Risk Factors Comparison 2024-02-09 to 2023-02-09 Form: 10-K

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The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward- looking statements we have made in this Annual Report on Form 10- K and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations. Summary Risk Factors We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include: • We may not be able to continue to successfully commercialize INGREZZA ~~, ONGENTYS,~~ or any of our other products, or any of our product candidates if they are approved in the future. • If physicians and patients do not continue to accept INGREZZA or do not accept ~~ONGENTYS, or do not accept~~ any of our other products, or our sales and marketing efforts are not effective, we may not generate sufficient revenue. • **Enacted healthcare reform, drug** ~~Governmental and third- party payors may impose additional sales and pharmaceutical~~ pricing **measures** ~~controls on our products or further limit coverage~~ and ~~/ or reimbursement for our products that~~ **other recent legislative initiatives, including the Inflation Reduction Act of 2022,** could **adversely affect** ~~negatively impact our product revenues and impact or~~ **our business** ~~delay sustained profitability~~ . • Our business could be adversely affected by the effects of health pandemics or epidemics, ~~including the COVID- 19 pandemic,~~ which could also cause significant disruption in the operations of third- party manufacturers, contract research organizations **(** ~~, or~~ CROs **)** , or other third parties upon whom we rely. • We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced. • Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates. • Our clinical trials may be delayed for safety or other reasons, or fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval ~~. • Several of our planned clinical trial sites have been impacted and could be delayed or suspended as a result of the conflict between Russia and Ukraine~~ . • We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. • Use of our approved products or those of our collaborators could be associated with side effects or adverse events. • We have ~~recently~~ increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations. • If we are unable to retain and recruit qualified scientists and other employees or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts or impact our commercialization of INGREZZA ~~, ONGENTYS,~~ or any of our other products, or any product candidate approved by the FDA in the future. • We currently have no manufacturing capabilities. If third- party manufacturers of INGREZZA ~~, ONGENTYS,~~ or any of our other products, or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, and our costs may rise. • We currently depend on a limited number of third- party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA ~~, ONGENTYS,~~ or any of our other products, could materially and adversely affect our ability to successfully commercialize INGREZZA ~~, ONGENTYS,~~ or any of our other products. • We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages. • If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products. • **Government** ~~Health care reform measures~~ and **third- party payors may impose sales and pharmaceutical pricing controls on our products, or limit coverage and / or reimbursement for our products or impose policies and / or make decisions that regarding** ~~other -- the recent legislative initiatives~~ **status of our products that** could **limit** ~~adversely affect~~ our ~~business~~ **product revenues and delay sustained profitability** . • Our indebtedness ~~and liabilities~~ could ~~limit the cash flow available for our operations,~~ expose us to risks that could adversely affect our business, financial condition and results of operations. • We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability. • Our customers are concentrated and therefore the loss of a significant customer may harm our business. • **We may need additional capital in the future.** If we cannot raise additional funding, we may be unable to ~~complete~~ **fund our business plan and our future research,** development **,** ~~of our product candidates or establish~~ commercial and manufacturing **efforts** ~~capabilities in the future~~ . Risks Related to Our Company Our ability to produce INGREZZA revenues consistent with expectations ultimately depends on our ability to continue to successfully commercialize INGREZZA and secure adequate third- party reimbursement. Our experience in marketing and selling pharmaceutical products began with INGREZZA' s approval in 2017, when we hired our sales force and established our distribution and reimbursement capabilities, all of which are necessary to successfully commercialize our current and future products. We have continued to invest in our commercial infrastructure and distribution capabilities ~~in the past four years~~ , including the expansion of our specialty sales force, which we announced in the third quarter of 2021 and completed in April 2022. While our team members and consultants have experience marketing and selling pharmaceutical products, we may face difficulties related to managing the rapid growth of our personnel and infrastructure, and there can be no guarantee that we will be able to maintain the personnel, systems, arrangements and capabilities necessary to continue to successfully commercialize INGREZZA ~~, or to successfully commercialize ONGENTYS~~ or any of our other products, or any product candidate approved by the FDA **, or equivalent foreign authorities,** in the future. In addition, our business has been and may

continue to be adversely affected by the effects of health pandemics or epidemics ~~, including the ongoing COVID- 19 pandemic~~ . In parts of the country ~~where the pandemic is having a greater impact~~ , some hospitals, community mental health facilities, and other healthcare facilities continue to have policies that limit access of our sales representatives, medical affairs personnel and patients to such facilities. ~~These policies are likely to change from time to time as communities or regions grapple with outbreaks. These facilities also may be facing staffing shortages that impact their ability to see patients and conduct necessary screenings.~~ In addition, many ~~health~~ **healthcare** ~~care~~ practitioners have adopted telehealth for patient interactions, which may impact the ability of the ~~health~~ **healthcare** ~~care~~ practitioner to screen for and diagnose tardive dyskinesia ~~. Further, during the COVID- 19 pandemic, the use of physician telehealth services increased significantly, fueled by an expansion of coverage and reimbursement from government and other payors. The limitations that telehealth places on the ability to conduct a thorough visual and physical examination may impact the ability of providers to screen for~~ **or chorea associated with Huntington' s disease** ~~movement disorders, leading to potentially fewer patients to be diagnosed and referred for treatment. The ultimate impact of the COVID- 19 pandemic, including any lasting effects on the way we conduct our business, is highly uncertain and subject to continued change. If we fail to maintain successful marketing, sales and reimbursement capabilities, our product revenues may suffer~~ . The commercial success of INGREZZA ~~, ONGENTYS,~~ or any of our other products will depend upon the acceptance of those products as safe and effective by the medical community and patients. The market acceptance of INGREZZA ~~, ONGENTYS,~~ or any of our other products could be affected by a number of factors, including: • the timing of receipt of marketing approvals for additional indications; • the safety and efficacy of the products; • the pricing of our products; • the availability of healthcare payor coverage and adequate reimbursement for the products; • public perception regarding any products we may develop; • the success of existing competitor products addressing our target markets or the emergence of equivalent or superior products; and • the cost- effectiveness of the products. If the medical community, patients and payors do not continue to accept our products as being safe, effective, superior and / or cost- effective, we may not generate sufficient revenue. ~~Governmental~~ **Government** and third- party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and / or reimbursement for our products or impose policies **and / or make decisions regarding the status of our products** that could limit our product revenues and delay sustained profitability. Our ability to continue to commercialize INGREZZA successfully or ~~to successfully commercialize ONGENTYS or~~ any of our other products ~~,~~ will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available. The continuing efforts of government and third- party payors to contain or reduce the costs of ~~health~~ **healthcare** ~~care~~ and the price of prescription drugs through various means may impact our revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future. Assuming we obtain coverage for a given product by a third- party payor, the resulting reimbursement ~~payment~~ rates may not be adequate or may require co- payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third- party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the out- of- pocket cost of our products. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available regardless of whether they are approved by the FDA for that particular use. Coverage decisions by payors for our competitors' products may also impact coverage for our products. Government authorities and other third- party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third- party payors in the ~~United States~~ **U. S** . Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. In addition, communications from government officials, media outlets, and others regarding ~~health~~ **healthcare** ~~care~~ costs and pharmaceutical pricing could have a negative impact on our stock price, even if such communications do not ultimately impact coverage or reimbursement decisions for our products. There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs or indications, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. **In addition, we could also be subject to amendments in our rebate agreements with pharmaceutical benefit managers that require us to pay larger rebate amounts or modify our formulary position, which could have a material adverse effect on our business.** Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. **For example, government authorities could make a decision that adversely impacts the status of one of our products, which could impact the eligibility and / or the amount of government reimbursement for that product. As a pharmaceutical manufacturer, we are subject to various federal statutes and regulations requiring the reporting of price data and the subsequent provision of concessions to certain purchasers / payors, including state Medicaid programs. Federal agencies issue guidance to manufacturers related to the interpretation of laws and regulations, and this guidance has changed and may change or be updated over time. In interpreting these laws, regulations and guidance, manufacturers may make reasonable assumptions to fill gaps, and these reasonable assumptions may need to be updated upon issuance of additional agency guidance.** If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may be unable to successfully commercialize INGREZZA ~~, ONGENTYS,~~ or any of our other products, or any other product candidate for which we obtain

