Risk Factors Comparison 2025-02-26 to 2024-02-15 Form: 10-K

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Investing in our common stock involves significant risks. Before investing, carefully consider the risks described below and the other information in this Annual Report on Form 10- K, including our consolidated financial statements and related notes. The risks and uncertainties described below are the ones we believe may materially affect us. There may be others of which we are unaware that could materially harm our business or financial condition and cause the price of our stock to decline, in which case you could lose all or part of your investment. Summary of Principal Risks The following bullet points summarize the principal risks we face, each of which could adversely affect our business, operations and financial results. Below, we have arranged these risks by the part of our business they most directly affect. Risks Related to our Commercial Activities • Failure to generate sufficient revenue from the sale of ~~Korlym~~ **our Products** would harm our financial results and would likely cause our stock price to decline. • ~~If a~~ **The availability of** generic ~~version~~ **versions** of Korlym **could adversely affect** ~~is successfully commercialized,~~ our business, results of operations and financial position ~~would be adversely affected~~ **. • Public perception of mifepristone or legislation limiting or barring its distribution or use for termination of early pregnancy may limit our ability to sell our Products** . • New laws, government regulations, or changes to existing laws and regulations could make it difficult or impossible for us to obtain acceptable prices or adequate insurance coverage and reimbursement for ~~Korlym~~ **our Products** , which would adversely affect our results of operations and financial position. Risks Related to our Research and Development Activities **• Vendors perform many of the activities necessary to carry out our clinical trials, including drug product distribution, trial management and oversight and data collection and analysis. Failure of these vendors to perform their duties or meet expected timelines may prevent or delay approval of our product candidates.** • Our efforts to discover, develop and commercialize our product candidates may not succeed. Clinical drug development is lengthy, expensive and often unsuccessful. Results of early studies and trials are often not predictive of later trial results. Failure can occur at any time. Even if we deem that our product candidates' clinical trial results demonstrate safety and efficacy, regulatory authorities may not agree. Failure to obtain or maintain regulatory approvals for our product candidates would prevent us from commercializing them. ~~• Vendors perform many of the activities necessary to carry out our clinical trials, including drug product distribution, trial management and oversight and data collection and analysis. Failure of these vendors to perform their duties or meet expected timelines may prevent or delay approval of our product candidates.~~ Risks ~~Relating~~ **Related** to our Intellectual Property • ~~To succeed, we must~~ **We may not be able to** secure, maintain ~~and~~ **or** effectively assert ~~adequate~~ patent protection for the composition ~~and~~ **, manufacture, or** methods of use of our proprietary, selective cortisol modulators and for the use of ~~Korlym~~ **our Products** to treat ~~Cushing' s syndrome~~ **hypercortisolism. Litigation is slow and expensive and its outcome is uncertain and subject to challenge on appeal** . Risks Related to our Stock • The price of our common stock fluctuates widely and is likely to continue to do so. Opportunities for investors to sell shares may be limited. • Our stock price may decline if our ~~financial~~ performance does not meet the guidance we have provided to the public, estimates published by research analysts or other investor expectations. General ~~Risks~~ **Risk Factors** • We rely on information technology to conduct our business. A breakdown or breach of our information technology systems or our failure to protect confidential information concerning our business, patients or employees could interrupt the operation of our business and subject us to liability. Risk Factors – Discussion The following section discusses the principal risks listed above, as well as other risks we believe to be material. Our ability to generate revenue and to fund our commercial operations and development programs is dependent on the sale of ~~Korlym~~ **our Products** to treat patients with **hypercortisolism** ~~Cushing' s syndrome~~ . Physicians will prescribe ~~Korlym only~~ **our Products** if they determine that it is preferable to other treatments, even if those treatments are not approved for **hypercortisolism** ~~Cushing' s syndrome~~ . Most physicians are inexperienced diagnosing or caring for patients with **hypercortisolism** ~~Cushing' s syndrome~~ and it can be hard to persuade them to identify appropriate patients and treat them with ~~Korlym~~ **our Products** . Many factors could limit our ~~Korlym~~ **product** revenue, including: • the preference of ~~some~~ physicians **or payors** for competing treatments for **hypercortisolism** ~~Cushing' s syndrome~~ , including **a lower- priced generic version of Korlym and** off- label treatments ~~and generic versions of Korlym~~ ; and • lack of availability of government or private insurance, the shift of a significant number of patients to Medicaid, which reimburses Korlym at a significantly lower price, or the introduction of government price controls or other price- reducing regulations, such as the Inflation Reduction Act of 2022, that may significantly limit Medicare reimbursement rates. Failure to generate sufficient ~~Korlym~~ **product** revenue could prevent us from fully funding our planned commercial and clinical activities and would likely cause our stock price to decline. **In January 2024** ~~The marketing exclusivity provided by Korlym' s orphan drug designation expired in February 2019~~ , **Teva launched** ~~which means other companies may now seek to introduce generic equivalents of Korlym for Korlym' s approved indication, provided such parties receive FDA approval and can show that they would not infringe our applicable patents or that those patents are invalid or unenforceable. If our patents are successfully challenged and~~ a generic version of Korlym ~~becomes available, our sales of Korlym tablets and their price could decline rapidly and significantly, which would reduce our revenue and materially harm our results of operations and financial position. Competition from a generic version of Korlym may also cause our revenue to be materially less than the public guidance we have provided, which would likely cause the price of our common stock to decline. Legal action to enforce or defend intellectual property rights is complex, costly and involves significant commitments of management time. There can be no assurance of a successful outcome~~ . We have sued Teva in Federal District Court with respect to its ~~proposed~~ generic ~~versions~~ **version** of Korlym. On December 29, 2023, the Court issued a ruling in that case finding that Teva' s generic product would not infringe the patents we have asserted against ~~Teva~~ **it** .

