virginia law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our shareholders. Certain provisions of Virginia law, the state in which we are incorporated, and our second amended and restated articles of incorporation and amended and restated bylaws could hamper a third party' s acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders to remove our Board of Directors or management or elect new directors to our Board of Directors. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to report our financial condition, results of operations or cash flows accurately, which may adversely affect investor confidence in us and, as a result, the value of our common stock. The Sarbanes- Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. We are required, under Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. Further, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to capital markets. **Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. Moreover, the exercise of options and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute your ownership interests and may adversely affect the future market price of our common stock. Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock. As of December 31, 2023, there were outstanding options to purchase an** 39