marketing approval in the future. Our inability to promptly obtain coverage and profitable reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Further, a majority of our current revenue is derived from federal healthcare program payors, including Medicare and Medicaid. Thus, changes in government reimbursement policies **, government negotiation of the price of any of products** , reductions in payments and / or our suspension or exclusion from participation in federal healthcare programs could have a material adverse effect on our business. Further, during the COVID- 19 pandemic, the use of physician telehealth services ~~has~~ rapidly increased, fueled by an unprecedented expansion of coverage and reimbursement **for telehealth services** across **public and private** insurers. The limitations that telehealth places on the ability to conduct a thorough physical examination may impact the ability of providers to screen for movement disorders, leading to fewer patients being diagnosed and / or treated. ~~Our business~~ **Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. The EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. To obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. The Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021 / 2282 on HTA, amending Directive 2011 / 24 / EU, was adopted in the EU. This regulation, which entered into force in January 2022 will apply as of January 2025. The regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU** could be ~~adversely~~ **negatively** affected ~~by~~ **. In light of the fact that the UK has left the EU, Regulation No 2021 / 2282 on HTA will not apply in the UK. However, the MHRA is working with UK HTA bodies and** ~~the~~ **other** ~~effects of~~ **national organizations, such as the Scottish Medicines Consortium, the National Institute for** ~~health~~ **Health** ~~pandemics or epidemics~~ **and Care Excellence** , ~~including~~ **and** the ~~COVID~~ **All** - ~~19 pandemic~~ **Wales Medicines Strategy Group** , ~~which could also cause significant disruption in~~ **to introduce new pathways supporting innovative approaches to** the ~~operations~~ **safe, timely and efficient development** of ~~third~~ **medicinal products. Legislators, policymakers and healthcare insurance funds in the EU and the UK may continue to propose and implement cost** - **containing measures to keep** ~~party manufacturers CROs, or other third parties upon whom we rely. Our business could be adversely affected by the effects of health~~ **healthcare costs down** ~~pandemics or epidemics~~ , **particularly due to** ~~which could also cause significant disruption in the operations of third- party manufacturers, CROs and other~~ -- **the financial strain** ~~third parties upon whom we rely. As a result of the ongoing COVID- 19 pandemic, we may experience disruptions~~ that ~~could severely impact our supply chain, ongoing and future clinical trials and commercialization of INGREZZA, ONGENTYS, or any of our other products. For example,~~ the COVID- 19 pandemic has **placed** resulted in travel restrictions and the shutdown..... which will depend, in part, on **national healthcare systems** ~~the length and severity~~ of ~~the restrictions and other~~ **European countries. These measures could include** limitations on ~~our ability to conduct our business in~~ the **prices** ~~ordinary course. Remote work may also create increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. In addition,~~ we ~~may face several challenges or disruptions upon a return back to the workplace, including re- integration challenges by our employees and distractions to management related to such transition. These and similar, and perhaps more severe, disruptions in our operations due to the COVID- 19 pandemic could~~ **would be able** ~~negatively impact our business, operating results and financial condition. We continue~~ to **charge** ~~evaluate the impact of the COVID- 19 pandemic on our business and will update our plans and policies as needed going forward. Quarantines, stay at home orders, travel restrictions and other state and local restrictions, or~~ **for** ~~the perception~~ **product candidates** that ~~such orders, shutdowns~~ **we may successfully develop and** ~~or~~ **for which we may obtain regulatory approval or** ~~other~~ -- **the level** ~~restrictions on the conduct~~ of **reimbursement available** ~~business operations could occur, related to COVID- 19 or~~ **for these products from governmental authorities or** ~~other infectious diseases, could impact personnel at~~ third- party **payors. Further,** ~~manufacturing facilities in the United States and~~ - **an increasing number of EU and other foreign countries use prices for medicinal products established in** other countries ~~, or~~ **as " reference prices " to help determine the price of the product in** ~~the~~ **their own territory** ~~availability or cost of materials, which would disrupt our supply chain~~ . **Consequently** ~~In addition~~ , **a downward trend in prices** ~~clinical site initiation and patient enrollment may be delayed due to concerns for patient safety and prioritization~~ of **medicinal products in** ~~healthcare resources toward the COVID- 19 pandemic. Some~~ **some countries** ~~patients may not be able to comply with clinical trial protocols if quarantines impede patient~~

~~travel or interrupt healthcare services. Similarly, our ability to recruit and retain patients, principal investigators and site staff may be hindered, which would adversely impact our clinical trial operations. Increases in COVID- 19 cases or hospitalizations in the future~~ could ~~cause us or any of our clinical sites to again limit or suspend our patient enrollment and screening activities. The COVID- 19 pandemic, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID- 19 pandemic may be difficult to assess or predict, the pandemic has caused disruption in the global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the COVID- 19 pandemic could materially affect our business and the value of our common stock. The effects of the COVID- 19 pandemic continue~~ **contribute** to ~~evolve. The ultimate impact of the COVID- 19 pandemic or a~~ similar **downward trends elsewhere** ~~health pandemic or epidemic is highly uncertain and subject to continued change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, or the operations of third parties on whom we rely~~ . The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our products and product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Competition may also arise from, among other things: • other drug development technologies; • methods of preventing or reducing the incidence of disease, including vaccines; and • new small molecule or other classes of therapeutic agents. Developments by others (including the development of generic equivalents) may render our product candidates or technologies obsolete or noncompetitive. We are commercializing and performing research on or developing products for the treatment of several disorders including endometriosis, tardive dyskinesia, **chorea associated with Huntington' s disease,** uterine fibroids ~~, essential tremor~~ , classic congenital adrenal hyperplasia, pain, Parkinson' s disease and other neurology, neuroendocrinology and neuropsychiatry- related diseases and disorders, and there are a number of competitors to our products and product candidates. If one or more of our competitors' products or programs are successful (including the development of generic equivalents), the market for our products may be reduced or eliminated. • INGREZZA competes with AUSTEDO ® (deutetrabenazine), ~~which was approved by the FDA for the treatment of tardive dyskinesia in adults in August 2017 and is~~ marketed by Teva ~~Pharmaceutical~~ **Pharmaceuticals** Industries, **for the treatment of** ~~and several clinical development- stage programs targeting~~ tardive dyskinesia **in adults** and ~~related movement disorders~~ **chorea associated with Huntington' s disease. A once- daily dosing of AUSTEDO (AUSTEDO XR) was introduced in February 2023** . Additionally, there are a number of commercially available medicines used to treat tardive dyskinesia off- label, such as XENAZINE ® (tetrabenazine) and generic equivalents, and various antipsychotic medications (e. g., clozapine), anticholinergics, benzodiazepines (off- label), and botulinum toxin. ~~• ONGENTYS competes with two other FDA- approved COMT inhibitors and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA- approved and in clinical development) for Parkinson' s patients which compete with ONGENTYS, including various L- dopa preparations, dopamine agonists, MAO- B inhibitors and others.~~ In **addition** ~~terms of potential future competition~~ , there are several programs in ~~late- stage~~ clinical development **by other companies targeting Huntington' s disease** . • ORILISSA and ORIAHNN each compete with several FDA- approved products for the treatment of endometriosis, uterine fibroids, infertility and central precocious puberty. Additionally, there is also competition from surgical intervention, including hysterectomies and ablations. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis or uterine fibroids directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications, including opioids. • For CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. In the ~~United States~~ **U. S.** alone, there are more than two dozen companies manufacturing steroid- based products. In addition, there are several programs in clinical development **by other companies** targeting ~~CAH and several companies developing medicinal treatments for~~ CAH. • Our investigational treatments for potential use in epilepsy may in the future compete with numerous approved anti- seizure medications and development- stage programs being pursued by several other companies. Commonly used anti- seizure medications include phenytoin, levetiracetam, brivaracetam, cenobamate, carbamazepine, clobazam, lamotrigine, valproate, oxcarbazepine, topiramate, lacosamide, perampanel and cannabidiol, among others. There are currently no FDA- approved treatments specifically indicated for the early infantile epileptic encephalopathy SCN8A- DEE; however, a number of different anti- seizure medications are currently used in these patient populations. • Our investigational treatments for potential use in schizophrenia **, anhedonia** and depression may in the future compete with several development- stage programs being pursued by other companies. Currently, there are no FDA- approved treatments specifically indicated for **anhedonia** ~~cognitive impairment associated with schizophrenia,~~ or CIAS; however, there are a number of different anti- psychotic medications currently used in these patient populations. • Our investigational treatments for potential use in neurology, neuroendocrinology and neuropsychiatry may in the future compete with numerous approved products and development- stage programs being pursued by several other companies. Compared to us, many of our competitors and potential competitors have substantially greater: • capital resources; • sales and marketing experience; • research and development resources, including personnel and technology; • regulatory experience; • preclinical study and clinical testing experience; • manufacturing, marketing and distribution experience; and • production facilities. Moreover, increased competition in certain disorders or therapies may make it more difficult for us to recruit or enroll patients in our clinical trials for similar disorders or therapies. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may: • be found ineffective or cause harmful side effects during preclinical studies or clinical trials; • fail to receive necessary regulatory approvals on a timely basis or at all; • be precluded from commercialization