We have appealed ~~that~~ **this adverse** decision to **the Court of Appeals for** the Federal Circuit ~~Court of Appeals~~, but there can be no assurance our appeal will be successful. ~~Because~~ **If** Teva **' s commercial efforts are** ~~has received FDA approval, it has been able, since August 2020, to market its generic product, notwithstanding our ongoing litigation. Teva has announced the launch of its generic product. If its launch is~~ successful, ~~it~~ **they** may materially harm our results of operations and financial condition, even if our ~~on- going~~ appeal is successful and Teva ~~were~~ **is** required to withdraw its product and pay us damages. We ~~had~~ **have made available our own generic version of Korlym. We** also ~~sued~~ **have litigation settlements with** Sun and Hikma ~~with respect~~ **that allow them** to **begin selling mifepristone** ~~their proposed generic versions of Korlym, although we settled those lawsuits in June 2021 and December 2022, respectively. The terms of these settlements permit entry by Sun and Hikma~~, with customary restrictions, ~~following~~ **provided the FDA has approved** ~~the~~ **their products and** ~~start of sales of~~ Teva' s generic product **remains commercially available** . ~~Market entry by~~ **The availability of generic versions of Korlym from** Sun or Hikma could materially harm our results of operations and financial condition, even if our on- going appeal **against Teva** is successful and ~~they~~ **Teva, Sun and Hikma** were required to withdraw ~~its~~ **their** ~~product~~ **products** and pay us damages. Please see " Part I, Item 3, Legal Proceedings " for additional details. **The availability of generic Korlym could cause our revenue to decline and materially harm our results of operations and financial position, by reducing the number of tablets we sell or lowering their price.** It **may also cause our revenue to be materially less than the public guidance we have provided, which would likely cause the price of our common stock to decline. Legal action to enforce or defend intellectual property rights** is ~~likely that~~ **complex, costly and involves significant commitments of management time.** ~~other~~ **Other** companies ~~will~~ **may** seek FDA approval to market ~~a~~ generic ~~version~~ **versions** of Korlym ~~. While~~ **, in which case** we will vigorously protect our intellectual property **. However** , there can be no assurance our efforts will be successful. **The active ingredient in our Products, mifepristone, is approved by** ~~Other --~~ **the** ~~companies offer different medications to treat patients with Cushing~~ **FDA in another drug for the termination of early pregnancy. In 2022, the United States Supreme Court published its decision in the case of Dobbs v. Jackson Women** ' s ~~syndrome~~ **Health Organization (" Dobbs "), which overturned Roe v** . **Wade, the 1973 Supreme** ~~The availability of competing treatments could limit our~~ **Court decision that had established** ~~revenue from Korlym. Since 2012,~~ a **woman** ~~medication owned by the Italian pharmaceutical company Recordati- S. p. A., the somatostatin analogue Signifor ® (pasireotide) Injection, has been marketed in both the United States and the EU for adult patients with Cushing~~ ' s ~~disease~~ **right to terminate her pregnancy, subject to certain limitations. Dobbs has stimulated many states to enact laws restricting the legality of abortion and mifepristone, including during early pregnancy and under specific conditions of use. More laws banning or heavily restricting termination of pregnancy may be adopted and existing laws may be made more restrictive. On June 13, 2024, in a highly publicized case, the Supreme Court ruled against plaintiffs seeking to restrict access to mifepristone for terminating pregnancy, holding that they lacked standing** (~~a subset of Cushing~~ **i. e., the right to sue), thus preserving current access to mifepristone. Because the Supreme Court** ' s ~~syndrome~~ **decision was made solely on procedural grounds, the ruling does not necessarily foreclose other challenges to the continued availability of mifepristone. The timing and outcome of any subsequent cases, as well as additional legislative changes are uncertain. In addition, heightened public awareness of mifepristone as an abortifacient may draw the attention of hostile state government officials or political activists to our Products – as could additional public debate concerning current or proposed restrictions on the distribution of mifepristone. This may be the case even though (i**) **our Products are not** ~~. On March 6, 2020, the FDA granted Recordati approval~~ **approved for the termination of pregnancy** ~~to market another cortisol synthesis inhibitor~~ , ~~Isturisa ®~~ (~~osilodrostat~~ **ii**) **we do not promote it** ~~tablets, to treat patients with Cushing' s disease. Osilodrostat is approved in the EU~~ for **that use and** ~~the treatment of patients with Cushing' s syndrome. On December 30, 2021, Xeris received FDA approval to market the cortisol synthesis inhibitor Recorlev ®~~ (~~levoketoconazole~~ **iii**) **we have taken measures** to **minimize** ~~treat patients with Cushing' s syndrome in~~ the **chance** ~~United States. Levoketoconazole is an enantiomer of the generic anti- fungal medication, ketoconazole,~~ that ~~is~~ **it will accidentally be** prescribed ~~off- label~~ to **a pregnant woman** ~~treat patients with Cushing' s syndrome. Osilodrostat and levoketoconazole have been designated orphan drugs in both the EU and the United States. Physician preference for any of these medications, or for the off- label use of generic medications such as ketoconazole, to treat patients with Cushing' s syndrome could reduce our revenue materially and harm our results of operations, which would cause our stock price to decline~~ . The commercial success of ~~Korlym~~ **our Products** depends on the availability of acceptable pricing and adequate insurance coverage and reimbursement. Government payers, including Medicare, Medicaid and the Veterans Administration, as well as private insurers and health maintenance organizations, are increasingly attempting to contain healthcare costs by limiting reimbursement for medicines. In many foreign markets, drug prices and the profitability of prescription medications are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed health care in the United States and recent laws and legislation intended to increase the public visibility of drug prices and reduce the cost of government and private insurance programs could significantly influence the purchase of health care services and products and may result in lower prices for ~~Korlym~~ **our Products** . If government or private payers cease to provide adequate and timely coverage, pricing and reimbursement for ~~Korlym~~ **our Products** , physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed, or the price we receive may be reduced, which would reduce our revenue. In the United States, there have been and continue to be legislative initiatives to contain healthcare costs. The **IRA significantly** ~~Patient Protection and Affordable Care Act (" ACA ") which was passed in 2010, substantially~~ changed the way ~~health care is financed by both governmental and private insurers. The IRA introduced some of the most significant changes to~~ Medicare ~~payment~~ **pays** for prescription drugs ~~since the ACA~~ . **The** ~~Among its many provisions, the~~ IRA requires the Secretary of the U. S. Department of Health and Human Services (" HHS ") to negotiate Medicare prices for selected drugs and biologicals, including both physician- administered products covered under Medicare' s Part B benefit and self- administered drugs **such as our Products that are** covered under the Part D benefit. Each

year, the Secretary will select for price negotiation a specified number of negotiation- eligible drugs with the highest total Part B or D expenditures over ~~a~~ **the** preceding 12- month period. To be eligible for price negotiation a drug must have been on the market for at least seven years without generic competition. Orphan drugs indicated for only one rare disease or condition and drugs with less than $ 200 million in annual Medicare expenditures are exempt from the negotiation program. For the first two years of the program, 2026 and 2027, only Part D drugs are eligible. The Secretary will publish the negotiated price, known as the " Maximum Fair Price " (" MFP "), for each of the selected products. Manufacturers of selected drugs would be required to offer the drug for Medicare recipients at the MFP. Manufacturers who fail to negotiate **with the Secretary** or offer **their drug to Medicare recipients at** the MFP can face significant civil money penalties or excise tax liability on sales of that drug. **If our Products** ~~Depending on the share of Medicare spending each year that is attributed to Korlym~~ or any ~~other~~ drug ~~candidate that~~ we **commercialize** ~~develop and whether or not those drugs become~~ **becomes** eligible for Medicare negotiation, ~~those~~ -- **the** ~~drugs and our~~ revenue **we generate from sales of that drug** may be **significantly reduced** ~~adversely impacted by this provision~~. The IRA also establishes an inflation rebate program that requires manufacturers to pay rebates to the Medicare program if any of the medications they provide Medicare recipients increase in price faster than the rate of inflation. The Part D inflation rebate provision went into effect on October 1, 2022. Although manufacturers are generally familiar with inflation rebates under the Medicaid program, where they have existed for decades, the IRA represents the first time that inflation rebates have been extended to the Medicare program. **The inflation rebate provision applies to any medication sold to Medicare recipients, whether or not that medication is subject to Medicare price negotiation.