by proprietary rights of third parties; • be difficult to manufacture on a large scale; or • be uneconomical to commercialize or fail to achieve market acceptance. If any of our product candidates encounters any of these potential problems, we may never successfully market that product candidate. Our clinical trials may be delayed for safety or other reasons or fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval. Before obtaining regulatory approval for the sale of any of our potential products, we must subject these product candidates to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete and the outcomes are uncertain. In connection with the clinical trials of our product candidates, we face the risks that: • the FDA or similar foreign regulatory authority may not allow an IND or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA **or similar foreign regulatory authorities** may require additional preclinical studies as a condition of the initiation of Phase ~~I~~ **1** clinical studies, or additional clinical studies for progression from Phase ~~I~~ **1** to Phase ~~II~~ **2**, or Phase ~~II~~ **2** to Phase ~~III~~ **3**, or for NDA approval; • the product candidate may not prove to be effective or as effective as other competing product candidates; • we may discover that a product candidate may cause harmful side effects or results of required toxicology or other studies may not be acceptable to the FDA **or similar foreign regulatory authorities**; • clinical trial results may not replicate the results of previous trials; • the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects; • we or the FDA or similar foreign regulatory authorities may suspend **or vary** the trials; • the results may not be statistically significant; • clinical site initiation or patient recruitment and enrollment may be slower or more difficult than expected; • the FDA **or similar foreign regulatory authorities** may not accept the data from any trial or trial site outside of the ~~United States~~ **U. S.**; • patients may drop out of the trials; • unforeseen disruptions or delays may occur, caused by man- made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the ~~COVID- 19 pandemic and the~~ conflict between Russia and Ukraine **and the conflict in the Middle East**; and • regulatory requirements may change. These risks and uncertainties impact all of our clinical programs and any of the clinical, regulatory or operational events described above could change our planned clinical and regulatory activities. ~~In addition~~ **For example**, ~~due to~~ the **conflict between Russia and Ukraine** ~~impact of the COVID- 19 pandemic~~, **together with sanctions imposed on Russia, caused us to suspend all planned** clinical **trial activities in Russia and Ukraine. As a result, our planned clinical development timelines for valbenazine and luvadaxistat were significantly delayed while we identified and operationalized alternative clinical trial** ~~site~~ **sites , which we have now done** ~~initiation and new patient enrollment has been negatively impacted~~. Additionally, any of these events described above could result in suspension of a program and / or obviate any filings for necessary regulatory approvals. In addition, late- stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial conduct, completion and results. Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business. Even if the clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. ~~In February 2022, Russia commenced a military invasion of Ukraine. We have planned clinical trial sites in both Russia and Ukraine, but no patients yet enrolled. Ongoing geopolitical turmoil and continuing military action in the region, together with widening sanctions imposed on Russia, have caused us to suspend all planned clinical trial activities in Russia and Ukraine. Alternative clinical trial sites that would fully and timely compensate for our planned clinical trial activities in Ukraine and Russia may not be available and we may need to find other countries in which to conduct such activities. Our planned clinical development timelines for valbenazine and luvadaxistat could be significantly delayed, which would increase our development costs and delay the development and / or regulatory approval process of such product candidates and jeopardize our ability to commence product sales and generate revenues.~~ We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. For example, we depend on AbbVie for the manufacture and commercialization of ORILISSA and ORIAHNN and for the continued development of elagolix. We collaborate with MTPC for the commercialization of DYSVAL in Japan and for the continued development and commercialization of valbenazine for movement disorders in other select Asian markets. **Our** ~~We also rely on BIAL for the commercial supply of ONGENTYS. In addition~~ **additional** ~~, we collaborate~~ **collaborators** ~~with~~ **include** Xenon Pharmaceuticals, Inc. ~~for the development of NBI- 921352~~, Idorsia Pharmaceuticals Ltd. ~~for the development of NBI- 827104~~, Takeda Pharmaceutical Company Limited ~~for the development of luvadaxistat~~, ~~NBI- 1065845 and NBI- 1065846 and~~ Heptares Therapeutics Limited **and Voyager Therapeutics, Inc** ~~for the development of NBI- 1117568~~. Our current and future collaborations and licenses could subject us to a number of risks, including: • strategic collaborators may sell, transfer or divest assets or programs related to our partnered product or product candidates; • we may be required to undertake the expenditure of substantial operational, financial and management resources; • we may be required to assume substantial actual or contingent liabilities; • we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our products or product candidates; • we may not be able to influence our strategic collaborator' s decisions regarding the development and collaboration of our partnered product and product candidates, and as a result, our collaboration partners may not pursue or prioritize the development and commercialization of those partnered products and product candidates in a manner that is in our best interest; • strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so; • strategic collaborators may not conduct collaborative activities in a timely manner,

provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing; • strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs; • disagreements or disputes may arise between us and our strategic collaborators that result in delays or in costly litigation or arbitration that diverts management' s attention and consumes resources; • strategic collaborators may experience financial difficulties; • strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation; • **we or** strategic collaborators could terminate the arrangement **(in whole or in part)** or allow it to expire, which would delay the development and commercialization ~~and~~ **, result in disagreements or disputes or** may increase the cost of developing and commercializing our products or product candidates; and • strategic collaborators could develop, either alone or with others, products or product candidates that may compete with ours. If any of these issues arise, it may delay and / or negatively impact the development and commercialization of drug candidates and, ultimately, our generation of product revenues ~~. We may not be able to successfully commercialize ONGENTYS. In April 2020, we received FDA approval for ONGENTYS as an adjunctive therapy to levodopa / DOPA decarboxylase inhibitors in adult Parkinson' s disease patients, and in September 2020, we launched the commercial sale of ONGENTYS with our existing commercial infrastructure. The successful commercialization of ONGENTYS is subject to many risks, and there are numerous examples of unsuccessful product launches and failures, including by pharmaceutical companies with more experience and resources than us. If we are unable to effectively train our employees and equip them with effective materials, including medical and sales literature to help them inform and educate health care practitioners about the benefits of ONGENTYS and its proper administration, our commercialization of ONGENTYS may not be successful. Even if we are successful in effectively training and equipping our sales force, there are many factors that could cause the commercialization of ONGENTYS to be unsuccessful, including a number of factors that are outside our control. Health care practitioners may not prescribe ONGENTYS and patients may be unwilling to use ONGENTYS if insurance coverage is not provided or reimbursement is inadequate. In addition, our ability to train our employees and effectively communicate with potential prescribers could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID- 19 pandemic~~ . As with most pharmaceutical products, use of our approved products or those of our collaborators could be associated with side effects or adverse events which can vary in severity (from minor adverse reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our products or those of our collaborators may be observed at any time, including after a product is commercialized, and reports of any such side effects or adverse events may negatively impact demand for our or our collaborators' products or affect our or our collaborators' ability to maintain regulatory approval for such products. Side effects or other safety issues associated with the use of our approved products or those of our collaborators could require us or our collaborators to modify or halt commercialization of these products or expose us to product liability lawsuits which will harm our business. We or our collaborators may be required by regulatory agencies to conduct additional studies regarding the safety and efficacy of our products which we have not planned or anticipated. Furthermore, there can be no assurance that we or our collaborators will resolve any issues related to any product related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition. **We are dependent on licenses from third parties for some of our key technologies.These licenses typically subject us to various commercialization,reporting and other obligations.If we fail to comply with these obligations,we could lose important rights.If we were to default on our obligations under any of our licenses,we could lose some or** all of our rights to develop,market and sell products covered by these licenses ~~.For example,BIAL may terminate our license agreement,pursuant to which we have rights to commercialize ONGENTYS,if we fail to use commercially reasonable efforts to comply with specified obligations under the license agreement,or if we otherwise breach the license agreement~~ .In addition,several of our collaboration and license agreements allow our licensors to terminate such agreements if we challenge the validity or enforceability of certain intellectual property rights or if we commit a material breach in whole or in part of the agreement and do not cure such breach within the agreed upon cure period.In addition,if we were to violate any of the terms of our licenses,we could become subject to damages.Likewise,if we were to lose our rights under a license to use proprietary research tools,it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations.We also face the risk that our licensors could,for a number of reasons,lose patent protection or lose their rights to the technologies we have licensed,thereby impairing or extinguishing our rights under our licenses with them. ~~The conditional conversion feature of the 2024 Notes,if triggered,may adversely affect our~~ As of December 31, ~~2022~~ **2023** , we had **approximately** ~~more than~~ 1, ~~200~~ **400** full- time employees. Although we have substantially increased the size of our organization, we may need to add additional qualified personnel and resources, especially with the recent increase in the size of our sales force. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on our organization, including the need to identify, recruit, maintain and integrate additional employees ~~,~~ and **implement and expand managerial, operational and financial systems and** may **be costly and** take time away from running other aspects of our business, including development and commercialization of our product candidates. **For example, we are in the process of implementing a new company- wide enterprise resource planning (ERP) system to streamline certain existing business, operational, and financial processes. This project has required and may continue to require investment of capital and human resources, the re- engineering of processes of our business, and the attention of many employees who would otherwise be focused on other aspects of our business. Any disruptions, delays, or deficiencies in the implementation or design of the ERP system could adversely affect the effectiveness of our internal control over financial reporting or our ability to accurately maintain our books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Any of these consequences could have an adverse**

effect on our results of operations and financial condition. Our future financial performance and our ability to commercialize INGREZZA ~~, ONGENTYS,~~ and any of our other products, or any of our product candidates that receive regulatory approval in the future, will partially depend on our ability to manage any future growth effectively. In particular, as we commercialize INGREZZA ~~and ONGENTYS~~ , we will need to support the training and ongoing activities of our sales force and will likely need to continue to expand the size of our employee base for managerial, operational, financial and other resources. To that end, we must be able to successfully: • manage our development efforts effectively; • integrate additional management, administrative and manufacturing personnel; • further develop our marketing and sales organization; • compensate our employees on adequate terms in an increasingly competitive, inflationary market; • attract and retain personnel; and • maintain sufficient administrative, accounting and management information systems and controls. We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects. We are highly dependent on the principal members of our management, commercial and scientific staff. The loss of any of these people could impede the achievement of our objectives, including the successful commercialization of INGREZZA ~~, ONGENTYS,~~ or any of our other products, or any product candidate approved by the FDA in the future. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future, along with personnel with experience marketing and selling pharmaceutical products, is critical to our success. We may be unable to attract and retain personnel on acceptable terms given ~~effects of the COVID- 19 pandemic, as well as~~ the competition among biotechnology, pharmaceutical and ~~health~~ **healthcare** ~~care~~ companies, universities and non- profit research institutions for experienced scientists and individuals with experience marketing and selling pharmaceutical products. We may face particular retention challenges in light of the recent rapid growth in our personnel and infrastructure and the perceived impact of those changes upon our corporate culture. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy and our commercialization strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us. We have in the past utilized, and intend to continue to utilize, third- party manufacturers to produce the drug compounds we use in our clinical trials and for the commercialization of our products. We have limited experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Establishing internal commercial manufacturing capabilities would require significant time and resources, and we may not be able to timely or successfully establish such capabilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA ~~and ONGENTYS~~ . If we are unable to obtain or retain third- party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA ~~and ONGENTYS~~ . The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA **and equivalent foreign** regulations, including current Good Manufacturing Practice regulations. Our third- party manufacturers ~~, including BIAL and its suppliers,~~ might not comply with FDA **or equivalent foreign** regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks: • contract manufacturers may encounter difficulties in achieving volume production, quality control or quality assurance, and also may experience shortages in qualified personnel **or materials and ingredients necessary to conduct their operations** . As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required; • switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all; • our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and • drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the ~~United States~~ **U. S.** Drug Enforcement Administration **, equivalent foreign regulatory authorities** , and other agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards. Our current dependence upon third parties for the manufacture of our products may reduce our profit margin, if any, on the sale of INGREZZA ~~, ONGENTYS,~~ or any of our other products, or our future products and our ability to develop and deliver products on a timely and competitive basis. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredients **(** ~~, or~~ API **)** , the finished drug product and packaging in sufficient quantities while meeting detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products may encounter difficulties in production, such as difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, compliance with strictly enforced ~~United States~~ **U. S.** , state and non- ~~United States~~ **U. S.** regulations, and disruptions or delays caused by man- made or natural disasters, pandemics or epidemics, or other business interruptions ~~, including, for example, the COVID- 19 pandemic and the conflict between Russia and Ukraine~~ . We depend on a limited number of suppliers for the production and packaging of INGREZZA and its API. If our third- party suppliers for INGREZZA encounter these or any other manufacturing, quality or compliance difficulties, we may be unable to meet commercial demand for INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. In addition, ~~under the terms of our agreement with BIAL, although we are responsible for the management of all ONGENTYS commercialization activities, we rely on BIAL and its suppliers to supply all drug product for the commercialization of ONGENTYS. BIAL relies on third- party contract manufacturers to produce ONGENTYS. These contract manufacturers may encounter difficulties in achieving volume production, quality control, or quality assurance. As a result, these contract manufacturers may not be able to adequately produce ONGENTYS in commercial quantities when required, which may impact our ability to deliver ONGENTYS on a timely basis. In addition,~~ if our

suppliers fail or refuse to supply us with INGREZZA or its API for any reason, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar ~~international~~ **foreign** regulatory ~~bodies~~ **authorities** must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in pharmaceutical products. The loss of a supplier could require us to obtain regulatory clearance and to incur validation and other costs associated with the transfer of the API or product manufacturing processes. If there are delays in qualifying new suppliers or facilities or if a new supplier is unable to meet FDA or a similar ~~international~~ **foreign** regulatory ~~body~~ **authority** ' s requirements for approval, there could be a shortage of INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. ~~If BIAL is unable or refuses to supply us with ONGENTYS drug product for any reason, or does not meet FDA or international regulators' requirements for approval, we have limited opportunity to qualify a new supplier. This could materially and adversely affect our ability to successfully commercialize ONGENTYS.~~ The independent clinical investigators and contract research organizations that we rely upon to conduct our clinical trials may not be diligent, careful or timely, ~~and~~ **or** may make mistakes ~~,~~ in the conduct of our trials. We depend on independent clinical investigators and CROs to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If our independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, or not in compliance with **GCPs** ~~Good Clinical Practices~~ , it may delay or prevent the approval of our regulatory applications and our introduction of new treatments. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position. We ~~do not and will not have access to all information regarding the products and product candidates we licensed to AbbVie. We do not and will not have access to all information regarding elagolix, including potentially material information about commercialization plans, medical information strategies, clinical trial design and execution, safety reports from clinical trials, safety reports, regulatory affairs, process development, manufacturing and other areas known by AbbVie. In addition, we have confidentiality obligations under our agreement with AbbVie. Thus, our ability to keep our shareholders informed about the status of elagolix will be limited by the degree to which AbbVie keeps us informed and allows us to disclose such information to the public. If AbbVie fails to keep us informed about commercialization efforts related to elagolix, or the status of the clinical development or regulatory approval pathway of other product candidates licensed to it, we may make operational and / or investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations. We~~ are subject to ongoing obligations and continued regulatory review for INGREZZA. Additionally, our other product candidates, if approved, could be subject to labeling and other post- marketing requirements and restrictions. Regulatory approvals for any of our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase ~~IV~~ **4** clinical trials, and surveillance to monitor the safety and efficacy of the product candidate ~~. For example, with respect to the FDA' s approval of INGREZZA for tardive dyskinesia in April 2017, we are subject to certain post- marketing requirements and commitments~~ . In addition, with respect to INGREZZA, and any product candidate that the FDA or a comparable foreign regulatory authority approves, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with **GCPs** ~~Good Clinical Practices~~ for any clinical trials that we conduct post- approval. Failure to comply with these ongoing regulatory requirements, or later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in, among other things: • restrictions on the marketing or manufacturing of the product, changes in the product' s label, withdrawal of the product from the market, or voluntary or mandatory product recalls; • fines, warning or untitled letters or holds on clinical trials; • refusal by the FDA **or similar foreign regulatory authorities** to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; • adverse inspection findings or other activities that temporarily delay manufacture and distribution of our products; • product seizure or detention, or refusal to permit the import or export of products; and • product injunctions or the imposition of civil or criminal penalties. The occurrence of any of these events may adversely affect our business, prospects and ability to achieve or sustain profitability on a sustained basis. If the market opportunities for our products and product candidates are smaller than we believe they are, our expected revenues may be adversely affected, and our business may suffer. Certain of the diseases that INGREZZA, ~~ONGENTYS~~ **crinecerfont,** and our other product candidates are being developed to address are in underserved and underdiagnosed populations. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who will seek treatment utilizing our products or product candidates, may not be accurate. If our estimates of the prevalence or number of patients potentially on therapy prove to be inaccurate, the market opportunities for INGREZZA, ~~ONGENTYS~~ **crinecerfont,** and our other product candidates may be smaller than we believe they are, our prospects for generating expected revenue may be adversely affected and our business may suffer. **Because** ~~We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. If we were to default on our obligations under any of our licenses, we could lose some or~~ **our** all of our rights to develop,..... may adversely affect our financial condition, operating results **may vary significantly in future periods** , ~~or~~ **our** ~~liquidity~~ **stock price may decline** . **Our quarterly revenues** ~~As of December 31~~ , ~~2022,~~ **expenses and operating results have fluctuated in** the ~~conditional conversion~~ **past and are likely to fluctuate significantly in the** ~~feature~~ **future** ~~of the~~