** Beginning in 2025, the IRA ~~will~~ also ~~shift~~ **shifts** a significant portion of the Medicare beneficiary costs from the government and beneficiaries to manufacturers. We anticipate that this provision will significantly limit the revenue we receive and may materially reduce our revenue and profits. We make grants to independent charitable foundations that help financially needy patients with their premium, co- pay, and co- insurance obligations with respect to their **hypercortisolism** ~~Cushing' s syndrome~~ treatment, **regardless of** whether that treatment includes ~~Korlym~~ **one of** ~~or~~ **our** ~~not~~ **Products**. There has been enhanced scrutiny of company- sponsored patient assistance programs, including insurance premium and co- pay assistance programs and donations to third- party charities that provide such assistance. As a result of this scrutiny, these assistance programs and charities may decide to reduce or eliminate entirely the assistance they provide to patients, which could result in fewer patients receiving the financial support they need to cover the cost of their **hypercortisolism** ~~Cushing' s syndrome~~ care, including the cost of medication, which may include **one** ~~Korlym. There continues to be federal and state initiatives to contain healthcare costs, in part informed by the current atmosphere~~ of **our Products** ~~mounting criticism of prescription drug costs in the United States~~. We expect governmental oversight and scrutiny of pharmaceutical companies ~~will continue~~ to increase and **that** there will ~~continue to~~ be ~~proposals~~ **additional attempts** to change the healthcare system in ways that could harm our ability to sell ~~Korlym~~ **our Products and any other drugs we commercialize** profitably ~~. We anticipate that the United States Congress~~, **including new** ~~state legislatures, and regulators may implement healthcare~~ policies intended to curb healthcare costs, such as federal and state controls on reimbursement for drugs (including under Medicare and commercial health plans), new or increased requirements to pay prescription drug rebates and penalties to government health care programs and policies that require drug companies to disclose and justify the prices they charge. ~~We depend on vendors~~ **Other companies offer different medications** to ~~manufacture Korlym~~ **treat patients with hypercortisolism. The availability of competing treatments could limit our product revenue. Since 2012, a medication owned by the Italian pharmaceutical company Recordati- S. p. A., the somatostatin analogue Signifor ® (pasireotide) Injection, has been marketed in both the United States and the EU for adult patients with Cushing** ' s ~~active ingredient~~ **disease (a subset of hypercortisolism). On March 6** , ~~form it into~~ **2020, the FDA granted Recordati approval to market another cortisol synthesis inhibitor, Isturisa ® (osilodrostat)** tablets, ~~package it and dispense it~~ to **treat** patients **with Cushing' s disease. Osilodrostat is approved in the EU for the treatment of patients with hypercortisolism. On December 30, 2021, Xeris received FDA approval to market the cortisol synthesis inhibitor Recorlev ® (levoketoconazole) to treat patients with hypercortisolism in the United States. Levoketoconazole is an enantiomer of the generic anti- fungal medication, ketoconazole, that is prescribed off- label to treat patients with hypercortisolism. Osilodrostat and levoketoconazole have been designated orphan drugs in both the EU and the United States. Physician preference for any of these medications, or for the off- label use of generic medications such as ketoconazole, to treat patients with hypercortisolism could reduce our revenue materially and harm our results of operations, which would cause our stock price to decline**. We ~~also~~ depend on vendors to manufacture the active pharmaceutical ingredient (" API ") and capsules or tablets for our **commercialized products as well as our** product candidates. **We also depend on vendors to package our products and dispense them to patients.** If our ~~suppliers~~ **vendors** become unable or unwilling to perform these functions and we cannot transfer these activities to ~~replacement~~ **other** vendors in a timely manner, our business will be harmed. In the event any of our vendors fails to perform its contractual obligations to us or is materially impaired in its performance, we may experience disruptions and delays in our ~~supply chain and our~~ ability to deliver ~~Korlym~~ **our commercialized products** to patients **or investigational drugs to patients in our clinical trials**, which would adversely affect our business, results of operations and financial position. Our single specialty pharmacy, Optime, dispenses ~~Korlym~~ **our Products** and performs related pharmacy and patient support services, including the collection of payments from insurers representing ~~approximately~~ **more than** 99 percent of our revenue. If Optime does not adhere to its agreements with payers or does not continue to meet regulatory requirements concerning pharmacy operations, it may not be able to collect **on our behalf** some or all of the payments due to us. In addition, if Optime becomes unable or unwilling to perform its obligations under our agreement, we may not be able to dispense ~~Korlym~~ **our Products** in a timely manner to some or all of our patients. ~~Our~~ **Effective April 1, 2024, we extended our** agreement with Optime **through** ~~extends to~~ March 31, ~~2024~~ **2027**, **with automatic renewal for successive three- year terms. The agreement is** subject to customary termination provisions, including the right of Optime to terminate in the event of a material breach by us that we do not cure in a reasonable period of time after

receiving written notice. In addition, we may terminate the agreement for convenience. The facilities used by our vendors to manufacture and package the API and drug product for ~~Korlym and~~ our **Products and** product candidates and distribute them to hospitals, clinics and patients, must be approved by government regulators in the United States, Europe, and elsewhere. We do not control the activities of these vendors, including whether they maintain adequate quality control and hire qualified personnel. We are dependent on them for compliance with the regulatory requirements known as current good manufacturing practices (" cGMPs ") **, which are subject to change at the regulators' discretion** . If our vendors cannot manufacture material that conforms to our specifications and the strict requirements of the FDA or others, they will not be able to maintain regulatory authorizations for their facilities and we could be prohibited from using the API or drug product they have provided. If the FDA, European Medicines Agency (" EMA "), the Medicines and Healthcare products Regulatory Agency (" MHRA ") or other regulatory authorities withdraw regulatory authorizations of these facilities, we may need to find alternative vendors or facilities, which would be time- consuming, complex and expensive and could significantly hamper our ability to develop, obtain regulatory approval for and market our ~~products~~ **Products** . Sanctions could be imposed on us, including fines, injunctions, civil penalties, refusal of regulators to approve our product candidates, delays, suspensions or withdrawals of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. ~~The unfavorable public perception of mifepristone may limit our ability to sell Korlym. The active ingredient in Korlym, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. On June 24, 2022, the United States Supreme Court published its decision in the case of Dobbs v. Jackson Women' s Health Organization (" Dobbs "), which overturned Roe v. Wade, the 1973 Supreme Court decision establishing a woman' s right to terminate her pregnancy, subject to certain limitations. Dobbs has stimulated many states to enact laws making abortion illegal in virtually every circumstance, including during early pregnancy. More laws banning or heavily restricting termination of pregnancy may be adopted and existing laws may be made more restrictive. Two highly publicized cases regarding mifepristone have been filed in the U. S. since the Dobbs decision, one of which seeks to invalidate the FDA' s approval of mifepristone and the other of which seeks to uphold the FDA' s approval in certain jurisdictions. On April 7, 2023, the United States District Court for the Northern District of Texas, Amarillo Division, issued a preliminary injunction blocking the FDA' s approval of mifepristone. This ruling has been stayed and will have no effect until the U. S. Supreme Court hears the case, which it is expected to do in 2024. The ultimate outcome is uncertain. Heightened public perception of mifepristone as an abortifacient may draw the attention of hostile state government officials or political activists to Korlym – even though Korlym is not approved for the termination of pregnancy, we do not promote it for that use and we have taken measures to minimize the chance that it will accidentally be prescribed to a pregnant woman.~~ In addition, **our reputation** ~~physicians and patients may choose not to use Korlym~~ as a ~~treatment~~ **reliable sponsor of clinical studies would be harmed, which would make it more difficult** for **us** ~~Cushing' s syndrome simply~~ to **develop our drug candidates** ~~avoid the risk of terminating a pregnancy~~ . Natural disasters, such as earthquakes, fires, extreme weather events or widespread outbreaks of a deadly disease such as COVID- 19, could disrupt our commercial and clinical activities or damage or destroy clinical trial sites, our office spaces, the residences of our employees or the facilities or residences of our vendors, contractors or consultants, which could significantly harm our operations. A resurgence of COVID- 19 or the widespread occurrence of another deadly illness could adversely affect our business, operations and financial results. The COVID- 19 pandemic made it difficult to grow our commercial business and slowed the pace of some of our clinical trials. We are also vulnerable to natural disasters, including earthquakes, fires, hurricanes, floods, blizzards and the extended periods of extreme heat, cold and precipitation made more frequent and severe by global warming. For example, our headquarters are in the San Francisco Bay Area, which experiences earthquakes, wildfires and flooding. Our specialty pharmacy, tablet manufacturers and warehouses are in areas subject to hurricanes and tornadoes. All our activities, as well as the activities of our vendors, consultants, clinical investigators, patients, physicians and regulators, are subject to the risks posed by global warming. The loss of life, property damage and disruptions to electrical power distribution, communications, travel and shipping caused by natural disasters could make it difficult or impossible to conduct our commercial activities or complete our drug discovery activities or clinical trials. Patients may be unwilling or unable to travel to clinical trial sites, for example, or clinical materials or data may be lost. Our insurance, if available at all, would likely be insufficient to cover losses resulting from disasters or other business interruptions. ~~We may not have adequate insurance to cover our exposure to product liability claims. We may be subject to product liability or other claims based on allegations that Korlym or one of our product candidates has harmed a patient. Such a claim may damage our reputation by raising questions about Korlym or our product candidates' safety and could prevent or interfere with product development or commercialization. Less common adverse effects of a pharmaceutical product are sometimes not known until long after the product is approved for marketing. Because the active ingredient in Korlym is used to terminate pregnancy, clinicians using Korlym in clinical trials and physicians prescribing the medicine to women must take strict precautions to ensure that it is not administered to pregnant women. Failure to observe these precautions could result in significant product liability claims. Our insurance may not fully cover our potential product liabilities. Inability to obtain adequate insurance coverage could delay development of our product candidates or result in significant uninsured liability. Defending a lawsuit could be costly and divert management from productive activities.~~ If we are unable to maintain regulatory approval of ~~Korlym~~ **our Products** or if we fail to comply with other requirements, we will be unable to generate revenue and may be subject to penalties. We are subject to oversight by the FDA and other regulatory authorities in the United States and elsewhere with respect to our research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, advertising, promotion, recordkeeping and sales and marketing activities. These requirements include submissions of safety information, annual updates on manufacturing activities and continued compliance with FDA regulations, including cGMPs, good laboratory practices and good clinical practices (" GCPs ") ~~. The FDA enforces~~ **, all of which are subject to change without notice and at** ~~these~~ **the** ~~regulations~~ **regulators ' sole discretion** ~~through inspections of us and the laboratories, manufacturers and clinical sites we use~~ . Foreign regulatory authorities have comparable requirements and enforcement

mechanisms **, which are also subject to change. The FDA and other regulators enforce these regulations through inspections of us and the laboratories, manufacturers and clinical sites we use** . Discovery of previously unknown problems with a product or product candidate, such as adverse events of unanticipated severity or frequency or deficiencies in manufacturing processes or management, as well as failure to comply with **current or future** FDA or other U. S. or foreign regulatory requirements, may subject us to substantial civil and criminal penalties, injunctions, holds on clinical trials, product seizure, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, product recalls, total or partial suspension of production, refusal to approve pending new drug applications (" NDAs ") or supplemental NDAs, and suspension or revocation of product approvals. We may be subject to civil or criminal penalties if our marketing of ~~Korlym~~ **our Products** violates FDA regulations or health care fraud and abuse laws. We are subject to ~~FDA~~ **statutes and** regulations governing the promotion and sale of ~~medications~~ **medicine** . Although physicians are permitted to prescribe drugs for any indication they choose, manufacturers may only promote products for their FDA- approved use. All other uses are referred to as " off- label ~~,~~" **;** manufacturers are prohibited from engaging in any " off- label " promotion. In the United States, we market ~~Korlym~~ **our Products** to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous **hypercortisolism** ~~Cushing' s syndrome~~ who have type 2 diabetes mellitus or glucose intolerance and for whom surgery has failed or is not an option. Among other activities, we provide promotional materials and training programs to physicians covering the use of ~~Korlym~~ **our Products** for this indication. The FDA may change its policies or enact new regulations at any time that may restrict our ability to promote our ~~products~~ **Products** , which could adversely impact our business. If the FDA **or a law enforcement agency** were to determine that we engaged in off- label promotion, **we** ~~the FDA~~ could **be** ~~require~~ **required** ~~us~~ to change our practices and **be** subject ~~us~~ to regulatory enforcement actions, including issuance of a public " warning letter, " untitled letter, injunction, seizure, civil fine or criminal penalties. ~~Other federal~~ **Federal** or state enforcement authorities ~~might~~ **may** act if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is determined that we are not in violation of these laws, we may receive negative publicity, incur significant expenses and be forced to devote management time to defending our position. In addition to laws prohibiting off- label promotion, we are also subject to federal and state healthcare fraud and abuse laws and regulations designed to prevent fraud, kickbacks, self- dealing and other abusive practices. The United States healthcare laws and regulations that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce 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 federal health care programs such as Medicare and Medicaid. And, although we structure our applicable business arrangements in accordance with the safe harbors, it is difficult to determine exactly how the law will be applied in specific circumstances. Accordingly, it is possible that certain practices of ours may be challenged under the federal Anti- Kickback Statute. From a liability perspective, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • federal false claims laws, including, without limitation, the False Claims Act, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal False Claims Act is unique in that it allows private individuals (whistleblowers) to bring actions on behalf of the federal government via qui tam actions. Importantly, under the False Claims Act the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary' s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; • HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • federal " sunshine " laws, including the federal Physician Payment Sunshine Act (or sometimes referred to as the Open PaymentsTM Program), that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the **Patient Protection and Affordable Care Act ("** ACA **")** on drug manufacturers regarding any " transfer of value " made or distributed to physicians, certain non- physician practitioners, teaching hospitals, and ownership or investment interests held by physicians and their immediate family members; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payer, including commercial 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 or otherwise restrict payments that may be made to healthcare providers; and • 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 and pricing information. The risk of being found in violation of these laws and regulations is increased by the fact that many of them have not been definitively interpreted by regulatory authorities or the courts and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under them, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers (some of whom recommend, purchase and / or prescribe our ~~products~~ **Products**) and the manner in which we promote our ~~products~~ **Products** , could be subject to challenge and scrutiny. We are also exposed to the risk that our employees, independent contractors, principal