~~2024 Notes had been triggered .~~ **. Our financial results are unpredictable and may fluctuate** , **for among** ~~allowing holders of 2024 Notes to convert their~~ **other** ~~2024 Notes at fluctuate,for among other~~ reasons,due to seasonality and timing of customer purchases and commercial sales of INGREZZA, ~~impact of the commercial launch of ONGENTYS and ORIAHNN,~~ royalties from out- licensed products,the impact of Medicare Part D coverage **,including redesign of the Part D benefit enacted as part of the Inflation Reduction Act** ,our achievement of product development objectives and milestones,clinical trial enrollment and expenses,research and development expenses and the timing and nature of contract manufacturing,contract research payments,fluctuations in our effective tax rate,and disruptions caused by man- made or natural disasters or public health pandemics or epidemics or other business interruptions,including,for example,the ~~COVID- 19 pandemic and the~~ conflict between Russia and Ukraine **,or in the Middle East** .Because a majority of our costs are predetermined on ~~an any~~ - an annual basis,due in part to our significant research and development costs,small declines in revenue could disproportionately affect financial results in a quarter.Thus,our future operating results and profitability may fluctuate from period to period,and even if we become profitable on a quarterly or annual basis,we may not be able to sustain or increase our profitability.Moreover,as our company and our market capitalization have grown,our financial performance has become increasingly subject to quarterly and annual comparisons with the expectations of securities analysts or investors.The failure of our financial results to meet these expectations,either in a single quarterly or annual period over a sustained period time ~~during the period beginning on January 1~~ , **could cause** ~~2023 and ending at the close of business on March 31, 2023. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of~~ our ~~common~~ stock **price** ~~during the prescribed measurement periods, and as a result, it is possible that holders of 2024 Notes will continue~~ to **decline** ~~be entitled to convert their 2024 Notes at any time during specified periods at their option. If one or more of the holders of the 2024 Notes elects to convert their 2024 Notes, we would be required to settle the principal amount of our conversion obligation in cash, which could adversely affect our liquidity~~ . In May 2017, we sold $ 517. 5 million aggregate principal amount of the 2024 Notes. In ~~the fourth quarter of~~ 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $ 136. 2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $ 186. 9 million in cash. In ~~the second quarter of~~ 2022, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $ 210. 8 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $ 279. 0 million in cash. As of December 31, ~~2022~~ **2023** , $ 170. 4 million aggregate principal amount of the 2024 Notes remained outstanding. We may also incur additional indebtedness to meet future financing needs. Our ~~indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things: • increasing our vulnerability to adverse economic and industry conditions; • limiting our ability to obtain additional financing; • requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes; • limiting our flexibility to plan for, or react to, changes in our business; • diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2024 Notes; and • placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital. Our~~ business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under the 2024 Notes and any additional indebtedness that we may incur ~~. In addition, our cash needs may increase in the future~~ . In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full. Since our inception, we have incurred significant net losses and negative cash flow from operations. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~406~~ **157** . ~~8~~ **1** million as a result of historical operating losses. We received FDA approval for INGREZZA for tardive dyskinesia in April 2017 and for ~~ONGENTYS for Parkinson's~~ **chorea associated with Huntington'** s disease in ~~April~~ **August** ~~2020~~ **2023** . Our partner AbbVie received FDA approval for ORILISSA for endometriosis in July 2018 and for ORIAHNN for uterine fibroids in May 2020. Additionally, our partner MTPC received Japanese Ministry of Health, Labour and Welfare approval for DYSVAL for the treatment of tardive dyskinesia in March 2022. However, we have not yet obtained regulatory approvals for any other product candidates. Even if we continue to succeed in commercializing INGREZZA, or ~~if we successfully commercialize ONGENTYS or~~ are successful in developing and commercializing any of our other product candidates, we may not be able to sustain profitability. We also expect to continue to incur significant operating and capital expenditures as we: • commercialize INGREZZA for tardive dyskinesia **and chorea associated with Huntington'** ~~; • commercialize ONGENTYS for Parkinson's~~ disease; • seek regulatory approvals for our product candidates or for additional indications for our current products; • develop, formulate, manufacture and commercialize our product candidates; • in- license or acquire new product development opportunities; • implement additional internal systems and infrastructure; and • hire additional clinical, scientific, sales and marketing personnel. We expect to increase our expenses and other investments in the coming years as we fund our operations and capital expenditures. Thus, our future operating results and profitability may fluctuate from period to period due to the factors described above, and we will need to generate significant revenues to achieve and maintain profitability and positive cash flow on a sustained basis. We may not be able to generate these revenues, and we may never achieve profitability on a sustained basis in the future. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock. We may be subject to claims that..... cause our stock price to decline. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations. Effective January 1, 2022, **legislation enacted in 2017, informally titled** the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the ~~United States~~ **U. S.** and over 15 years for research

activities conducted outside the ~~United States~~ **U. S** . Unless the ~~United States~~ **U. S.** Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, we expect a material decrease in our cash flows from operations and an offsetting similarly sized increase in our net deferred tax assets over these amortization periods. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur and whether we conduct our research and development activities inside or outside the ~~United States~~ **U. S** . In addition, new income, sales, use, excise or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, ~~changed,~~ modified or applied adversely to us. For example, **the** Tax ~~Cut~~ **Cuts** and Jobs Act of 2017, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the ~~United States~~ **U. S.** tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Furthermore, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future ~~United States~~ **U. S.** tax expense. Our ability to use ~~net operating loss carryforwards and certain other~~ tax attributes may be limited. ~~Our net operating loss, or NOL, carryforwards generated in tax years beginning on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable United States tax law.~~ Under ~~current law, our federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under~~ Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ~~, and corresponding provisions of state law~~ , if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use ~~its~~ **certain** pre- change **federal** ~~NOL carryforwards and other pre- change~~ tax attributes **such as research and development tax credits** to offset its post- change income or taxes may be limited. Based on completed Section 382 analysis done **annually** , we do not believe we have experienced any previous ownership changes, but the determination is complex and there can be no assurance we are correct. Furthermore, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. ~~As a result, our pre- 2018 NOL carryforwards may expire prior to being used and our NOL carryforwards generated in tax years beginning after December 31, 2017, will be subject to a percentage limitation and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre- change NOLs and other pre- change tax attributes (such as research tax credits) to offset our post- change income or taxes may be limited.~~ Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes **, including net operating loss (NOL) carryforwards** . In addition, at the state level, there may be periods during which the use of NOLs **or credits** is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOLs **, research and development credits,** and other tax attributes, which could adversely affect our future cash flows. Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. Our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each such place. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including the impact of stock- based compensation, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements. ~~In addition, on December 31, 2020, we determined, based on our facts and circumstances, that it was more likely than not that a substantial portion of our deferred tax assets would be realized and, as a result, substantially all of our valuation allowance against our deferred tax assets was released. Therefore, beginning in 2021, we commenced recording income tax expense at an estimated tax rate that will likely approximate statutory tax rates, which could result in a significant reduction in our net income and net income per share.~~ The price of our common stock is volatile. The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The COVID- 19 pandemic, for example, ~~has~~ negatively affected the stock market and investor sentiment and ~~has~~ resulted in significant volatility **, as has the applicability of the Medicare drug price negotiation provisions in the Inflation Reduction Act** . Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last 12 months, the price of our common stock has ranged from approximately $ ~~72~~ **89** per share to approximately $ ~~129~~ **143** per share. The market price of our common stock may fluctuate in response to many factors, including: • sales of INGREZZA and our other products ~~; • the status and cost of our post- marketing commitments for INGREZZA~~ ; • the results of our clinical trials; • reports of safety issues related to INGREZZA ~~, ONGENTYS~~ , ORILISSA, ORIAHNN, DYSVAL, or any of our other products; • developments concerning new and existing collaboration agreements; • announcements of technological innovations or new therapeutic products by us or others **, including our competitors** ; • general economic and market conditions, including economic and market conditions affecting the biotechnology industry; •

developments in patent or other proprietary rights; • developments related to the FDA **, CMS** and foreign regulatory agencies **; • government regulation, including the Inflation Reduction Act** ; • future sales of our common stock by us or our stockholders; • comments by securities analysts; • additions or departures of key personnel; • fluctuations in our operating results; • potential litigation matters ~~and developments in existing litigation matters, such as the ANDA litigation matters; • government regulation~~ ; • government and third- party payor coverage and reimbursement; • failure of any of our product candidates, if approved, to achieve commercial success; • disruptions caused by man- made or natural disasters, pandemics or epidemics or other business interruptions, including, for example, the COVID- 19 pandemic and the conflict between Russia and Ukraine; and • public concern as to the safety of our drugs. In addition, we are a member of the S & P MidCap 400 index. If we cease to be represented in the S & P MidCap 400 index, or other indexes or indexed products, as a result of our market capitalization falling below the threshold for inclusion in the index, certain institutional shareholders may, due to their internal policies and investment guidelines, be required to sell their shareholdings. Such sales may result in further negative pressure on our stock price and, when combined with reduced trading volume and liquidity, could adversely affect the value of your investment and your ability to sell your shares. We have entered into agreements for the distribution of INGREZZA with a limited number of specialty pharmacy providers and distributors, and all of our product sales of INGREZZA are to these customers. Four of these customers represented approximately ~~89~~ **91** % of our total product ~~revenue~~ **sales** for ~~the twelve months ended December 31, 2022~~ **2023** and approximately ~~95~~ **98** % of our accounts receivable balance as of December 31, ~~2022~~ **2023** . If any of these significant customers becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose any of these significant customers, our revenue, results of operations and cash flows would be adversely affected. Even if we replace the loss of a significant customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows. **Our** ~~We may require additional funding to continue our research and development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, and the cost of product in- licensing and any possible acquisitions. In addition, we may require additional funding to establish manufacturing and marketing capabilities in the~~ future ~~. We believe that our existing capital resources and anticipated revenues will be sufficient to satisfy our current and projected~~ funding requirements **will depend on many factors and we may need** ~~for at least the next 12 months. However, these resources might be insufficient~~ to ~~conduct~~ **raise additional capital to fund our business plan and our future** research ~~and ,~~ development ~~programs~~ , ~~the cost of product in- taking and possible acquisitions, fully commercialize products and operate the company to the full extent currently planned. If we cannot obtain adequate funds, we may be required to significantly curtail our~~ commercial ~~plans or one or more of our research~~ and **manufacturing efforts** ~~development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates~~ . Our future capital requirements will depend on many factors, including: • the commercial success of INGREZZA, ~~ONGENTYS,~~ ORILISSA, ORIAHNN, DYSVAL, and / or any of our other products; • debt services obligations on the 2024 Notes; • continued scientific progress in our R & D and clinical development programs; • the magnitude and complexity of our research and development programs; • progress with preclinical testing and clinical trials; • the time and costs involved in obtaining regulatory approvals; • the cost involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation; • **costs associated with securing adequate coverage and reimbursement for our products; •** competing technological and market developments; • developments related to any future litigation; • the cost of commercialization activities and arrangements, including advertising campaigns; • the cost of manufacturing our product candidates; • the impact of the COVID- 19 pandemic **or a future pandemic or epidemic** on our business; and • the cost of any strategic alliances, collaborations, product in- licensing, or acquisitions. We intend to seek additional funding through strategic alliances and may seek additional funding through public or private sales of our securities, including equity securities. In addition, during the second quarter of 2017, we issued the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. In ~~the fourth quarter of~~ 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $ 136. 2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $ 186. 9 million in cash. In ~~the second quarter of~~ 2022, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $ 210. 8 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $ 279. 0 million in cash. As of December 31, ~~2022~~ **2023** , $ 170. 4 million aggregate principal amount of the 2024 Notes remained outstanding. Additional equity or debt financing might not be available on reasonable terms, if at all ~~. In addition, disruptions due to the COVID- 19 pandemic could make it more difficult for us to access capital~~ . Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd- Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and Nasdaq rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased selling, general and administrative expenses and management time related to compliance activities. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect

our financial results and the market price of our common stock. Increasing use of social media could give rise to liability and result in harm to our business. Our employees are increasingly utilizing social media tools and our website as a means of communication. Despite our efforts to monitor social media communications, there is risk that the unauthorized use of social media by our employees to communicate about our products or business, or any inadvertent disclosure of material, nonpublic information through these means, may result in violations of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact on our business, financial condition and results of operations. Furthermore, negative posts or comments about us or our products on social media could seriously damage our reputation, brand image and goodwill. **resulted** ~~cause significant disruption~~ in **travel restrictions and** the ~~operations~~ **shutdown or delay** of **business activities in various regions** ~~third- party manufacturers,CROs and other third parties upon whom we rely.As a result,we may experience disruptions that could severely impact our supply chain,ongoing and future clinical trials and commercialization of INGREZZA or any of our other products~~ .In response to the COVID- 19 pandemic,we implemented a remote work model for all employees except certain key essential members involved in business- critical activities. ~~Our~~ **Most of our field- based** employees have resumed in- person interactions ~~and~~ **in accordance with location- specific guidance.Our office- based employees** have returned to the office under flexible work guidelines **to help balance business needs,employee health,well- being and safety and the evolving work environment** .However **,as the effects of the pandemic continue to rapidly evolve with the emergence of new COVID- 19 variants and spikes or surges in infection and hospitalization rates** ,a remote work model may nevertheless need to be reinstated at some point in the future.The effects of a remote and flexible work model may negatively impact productivity,disrupt our business and delay our clinical programs and timelines,the magnitude of which will depend **,** ~~on our ability to conduct our business~~ in **part** ~~the ordinary course.Remote work may also create increased risks to our information technology systems and data~~ , ~~as more of our~~ Risks Related to Our Industry Our success will depend on our ability to, among other things: • obtain patent protection for our products; • preserve our trade secrets; • prevent third parties from infringing upon our proprietary rights; and • operate without infringing upon the proprietary rights of others, both in the ~~United States~~ **U. S.** and internationally. Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds. **Additionally, if our employees, commercial collaborators or consultants use generative artificial intelligence (AI) technologies to develop our proprietary technology and compounds, it may impact our ability to obtain or successfully defend certain intellectual property rights.** We also rely upon unpatented trade secrets and improvements, unpatented know- how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors. In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. In addition, potential competitors have in the past and may in the future file an **abbreviated new drug application (** ANDA **)** with the FDA seeking approval to market a generic version of our products, or our competitors' products, before the expiration of the patents covering our products or our competitors' products, as applicable. To prevent infringement or unauthorized use, we have in the past and may in the future need to file infringement claims, which are expensive and time- consuming. ~~For example, we are currently engaged in various~~ **Refer to Note 13 to the consolidated financial statements for a description of our legal proceedings related to** intellectual property ~~litigation matters against potential competitors related to INGREZZA. Refer to Item 1. Legal Proceedings for a more detailed description of these~~ matters. In addition, in an infringement proceeding a court may decide that a patent of ours or a patent of a competitor is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. Derivation proceedings declared by the ~~United States~~ **U. S.** Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications (or those of our licensors) or a patent of a competitor. Litigation or derivation proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. Litigation or derivation proceedings, including proceedings of a competitor, may also result in a competitor entering the marketplace faster than expected. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the ~~United States~~ **U. S** . Enacted ~~health~~ **healthcare** ~~care~~ reform **, drug pricing** measures and other recent legislative initiatives could adversely affect our business. The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of ~~governmental~~ -- **government** and third- party payors to contain or reduce the costs of ~~health~~ **healthcare** ~~care~~ and to lower drug prices. In the ~~United States~~ **U. S.** , comprehensive **drug pricing** ~~health care reform~~ legislation ~~has been~~ enacted by the Federal government ~~to implement~~ **implements , for the first time,** government control over the pricing of **certain** prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is also subject to government

control. Additionally, other federal and state ~~legislation~~ **laws** impose obligations on manufacturers of pharmaceutical products, among others, related to disclosure of new drug products introduced to the market and increases in drug prices above a specified threshold. For example, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022, or the IRA, which, among other things ~~,~~ **:** (1) directs the Secretary of the ~~U. S. Department of Health and Human Services, or~~ HHS ~~,~~ to negotiate the price of certain high- expenditure, single- source drugs and biologics covered under Medicare ~~,~~ **;** (2) redesigns the Medicare Part D prescription drug benefit to lower patient out- of- pocket costs and increase manufacturer liability **;** and (3) requires drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in the ACA marketplaces through plan year 2025 and **beginning in 2025,** eliminates the " donut hole " under the Medicare Part D program ~~beginning in 2025 by significantly lowering the~~ **and creates a new, permanent cap on** beneficiary ~~maximum~~ out- of- pocket **spending** ~~cost to $ 2, 000 through~~ **in addition to** a newly established manufacturer discount program. **The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and updated and will continue to issue and update guidance as these programs are implemented.** These provisions ~~will~~ take effect progressively starting in 2023 **. On August 29, 2023, HHS announced the list of the first 10 drugs that will be subject to price negotiations** , although ~~they~~ **the** ~~may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges. It is currently ~~unclear~~ **uncertain** how the IRA will be implemented **over time** ; however, it is likely to have a significant impact on the pharmaceutical industry and prescription drug pricing. While the IRA **drug price negotiation program** targets high- expenditure drugs that have been on the market for several years without generic or biosimilar competition, we ~~have~~ **believe we will** ~~qualified~~ **qualify** for the small biotech ~~manufacturer exemption~~ **exception from negotiation** that is set to expire in 2029. However, the qualification for this ~~exemption~~ **exception** is subject to various requirements and there is no assurance that we will continue to qualify for this exemption in the future. Further, the loss of this ~~exemption~~ **exception** or the potential loss of this ~~exemption~~ **exception** , including as a result of a potential acquisition or strategic transaction, could have an adverse impact on our business. Prior to the IRA' s enactment, the most significant recent federal legislation impacting the pharmaceutical industry occurred in March 2010 ~~. The Patient Protection and Affordable Care Act~~ , **when** ~~as amended by the Health Care and Education Reconciliation Act of 2010, or collectively~~ the ACA ~~,~~ was signed into law ~~, which~~ **. The ACA** was intended to broaden access to health insurance and reduce the number of uninsured individuals, 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 taxes and fees on the health industry and impose additional health policy reforms. Other legislative changes have been adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act **and Consolidated Appropriations Act of 2023** , will remain in effect until ~~2031~~ **2032** ~~, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID- 19 pandemic. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequestration~~ . The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, ~~including~~ price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. For example, on January 5, 2024, the FDA approved Florida' s SIP proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Further, certain states through legislation have created a state PDAB to help control costs of drugs for that state. The functions of the PDABs vary by state, and may include among other things, recommending or setting upper limits on the price the state pays for certain drugs, performing drug affordability reviews, and advising state lawmakers on additional ways to reduce the state' s drug spending. It is possible that the actions taken by the PDABs may result in lower prices for certain drug products sold in their in states** . The implementation of these cost containment measures may prevent us from being able to generate revenue, attain sustained profitability or commercialize our drugs, particularly since the majority of our current revenue is derived from federal healthcare programs, including Medicare and Medicaid. Proposed ~~health~~ **healthcare** ~~care~~ reform **, drug pricing** measures and other prospective legislative initiatives could adversely affect our business. ~~The United States and some foreign jurisdictions are considering a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. The business and financial condition of pharmaceutical and biotechnology companies may be affected by the efforts of governmental and third- party payors to contain or reduce the costs of health care and to lower drug prices. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.~~ We expect that there will continue to be a number of federal and state proposals to implement **additional** government ~~control~~ **controls** over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of ~~health~~ **healthcare** ~~care~~ in the ~~United States~~ **U. S.** will continue to put pressure on the pricing and reimbursement of prescription pharmaceuticals. ~~The heightened governmental scrutiny over pharmaceutical pricing practices has resulted in several Congressional hearings and proposed and enacted federal and state legislation designed~~