investigators, consultants, vendors, distributors and contract research organizations (“ CROs ”) may engage in fraudulent or other illegal activity. Although we have policies and procedures prohibiting such activity, it is not always possible to identify and deter misconduct and the precautions we take may not be effective in controlling unknown risks or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with applicable laws and regulations. In November 2021, we received a records subpoena from the United States Attorney’ s Office for the District of New Jersey (the “ NJ USAO ”) seeking ~~information~~ **documents** relating to the sale and promotion of Korlym, our relationships with and payments to health care professionals who can prescribe or recommend Korlym and prior authorizations and reimbursement for Korlym. The NJ USAO has informed us that it is investigating whether any criminal or civil violations by us occurred in connection with the matters referenced in the subpoena. It has also informed us that it does not currently consider us a defendant but rather an entity whose conduct is within the scope of the government’ s investigation. We are cooperating with the investigation. Please see “ Part I, Item 3, Legal Proceedings ” for additional details. If we are found in violation of any of the laws described above or any other government regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non- compliance, individual imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our financial results and ability to operate. **Third- party clinical investigators** ~~Our efforts to discover, develop~~ and ~~commercialize~~ clinical sites enroll patients and CROs manage many of our trials and perform data collection and analysis.Although we control only certain aspects of these third parties’ activities,we are responsible for ensuring that every study adheres to its protocol and meets regulatory and scientific standards.If any of our vendors does not perform its duties or meet expected deadlines or fails to adhere to applicable GCPs,or if the quality or accuracy of the data it produces is compromised,affected clinical trials may be extended,delayed or terminated and we may be unable to obtain approval for our product candidates **.Outside** parties may have staffing difficulties,may undergo changes in priorities or may become financially distressed,adversely affecting their willingness or ability to conduct our clinical trials.Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternative service provider.However,making this change may be costly and may delay our trials,and it may be challenging to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.Failure of our manufacturing vendors to perform their duties or comply with cGMPs may require us to recall drug product or repeat clinical trials,which would delay regulatory approval.If our agreements with any of these vendors terminate,we ~~may not~~ may not **be able to enter into alternative arrangements in a** ~~succeed. Clinical drug development is lengthy, expensive and often unsuccessful. Results of early studies and trials are often not predictive of later trial results. Failure can occur at any time~~ **timely manner** ~~. Even if we deem that our~~ **or on reasonable terms** ~~product candidates' clinical trial results demonstrate safety and efficacy, regulatory authorities may not agree. Failure to obtain or maintain regulatory approvals for our product candidates would prevent us from commercializing them~~ . Clinical development is costly, time- consuming and unpredictable. Positive data from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The results from early clinical trials are often not predictive of results in later clinical trials. Product candidates may fail to show the desired safety and efficacy traits despite having produced positive results in preclinical studies and initial clinical trials. Many companies have suffered significant setbacks in late- stage clinical trials due to lack of efficacy or unanticipated or unexpectedly severe adverse events. Our current clinical trials may prove inadequate to support marketing approvals. Even trials that generate positive results may have to be confirmed in much larger, more expensive and lengthier trials before we could seek regulatory approval. Clinical trials may take longer to complete, cost more than expected and fail for many reasons, including: • failure to show efficacy or acceptable safety; • slow patient enrollment or delayed activation of clinical trial sites; • delays obtaining regulatory permission to start a trial, changes to the size or design of a trial or changes in regulatory requirements for a trial already underway; • inability to secure acceptable terms with vendors and an appropriate number of clinical trial sites; • delays or inability to obtain institutional review board (“ IRB ”) approval at prospective trial sites; • failure of patients or investigators to comply with the clinical trial protocol; • unforeseen safety issues; and • negative findings of inspections of clinical sites or manufacturing operations by us, the FDA or other authorities. A trial may also be suspended or terminated by us, the trial’ s data safety monitoring board, the IRBs governing the sites where the trial is being conducted or the FDA for many reasons, including failure to comply with regulatory requirements or clinical protocols, negative findings in an inspection of our clinical trial operations or trial sites by the FDA or other authorities, unforeseen safety issues, failure to demonstrate a benefit or changes in government regulations. ~~During~~ **At any time prior to** the ~~development~~ **regulatory approval** of a product candidate, we may decide, or the FDA or other regulatory authorities may require us, to conduct more pre- clinical or clinical studies **, provide additional analysis of existing data** or ~~to~~ change the size or design of a trial already underway **. Such additional or changed requirements** , ~~thereby~~ **which regulators may impose in their sole discretion, may** ~~delaying~~ **delay** or ~~preventing~~ **prevent** the completion of development **, submission of** ~~and~~ **an NDA or the completion of regulatory review, which would** increase ~~its~~ **our** ~~cost~~ **costs and adversely impact future revenue** . Even if we conduct the clinical trials and supportive studies that we consider appropriate and the results are positive, we may not receive regulatory approval. Following regulatory approval, there ~~are significant risks to its~~ **is no assurance of** commercial success , such as development of competing products..... failures to meet applicable requirements went undetected . We may be unable to obtain or maintain regulatory approvals for our ~~product~~ **Products** or product candidates, which would prevent us from commercializing our product candidates. We cannot sell a product without the approval of the FDA or comparable foreign regulatory authority. Obtaining such approval is difficult, uncertain, lengthy and expensive. Failure can occur at any stage. In order to receive FDA approval for a new drug, we must demonstrate to the FDA’ s satisfaction that the new drug is safe and effective for its intended use and that our manufacturing processes comply with cGMPs. Our inability or the inability of our vendors to comply with applicable FDA and other regulatory requirements can result in delays in or denials of new product approvals, warning letters, untitled letters, fines, consent decrees restricting or suspending manufacturing

operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of product sales and criminal prosecution. We may seek to commercialize our ~~products~~ **Products** in international markets, which would require us to receive a marketing authorization and, in many cases, pricing approval, from the appropriate regulatory authorities. Approval procedures vary between countries and can require additional pre- clinical or clinical studies. Obtaining approval may take longer than it does in the United States. Although approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by others, failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Any of these or other regulatory actions could materially harm our business and financial condition. If we receive regulatory approval for a product candidate, we will be subject to ongoing requirements and oversight by the FDA and other regulatory authorities, such as continued safety and other reporting requirements and possibly post- approval marketing restrictions and additional costly clinical trials. If we are not able to maintain regulatory compliance, we may be required to stop development of a product candidate or to stop selling a product that has already been approved. We may also be subject to product recalls or seizures. Future governmental action or changes in regulatory authority policy or personnel may also result in delays or rejection of pending or anticipated product approvals. Our ~~products~~ **Products** and product candidates may cause undesirable side effects that halt their clinical development, prevent their regulatory approval, limit their commercial potential or cause us significant liability. Patients in clinical trials report changes in their health, including new illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not these conditions were caused by the drug candidate being studied or something else. As we test our product candidates in larger, longer and more extensive clinical trials, or as use of them becomes more widespread if we receive regulatory approval, patients may report serious adverse events that did not occur or went undetected in previous trials. Many times, serious side effects are only detected in large- scale, Phase 3 clinical trials or following commercial approval. Adverse events reported in clinical trials can slow or stop patient recruitment, prevent enrolled patients from completing a trial and could give rise to liability claims. Regulatory authorities could respond to reported adverse events by interrupting or halting our clinical trials or limiting the scope of, delaying or denying marketing approval. If we elect, or are required by authorities, to delay, suspend or terminate a clinical trial or commercialization efforts, the commercial prospects of the affected product candidates or products may be harmed and our ability to generate product revenues from them may be delayed or eliminated. If one of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events, potentially significant negative consequences could result, including but not limited to: • regulatory authorities may suspend, limit or withdraw approvals of such product; • regulatory authorities may require additional warnings on the label, including " boxed " warnings, or issue safety alerts and other safety information about the product; • we may be required to change the way the product is administered or conduct additional studies or clinical trials; • we may be required to create a Risk Evaluation and Mitigation Strategy, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and / or other elements to assure safe use; • the product may become less competitive; • we may be subject to fines, injunctions or the imposition of criminal penalties; and • we could be sued and held liable for harm caused to patients. Any of these events could seriously harm our business. Risks Related to our Capital Needs and Financial Results We may need additional capital to fund our operations or for strategic reasons. Such capital may not be available on acceptable terms or at all. We are dependent on revenue from the sale of ~~Korlym~~ **our Products** and our cash reserves to fund our commercial operations and development programs. If ~~Korlym~~ **our** revenue declines significantly, we may need to curtail our operations or raise funds to support our plans. We may also choose to raise funds for strategic reasons. We cannot be certain funding will be available on acceptable terms or at all. Equity financing would cause dilution, debt financing may involve restrictive covenants. Neither type of financing may be available to us on attractive terms or at all. If we obtain funds through collaborations with other companies, we may have to relinquish rights to one or more of our product candidates. If our revenue declines and our cash reserves are depleted, and if adequate funds are not available from other sources, we may have to delay, reduce the scope of, or eliminate one or more of our development programs. Patents are uncertain, involve complex legal and factual questions and are frequently the subject of litigation. The patents issued or licensed to us may be challenged at any time. Competitors may take actions we believe infringe our intellectual property, causing us to take legal action to defend our rights. Intellectual property litigation is lengthy, expensive and requires significant management attention. Outcomes are uncertain. If we do not protect our intellectual property, competitors may erode our competitive advantage. Please see " Part I, Item 3, Legal Proceedings " for additional information. Our patent applications may not result in issued patents and patents issued to us may be challenged, invalidated, held unenforceable or circumvented. Our patents may not prevent third parties from producing competing products. The foreign countries where we may someday operate may not protect our intellectual property to the extent the laws of the United States do. If we fail to obtain adequate patent protection in other countries, others may produce products in those countries based on our technology. We cannot assure investors that a liquid trading market for our common stock will exist at any particular time. As a result, holders of our common stock may not be able to sell shares quickly or at the current market price. During the 52- week period ended February ~~6~~ **18**, ~~2024~~ **2025**, our average daily trading volume was approximately ~~902~~ **970**, ~~095~~ **395** shares and the intra- day sales prices per share of our common stock on The Nasdaq Stock Market ranged from $ ~~17~~ **20**. ~~86~~ **84** to $ ~~34~~ **74**. ~~28~~ **61**. As of February ~~6~~ **18**, ~~2024~~ **2025**, our officers, directors and principal stockholders beneficially owned approximately ~~20~~ **21** percent of our common stock. Our stock price can experience extreme price and volume fluctuations that are unrelated or disproportionate to our operating performance or prospects. Securities class action lawsuits are often instituted against companies following periods of stock market volatility. Such litigation is costly and diverts management' s attention from productive efforts. Factors that may cause the price of our common stock to fluctuate rapidly and widely include: • actual or anticipated variations in our operating results or changes to any public guidance we have provided; • actual or anticipated timing and results of our clinical trials; • actual or anticipated regulatory approvals of our product candidates; • disputes or other developments relating to our intellectual property, including

developments in **generic- related** ~~Abbreviated New Drug Application~~ litigation; • changes in laws or regulations applicable to the pricing, availability of insurance reimbursement, or approved uses of ~~Korlym~~ **our commercialized products** , our product candidates or our competitors' products; • short- selling of our common stock, the publication of ~~speculative~~ **negative** opinions about our business or other market manipulation activities that are intended to lower our stock price or increase its volatility **; • sales of a substantial number of shares of our stock in the public market, leading to reductions in its price** ; • changes in estimates or recommendations by securities analysts or the failure of our performance to meet the published expectations of those analysts or public guidance we have provided; • purchases of our common stock pursuant to our **stock repurchase program (the "** Stock Repurchase Program **")** or changes to that program; • general market and economic conditions ~~, including the effects of the COVID- 19 pandemic~~ ; • changes in the expected or actual timing of our competitors' development programs and the approval of competing products; • purchases or sales of our common stock by our officers, directors or stockholders; • technological innovations by us, our collaborators or our competitors; • conditions in the pharmaceutical industry, including the market valuations of companies similar to ours; • additions or departures of key personnel; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; and • additional financing activities. **Our stock price may decline if our financial performance does not meet the guidance we have provided to the public, estimates published by research analysts or other investor expectations.** The guidance we provide as to our expected revenue is only an estimate of what we believe is realizable at the time we give such guidance. ~~It is~~ **Our revenue depends on many factors, including, without limitation, the efficacy of our sales and marketing efforts, the price we receive from private and government payors, competition from alternate treatments for patients with hypercortisolism, including from generic versions of Korlym and changes in government regulations. Our guidance estimate considers all of these factors, but they are** difficult to predict **. As a result,** our revenue ~~and our actual results~~ may vary materially from our guidance ~~. In addition, the rate of physician adoption of Korlym and the actions of government and private payers is uncertain. We may experience competition from generic versions of Korlym, which our public revenue guidance does not anticipate. We may not meet our financial guidance or other investor expectations for other reasons, including those arising from the risks and uncertainties described in this report and in our other public filings and public statements~~ . Research analysts publish estimates of our future revenue and earnings based on their own analysis. The revenue guidance we provide may be one factor they consider when determining their estimates. ~~General Risk Factors~~ **If our revenue is materially less than the guidance we or the research analysts who cover our stock provide investors, our stock price may decline. We have in the past and may in the future be subject to short selling strategies that may drive down the market price of our common stock and increase its volatility. Short sellers have, and likely will continue to, attempt to drive down the price of our common stock. Short selling is the practice of selling stock the seller does not own with the intention of buying it back later at a lower price, thereby profiting from any decline in the price of the stock between the time it is sold and the time it is repurchased. To support their efforts, short sellers often publish, or arrange for others to publish, negative opinions regarding the relevant issuer and its business prospects. These publications are often made to appear as if they were objective journalism or unbiased " research reports " of the type distributed by credible Wall Street firms and independent research analysts. Short seller publications are not regulated by any governmental, self- regulatory organization or other authority in the United States and the opinions they express are often based on distortions, omissions or fabrications. Short attacks supported by such publications have, in the past, led to selling of our stock and at least temporary reductions in its price. Companies that are subject to unfavorable allegations, even if untrue, may have to expend a significant amount of resources to investigate such allegations and / or defend themselves, including shareholder suits against the company that may be prompted by such allegations. We have been, and may in the future be, the subject of shareholder suits prompted by allegations made by short sellers.