~~to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.~~ For example, in **response to** ~~July 2021,~~ the Biden administration ~~released an~~ **' s October 2022** executive order, ~~" Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order,~~ on ~~September 9~~ **February 14** , ~~2021~~ **2023** , HHS released a ~~Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a~~ report ~~within 90 days on how~~ **outlining three new models for testing by** the Center for Medicare and Medicaid Innovation ~~can~~ **which will** be ~~further leveraged~~ **evaluated on their ability** to ~~test new models for lowering~~ --- **lower** ~~drug~~ **the** ~~costs~~ - **cost** ~~for Medicare~~ **of drugs, promote accessibility,** and ~~Medicaid beneficiaries~~ **improve quality of care** . It is unclear whether **the models** ~~this executive order or similar policy initiatives~~ will be ~~implemented~~ **utilized in any health reform measures** in the future. **In addition, certain jurisdictions outside of the U. S., including the EU, have instituted price ceilings on specific products and therapies, as described further in the risk factor titled " Government and third- party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and / or reimbursement for our products or impose policies and / or make decisions regarding the status of our products that could limit our product revenues and delay sustained profitability. "** We are currently unable to predict what other additional legislation or regulation, if any, relating to the ~~health~~ **healthcare** ~~care~~ industry may be enacted in the future or what effect recently enacted federal **or equivalent foreign** legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products. Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third- party payors in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations. Our business operations and activities may be directly, or indirectly, subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as current and future sales, marketing, patient co-payment assistance and education programs. Such laws include: • the federal Anti- Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • the federal civil and criminal false claims laws, including the federal civil False Claims Act, and Civil Monetary Penalties Laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • ~~the Health Insurance Portability and Accountability Act, or~~ HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • HIPAA, as amended by **HITECH** ~~the Health Information Technology for Economic and Clinical Health Act,~~ and its ~~(HITECH)~~ implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and • analogous state, local and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state laws that require disclosure of price increases above certain identified thresholds as well as of new commercial launches in the state; state **laws that create Prescription Drug Price Affordability Boards to review or attempt to cap drug spending; state** and local laws that require the registration of pharmaceutical sales representatives; state and local " drug take back " laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. While our interactions with healthcare professionals, including our speaker programs and other arrangements have been structured to comply with these

laws and related guidance, it is possible that governmental and enforcement authorities will conclude that our business practices **, or a rogue employee' s activities,** may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. For example, we maintain a patient assistance program to help eligible patients afford our products. These **and other** types of programs have become the subject of governmental scrutiny, and numerous organizations, including pharmaceutical manufacturers, have been subject to litigation, enforcement actions and settlements related to their patient assistance programs. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate. In addition, any sales of our product once commercialized outside the ~~United States~~ **U. S.** will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. We could face liability if a regulatory authority determines that we are promoting INGREZZA ~~,~~ ~~ONGENTYS~~ or any of our product candidates that receives regulatory approval, for " off- label " uses. A company may not promote " off- label " uses for its drug products. An off- label use is the use of a product for an indication that is not described in the product' s FDA- approved label in the ~~United States~~ **U. S.** or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off- label uses. Although the FDA and other regulatory agencies do not regulate a physician' s choice of drug treatment made in the physician' s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off- label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product' s FDA approved labeling. A company that is found to have promoted off- label use of its product may be subject to significant liability, including civil and criminal sanctions. ~~We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, including INGREZZA and ONGENTYS, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management' s attention could be diverted to handle any such alleged violations.~~ If the FDA or any other governmental agency **, including equivalent foreign authorities,** initiates an enforcement action against us, or if we are the subject of a qui tam suit brought by a private plaintiff on behalf of the government, and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation. If our information technology systems **, those third parties upon which we rely, or** ~~or~~ **our** data is or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, **regulatory investigations or actions, litigation, fines and penalties,** and a loss of customers or sales. We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we **and the third parties upon which we rely,** collect **, receive, store, process, generate, disclose, make accessible, protect, dispose of, transmit** , use, safeguard, share and transfer, or collectively, process, confidential and sensitive electronic information on our networks and in our data centers. This information includes, among other things, de- identified or pseudonymous sensitive personal data (including health data), our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personal data of our employees. It is important to our operations and business strategy that this electronic information remains secure and is perceived to be secure. The size and complexity of our information technology systems, and those of third- party vendors with whom we contract, and the volume of data we retain, make such systems potentially vulnerable to ~~breakdown~~ **a variety of evolving threats, including but not limited to social- engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks)** , malicious ~~intrusion~~ **code** , ~~security breaches~~ **malware (such as malicious code, adware, and command and control (C2)), denial- of- service attacks, credential harvesting, personnel misconduct or error** , ransomware ~~attacks, social engineering~~ attacks, supply- chain attacks, ~~and~~ **software bugs, server malfunctions, software or hardware failures, loss of data or** other ~~cyber-~~ **information technology assets,** attacks **enhanced or facilitated by AI, telecommunications failures, and other similar threats** . Cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors **(also referred to as APTs)** . Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, ~~that~~ **which** could materially disrupt our systems and operations, as well as our ability to conduct clinical trials. Ransomware attacks are also becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations **(including our ability to conduct clinical trials)** , loss of sensitive data **(including related to our clinical trials)** and income, reputational harm, and diversion of funds. To alleviate the financial, operational and reputational impact of a

ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties in our supply chain have not been compromised or that they do not contain exploitable defects **, vulnerabilities,** or bugs that could result in a breach of or disruption to our information technology systems and infrastructure or the information technology systems and infrastructure of third parties that support our operations. ~~Furthermore, if the COVID- 19 pandemic requires us to reinstate a remote~~ **Remote** ~~workforce model,~~ **work has become more common and has increased risks to** our information technology systems and data **,** ~~will be at increased risk~~ as more of our employees work from home, utilizing network connections **, computers and devices** outside our premises **, including at home, while in transit or in public locations** . Additionally, natural disasters, public health pandemics or epidemics ~~(including, for example, the COVID- 19 pandemic)~~ , terrorism, war and geopolitical conflicts ~~(including , for example, the conflict between Russia and Ukraine)~~ and telecommunication and electrical failures may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal data. ~~Information~~ **Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover** security **issues that were not found during** ~~risks have significantly increased in recent years in part~~ due **diligence** ~~to the proliferation~~ of ~~new~~ **such acquired or integrated entities, and it may be difficult to integrate companies into our information** ~~technologies~~ **technology environment** and **security program** ~~the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign private parties and state actors~~ . As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities ~~. Our efforts~~ **or modify our business activities (including our clinical trial activities)** to ~~identify~~ **try to protect against security incidents. We take steps designed to detect, mitigate,** and remediate **vulnerabilities in our information security systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not, however, detect and remediate all** such vulnerabilities ~~may not be successful and~~ **including on a timely basis. Further,** we may experience delays in developing and deploying remedial measures **and patches** designed to address ~~any such~~ identified vulnerabilities. **Vulnerabilities could** ~~Further, we may~~ be **exploited** ~~unable to detect such vulnerabilities in the future because such threats~~ and **result** ~~techniques change frequently, are often sophisticated~~ in ~~nature and may not be detected until after~~ a security **incident** ~~breach has occurred~~ . We ~~may~~ rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email and other functions. We ~~may~~ also rely on third- party service providers to provide other products, services, parts, or otherwise to operate our business, including clinical trial sites and investigators, contractors, manufacturers, suppliers and consultants. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers or CROs experience a security incident or other interruption, we could experience adverse consequences. **In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or otherwise subject to a security incident.** While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Although to our knowledge we, or the third parties upon who we rely, have not experienced ~~any~~ **a security incident or disruption to date that is** material ~~incident or disruption~~ to ~~date~~ **us** , we and our vendors have been **, either directly or indirectly,** the target of cybersecurity incidents ~~of this nature~~ and expect them to continue. While we have implemented security measures **designed** to protect our data security and information technology systems, such measures may not prevent such events **. Furthermore, while we have implemented and are planning to implement redundancies designed to avoid interruptions to our operations, not all potential events can be anticipated and interruptions to our operations could lead to decreased productivity** . If we (or a third party upon whom we rely) experience a security ~~breach~~ **incident, ransomware attack** or are perceived to have experienced a security ~~breach~~ **incident** , we may experience adverse consequences. Such consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm (including but not limited to damage to our patient, partner, or employee relationships); monetary fund diversions; **diversion of management' s attention;** interruptions in our operations (including availability of data **, loss of connectivity to our network or internet**); financial loss **(including decreased productivity resulting from interruptions in our operations)** ; and other similar harms. Similarly, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Applicable data privacy and security obligations may also require us to notify relevant stakeholders **, including affected individuals, customers, regulators, and investors,** of security ~~breaches or~~ incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Our contracts, with for example third parties or CROs, may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We also cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable

terms or at all, or that such coverage will pay future claims **. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel' s, or vendors' potential use of generative AI technologies** . If we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed. In addition to any patent protection, we rely on forms of regulatory exclusivity to protect our products such as orphan drug designation. A product candidate that receives orphan drug designation can benefit from a streamlined regulatory process as well as potential commercial benefits following approval. Currently, this designation provides market exclusivity in the ~~United States~~ **U. S.** for seven years and **EU** ~~the European Union~~ for 10 years if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the **EU** ~~European Union~~ , orphan exclusivity may be reduced to ~~6~~ **six** years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is " clinically superior " to the original orphan drug. If we do not have adequate patent protection for our products, then the relative importance of obtaining regulatory exclusivity is even greater. We may not be successful obtaining orphan drug designations for any indications and, even if we succeed, such product candidates with such orphan drug designations may fail to achieve FDA approval. Even if a product candidate with orphan drug designation may receive marketing approval from the FDA, it may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position. The technologies we use in our research as well as the drug targets we select may infringe the patents or violate the proprietary rights of third parties. We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaborators with respect to technologies used in potential products. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party' s intellectual property unless that party grants us or our collaborators rights to use its intellectual property. In such cases, we could be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaborators or we were able to obtain rights to the third party' s intellectual property, these rights may be non- exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business. Our business operations may subject us to disputes, claims and lawsuits, which may be costly and time- consuming and could materially and adversely impact our financial position and results of operations. From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture- related matters. Any dispute, claim or lawsuit may divert management' s attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. For example, we **recently settled** ~~are currently engaged in~~ various intellectual property litigation matters against potential competitors related to INGREZZA. Refer to ~~Item 1. Legal Proceedings~~ **Note 13 to the consolidated financial statements** for a more detailed description of these matters. Litigation related to these disputes may be costly and time- consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price. Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, or by employees of our commercial partners could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately, to maintain the confidentiality of our trade secrets or the trade secrets of our commercial partners, or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self- dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any action against our employees, independent contractors, principal investigators, consultants, commercial partners or vendors for violations of these laws could result in significant civil, criminal and administrative penalties, fines and imprisonment. We face potential product liability exposure far in excess of our insurance coverage. The use of any of our potential products in clinical trials, and the sale of any approved products, including INGREZZA ~~and ONGENTYS~~ , may expose us to liability claims. These claims might be made directly by consumers, ~~health~~ **healthcare** ~~care~~ providers, pharmaceutical companies or others selling our products. We have product liability insurance coverage for **both** our clinical trials **as well as** ~~in the amount of $ 45. 0 million per occurrence and $ 45. 0 million in the~~