** We need to increase the size of our organization and may experience difficulties in managing growth. Our commercial and research and development efforts are constrained by our limited administrative, operational and management resources. To date, we have relied on a small management team. Growth will impose significant added responsibilities on members of management, including the need to recruit and retain additional employees. Our financial performance and ability to compete will depend on our ability to manage growth effectively. To that end, we must: • **continue to add talented, experienced personnel to our endocrine, oncology and emerging markets businesses; •** manage our ~~sales and marketing efforts,~~ clinical trials, research and manufacturing activities effectively; • hire more **general** management, clinical development, administrative and sales and marketing personnel; and • continue to develop our administrative systems and controls. Failure to accomplish any of these tasks could harm our business. If we lose key personnel or are unable to attract more skilled personnel, we may be unable to pursue our product development and commercialization goals. Our ability to operate successfully and manage growth depends upon hiring and retaining skilled managerial, scientific, sales, marketing and financial personnel. The job market for qualified personnel is intensely competitive and turnover rates have reached record highs within our industry and the geographical areas from which we recruit. We depend on the principal members of our management and scientific staff. Any officer or employee may terminate his or her relationship with us at any time and work for a competitor. We do not have employment insurance covering any of our personnel. The loss of key individuals could delay our research, development and commercialization efforts. We are subject to ~~government regulation~~ **regulations** and other legal obligations relating to **drug development and commercialization, the conduct of business as an issuer of publicly traded securities and individual** privacy and data protection. Compliance with these ~~requirements~~ **obligations** is complex and costly. Failure to comply could materially harm our business **. New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning taxes and the development, approval, marketing and pricing of medications, the provisions of the ACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes- Oxley Act of 2002, the Dodd Frank Act of 2010 and rules adopted by the SEC and by The Nasdaq Stock Market have and will likely continue to increase our cost**

of doing business and divert management' s attention from revenue- generating activities . We and our partners are subject to federal, state and foreign laws and regulations concerning data privacy and security, including HIPAA and the EU General Data Protection Regulation (~~the~~ " GDPR "). These and other regulatory frameworks are evolving rapidly as new rules are enacted and existing ones updated and made more stringent. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy, laws, and federal and state consumer protection laws and regulations (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health- related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. **Requirements for compliance under HIPAA are also subject to change, as the U. S. Department of Health and Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates.** Even when HIPAA does not apply, according to the Federal Trade Commission (the " FTC "), violating consumers' privacy or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In ~~2022~~ **2024** , the FTC also ~~began a~~ **finalized its** rulemaking **on** ~~proceeding to develop~~ additional data privacy rules and requirements, which may add additional complexity to compliance obligations going forward. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and / or criminal penalties and private litigation. For example, the California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Further, the California Consumer Privacy Act, ~~or the CCPA,~~ which took effect on January 1, 2020 **, and was later revised and expanded by the California Privacy Rights Act, collectively the CCPA** , created individual privacy rights for California consumers and increased the privacy and security obligations of entities handling certain personal information **as well as limitation on data uses, audit requirements for higher risk data, and opt outs for certain uses of sensitive data** . The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability ~~. Further, the California Privacy Rights Act, or CPRA, revised and expanded the CCPA, adding additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data~~ . It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. ~~The CPRA is in full effect as of January 1, 2023, and similar~~ **Similar** laws passed in Virginia, Colorado, Connecticut **, Montana, Oregon, Texas** and Utah have taken effect **in 2023 and 2024** and other states **, including Delaware, Indiana, Iowa, Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, Rhode Island, and Tennessee,** have passed similar laws that will take effect in or after **2025. In addition, along with the CPRA, some of these laws, along with other standalone health privacy laws, subject health- related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the Washington My Health My Data Privacy Law, which became effective in** 2024 **, Nevada' s Consumer Health Data Privacy Law, which became effective in 2024, and Connecticut' s amendments to its privacy law to address health data, which became effective in 2023** . As a result, additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA ~~, the CPRA~~ or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Additional legislation proposed at the federal level and in other states, along with increased regulatory action, reflect a trend toward more stringent privacy legislation in the United States. Outside the United States, many jurisdictions have or are in the process of enacting sweeping data privacy regulatory regimes. In Europe, the GDPR took effect in 2018, and is imposing stringent requirements for controllers and processors of personal data of individuals within the EEA, particularly with respect to clinical trials. The GDPR provides that EEA member states may make their own further laws and regulations limiting the processing of health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. In addition, the GDPR increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. ~~Recent legal~~ **Legal** developments have added complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. Following EU court decisions, updated standard contractual clauses (" SCCs ") were adopted to account for these judicial decisions, imposing new requirements on data transfers. The revised SCCs must be used for relevant new data transfers from September 27, 2021, and existing SCC arrangements were required to be migrated by December 27, 2022. ~~There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non- EEA entities subject to the GDPR.~~ As supervisory authorities issue further guidance on personal data export mechanisms, ~~including circumstances where the SCCs cannot be used,~~ and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it

could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results **. Further, on July 10, 2023, the European Commission adopted its adequacy decision on the E. U.- U. S. Data Privacy Framework or DPF. The decision, which took effect on the day of its adoption, concludes that the United States ensures an adequate level of protection for personal data transferred from the EEA to companies certified to the DPF. It is currently unclear how the future of DPF will evolve and what impact it will have on our international activities** . The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue for the preceding financial year or € 20 million, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with European data protection laws is a rigorous and time intensive process that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. From January 1, 2021, we have had to comply with the GDPR and separately the **UK** ~~United Kingdom~~ GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law, each regime having the ability to fine up to the greater of € 20 million / £ 17. 5 million or 4 percent of global turnover. It is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term and these changes may lead to additional costs and increase our overall risk exposure. ~~On~~ **Further, on** June 28, 2021, the EC adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the EC renews or extends that decision and remains under review by the Commission during this period. **Preparing for and** ~~Complying~~ **complying** with U. S. and foreign privacy and security laws and regulations is complex and costly **as it is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, CROs, contractors or consultants that process or transfer personal data collected in the EU** . ~~Failure~~ **The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal data from our clinical trials, and access** to ~~comply by~~ **certain data such as the European Health Data Space Regulation, could require** us **to change** ~~or~~ **our business practices and put in place additional compliance mechanisms, may interrupt** ~~our~~ **or** ~~vendors~~ **delay our development, regulatory and commercialization activities and increase our cost of doing business, and** could **lead** ~~subject us~~ to ~~litigation,~~ government enforcement actions **, private litigation** and ~~substantial~~ **significant fines and** penalties **against us** and **could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal data could expose us to** fines **and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity** , which could harm **our reputation and** our business. We store valuable confidential information relating to our business, patients and employees on our computer networks and on the networks of our vendors. In addition, we rely heavily on internet technology, including video conference, teleconference and file- sharing services, to conduct business. Despite our security measures, our networks and the networks of our vendors are at risk of break- ins, installation of malware or ransomware, denial- of- service attacks, data theft and other forms of malfeasance by persons seeking to commit fraud or theft, which could result in unauthorized access to, and / or misuse of, our clinical data or other confidential information, including confidential information relating to our patients or employees. We may continue to increase our cybersecurity risks, due to our reliance on internet technology and the number of our employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. We and our vendors have