~~aggregate. In addition, we have product liability insurance~~ related to the sale of INGREZZA ~~and ONGENTYS~~ in ~~the amount~~ **amounts consistent with customary industry practices** ~~of $ 45. 0 million per occurrence and $ 45. 0 million in the aggregate~~. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability from any current or future clinical trials or approved products. A successful product liability claim, or series of claims, brought against us would decrease our cash reserves and could cause our stock price to fall. Furthermore, regardless of the eventual outcome of a product liability claim, any product liability claim against us may decrease demand for our approved products, including INGREZZA ~~and ONGENTYS~~, damage our reputation, result in regulatory investigations that could require costly recalls or product modifications, cause clinical trial participants to withdrawal, result in costs to defend the related litigation, decrease our revenue, and divert management' s attention from managing our business. Our activities involve hazardous materials, and we may be liable for any resulting contamination or injuries. Our research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurs, a court may hold us liable for any resulting damages, which may harm our results of operations and cause us to use a substantial portion of our cash reserves, which would force us to seek additional financing. We are subject to stringent and changing obligations related to data privacy and information security. Our actual or perceived failure to comply with such obligations could have a material adverse effect on our reputation, business, financial condition or results of operations. In the ordinary course of our business, we ~~collect, receive, store,~~ process ~~, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing)~~ confidential and sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about clinical trial participants in connection with clinical trials, and sensitive third- party data, on our networks and in our data centers. We are subject to numerous federal, state, local and foreign laws, orders, codes, regulations and regulatory guidance regarding privacy, data protection, information security and the processing of personal information (including clinical trial data), the number and scope of which are expanding, changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions. Our data processing activities may also subject us to other data privacy and security obligations, such as industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of data by us and by third parties on our behalf. Laws regarding privacy, data protection, information security and the processing of personal data are becoming increasingly common in the ~~United States~~ **U. S.** at both the federal and state level **. Additionally, in the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance** . For example, the California Consumer Privacy Act, **as amended by** ~~or CCPA, which went into effect in 2020, imposes obligations on businesses to which it applies. These obligations include, without limitation, providing specific disclosures in privacy notices, affording California residents certain rights related to their personal data, and requiring businesses subject to the CCPA to implement certain measures to effectuate California residents' personal data rights. The CCPA allows for statutory fines for noncompliance (up to $ 7, 500 per violation). In addition,~~ the California Privacy Rights Act of 2020 **(** ~~, or the~~ CPRA **) (collectively** , ~~which became effective January 1, 2023, expands the~~ CCPA ~~by establishing a new~~ **), requires businesses to provide specific disclosures in privacy notices, and honor requests of** California **residents to exercise certain** ~~Privacy~~ **privacy rights. The** ~~Protection Agency to implement and enforce the~~ CCPA **allows for fines for noncompliance** (~~as amended~~ **up to $ 7, 500 per intentional violation**) **. Although some U. S. comprehensive privacy laws and the CCPA exempt some data processed in the context of clinical trials** , ~~which could~~ **these laws may** increase **compliance costs** ~~the risk of an~~ **and** ~~enforcement action~~ **potential liability with respect to other personal data we may maintain about California residents** . Other states have also enacted data privacy laws ~~. For example, Virginia~~ **and we expect more jurisdictions to** ~~passed~~ -- **pass** ~~its Consumer Data Protection Act, Colorado passed the Colorado Privacy Act, and Utah passed the Utah Consumer Privacy Act, all of which become effective in 2023. Similar~~ **similar** laws ~~are being considered~~ in ~~several other~~ -- **the future** ~~states, as well as at the federal and local levels~~. These developments may further complicate compliance efforts, and may increase legal risk and compliance costs for us and the third parties upon whom we rely. Additionally, ~~the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA ")~~, as amended by ~~the Health Information Technology for Economic and Clinical Health Act (" HITECH ")~~, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Laws in Europe regarding privacy, data protection, information security and the processing of personal data have also been significantly reformed and continue to undergo reform. For example, the **EU** ~~European Union~~ ' s General Data Protection Regulation **(** ~~, or the~~ EU GDPR ~~,~~ **)** and the **UK** ~~United Kingdom~~ ' s GDPR **(** ~~, or the~~ UK GDPR **) (collectively** , **GDPR)** impose strict requirements for processing the personal data of individuals located, respectively, within the European Economic Area **(** ~~, or~~ EEA ~~,~~ **)** and ~~the United Kingdom, or~~ the UK. The ~~EU~~ GDPR **provides for** ~~and the UK GDPR enhance~~ **enhanced** data protection obligations for processors and controllers of personal data, including, for example, obligations relating to: processing health and other sensitive data; obtaining consent of individuals; providing notice to individuals regarding data processing activities; responding to data subject requests; taking certain measures when engaging third- party processors; notifying data subjects and regulators of data breaches; and implementing safeguards to protect the security and confidentiality of personal data. The ~~EU GDPR and the UK~~ GDPR impose substantial fines for breaches

of data protection requirements. For example, under the ~~EU~~ GDPR, such fines can be up to four percent of global revenue or 20 million euros **under the EU GDPR / 17. 5 million pounds sterling under the UK GDPR** , whichever is greater **in either case** , and also allow for private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. The ~~EU GDPR, the UK~~ GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as EU regulations governing clinical trial data and other healthcare data, could require us to change our business practices or lead to government enforcement actions, private litigation or significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations. We may be subject to additional foreign data laws. For example, in Canada, the Personal Information Protection and Electronic Documents Act (~~"~~ PIPEDA ~~"~~) and various related provincial laws, as well as Canada' s Anti- Spam Legislation (~~"~~ CASL ~~"~~), may apply to our operations. As another example, the General Data Protection Law ~~(~~ **,** Lei Geral de Proteção de Dados Pessoais **(** ~~, or "~~ LGPD ~~"~~) (Law No. 13, 709 / 2018) **,** may apply to our operations. The LGPD broadly regulates processing personal data of individuals in Brazil and imposes compliance obligations and penalties comparable to those of the EU GDPR. We also target customers in Asia and may be subject to new and emerging data privacy regimes in Asia, including Japan' s Act on the Protection of Personal Information and Singapore' s Personal Data Protection Act. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the ~~United States~~ **U. S.** or other countries. Certain jurisdictions have enacted data localization laws and cross- border personal data transfers laws. For example, **countries in** ~~absent appropriate safeguards or other~~ **the** ~~circumstances,~~ **EEA and** the ~~EU GDPR may~~ **UK have significantly** ~~restrict~~ **restricted** the transfer of personal data to **the U. S. and other** countries ~~outside of the EEA~~ , **whose privacy laws it generally believes are** ~~such as the United States, which the European Commission does not consider to provide an adequate~~ **inadequate** ~~level of personal data protection~~ . Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the ~~United States~~ **U. S.** in compliance with law, such as the EEA ~~and~~ **standard contractual clauses, the** UK' s ~~standard contractual clauses~~ **International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers for to relevant U. S.- based organizations who self- certify compliance and participate in the Framework)** , these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the ~~United States~~ **U. S** . If we cannot implement a valid compliance mechanism for cross- border personal data transfers **or if the requirements for a legally- compliant transfer are too onerous** , we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the ~~United States~~ **U. S.** may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and / or elsewhere at significant expense. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. **Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. Our employees and personnel may use generative AI technologies to perform some of their work, and the disclosure and use of personal information data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. Furthermore, any use of generative AI to develop our proprietary technology and compounds may also impact our ability to obtain or successfully defend certain intellectual property rights. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. In addition to data privacy and security laws, we may contractually be subject to industry standards adopted by industry groups and, we are, or may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.** Our obligations related to data privacy and security **(and consumers' data privacy expectations)** are quickly changing in an increasingly stringent fashion **and creating uncertainty** . These obligations may be subject to differing applications and interpretations, which may be inconsistent among jurisdictions or in conflict. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time- related resources). These obligations may necessitate changes to our information technologies, systems and practices and those of any third parties that process personal data on our behalf. In addition, these obligations may even require us to change ~~to~~ our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third- parties upon whom we rely may fail to comply such obligations that impacts our compliance posture. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions, litigation **(including class claims)** , additional reporting requirements and / or oversight, bans on processing personal data, imprisonment of company officials, and orders to destroy or not use personal data **. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental**

statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, financial condition or results of operations.