experienced data breaches, theft, " phishing " attacks and other unauthorized access to confidential data and information. There can be no assurance that our cybersecurity systems and processes will prevent unauthorized access in the future that causes serious harm to us, our patients or employees. We may also experience security breaches that remain undetected for an extended period. Disruptions or security breaches that result in the disclosure of confidential or proprietary information could cause us to incur liability and delay or otherwise harm our research, development and commercialization efforts. We may be liable for losses suffered by patients or employees or other individuals whose confidential information is stolen as a result of a breach of the security of the systems that we or third parties and our vendors store this information on, and any such liability could be material. Even if we are not liable for such losses, any breach of these systems could expose us to material costs in notifying affected individuals, as well as regulatory fines or penalties. In addition, any breach of these systems could disrupt our normal business operations and expose us to reputational damage and harm our business, operating results and financial condition. Any insurance we maintain against the risk of this type of loss may not be sufficient to cover actual losses or may not apply to the circumstances relating to any particular loss. Changes in federal, state and local tax laws may reduce our net earnings. Our earnings are subject to federal, state and local taxes. We offset a portion of our earnings using net operating losses and our taxes using research and development tax credits, which reduces the amount of tax we pay. Some jurisdictions require that we pay taxes or fees calculated as a percentage of sales, payroll expense, or other indicia of our activities. Please see " Part IV, Item 15, Notes to Consolidated Financial Statements – Income Taxes. " Changes to existing tax laws could materially increase the amounts we pay, which would reduce our after tax net income. Research analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports. The market for our common stock may be affected by the reports financial analysts publish about us. If any of the analysts covering us downgrades or discontinues coverage of our stock, the price of our common stock could decline rapidly and significantly. Paucity of research coverage may also adversely affect our stock price. **Any** ~~Acquisition~~ **acquisition** of Corcept shares through our stock repurchase program **or, in certain cases, pursuant to the exercise of stock options,** will reduce our cash reserves. In January 2024, our Board of Directors authorized the repurchase of up to $ 200 million of our common stock pursuant to the Stock Repurchase Program. ~~The~~ **In addition, we sometimes accept, in our sole discretion, shares equal in value to any tax**

and exercise price liability due from option holders at the time of exercise and remit the applicable tax amounts to the tax authorities. Neither our Stock Repurchase Program ~~does not~~ **nor the acceptance of shares at the time of options exercise** require us to acquire ~~any specific number of~~ shares ~~and it~~ **. Furthermore, the Stock Repurchase Program** may be modified, suspended or discontinued at any time without notice. It is possible that other uses of our capital would have been more advantageous or that our future capital requirements increase unexpectedly. By reducing our cash balance, our repurchases of common stock could hamper our ability to execute our plans, meet financial obligations or access financing ~~. Sale of a substantial number of shares of our common stock may cause its price to decline. Sales of a substantial number of shares of our stock in the public market could reduce its price. As additional shares of our stock become available for public resale, whether by the exercise of stock options by employees or directors or because of an equity financing by us, the supply of our stock will increase, which could cause its price to fall. Substantially all of our outstanding shares are eligible for sale, subject to applicable volume and certain other resale restrictions. Changes in laws and regulations may significantly increase our costs or reduce our revenue, which could harm our financial results. New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning taxes and the development, approval, marketing and pricing of medications, the provisions of the ACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes- Oxley Act of 2002, the Dodd Frank Act of 2010 and rules adopted by the SEC and by The Nasdaq Stock Market have and will likely continue to increase our cost of doing business and divert management' s attention from revenue- generating activities~~ . Anti- takeover provisions in our charter and bylaws and under Delaware law may make an acquisition of us or a change in our management more expensive or difficult, even if an acquisition or a management change would be beneficial to our stockholders. Provisions in our charter and bylaws may delay or prevent an acquisition of us or a change in our management. Some of these provisions allow us to issue preferred stock without any vote or further action by the stockholders, require advance notification of stockholder proposals and nominations of candidates for election as directors and prohibit stockholders from acting by written consent. In addition, a supermajority vote of stockholders is required to amend our bylaws. Our bylaws provide that special meetings of the stockholders may be called only by our Chairman, President or the Board of Directors and that the authorized number of directors may be changed only by resolution of the Board of Directors. These provisions may prevent or delay a change in our Board of Directors or our management, which our Board of Directors appoints. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. Section 203 may prohibit large stockholders, in particular those owning 15 percent or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter and bylaws and under Delaware law could reduce the price that investors would be willing to pay for shares of our common stock. Our officers, directors and principal stockholders, acting as a group, could significantly influence corporate actions. As of February ~~6~~ **18** , ~~2024~~ **2025** , our officers and directors beneficially owned approximately ~~20~~ **21** percent of our common stock. Acting together, these stockholders could significantly influence any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling stockholders. We **face unprecedented political, legal, governmental, regulatory and economic uncertainty and risks that may adversely affect our business. Steps taken by the presidential administration in the United States** have ~~in~~ **caused great uncertainty regarding** the **continuity** ~~past and may in the future be subject to short selling strategies that may drive down the market price~~ of **government funding, policies** ~~our common stock. Short sellers have in the past~~ and **operations** ~~may attempt in the future to drive down the market price of our common stock. Short selling is the practice of selling securities that the seller does not own but may have borrowed with the intention of buying identical securities back at a later date~~ . The **scope** ~~short seller hopes to profit from a decline in the value of the securities between the time the securities are borrowed~~ and ~~the time~~ **direction of** ~~they~~ -- **the administration** ~~are replaced. As it is in the short seller~~ ' s ~~best interests~~ **policies and their implementation are unpredictable. New policies may be adopted or actions taken, without notice, that adversely affect our commercial efforts or make it more challenging or costly to develop our product candidates. Significant cuts or disruptions to government employment and spending may delay review of our NDA** for **relacorilant** ~~the price of the stock to decline, many short sellers (sometime known~~ as **a treatment** ~~" disclosed shorts ") publish, or arrange~~ for **patients with hypercortisolism or constrain our ability to advance our** ~~the~~ **other clinical development programs** ~~publication of, negative opinions regarding the relevant issuer~~ and ~~its~~ **the development programs of our academic collaborators. The imposition of tariffs such as the administration has threatened to impose on materials we or our vendors use to conduct experiments or to make our Products or product candidates would increase our cost of doing** business ~~prospects to create negative market momentum . Although traditionally~~ **Additionally ,** ~~these~~ -- **the** ~~disclosed shorts were limited in~~ **laws and regulations governing our operations, as well as** ~~their~~ -- **the** ~~ability~~ **application of such laws and regulations, may change abruptly. Failure** to ~~access mainstream~~ **comply with new laws or regulations, whether by us or by our vendors, as well as changes in the application of existing laws and regulations, could adversely affect our operations, cash flow and financial condition or otherwise harm our** business ~~media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by weblog (" blogging ") have allowed many disclosed shorts to publicly attack a company' s credibility, strategy and veracity by means of so- called " research reports " that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts . These short attacks have, in the past, led to selling of shares in the market. Further, these short seller publications are not regulated by any governmental, self- regulatory organization or other official authority in the U. S. and they are not subject to certification requirements imposed by the SEC. Accordingly, the opinions they express may be based on distortions, omissions or fabrications. Companies that are subject to unfavorable allegations, even if untrue, may have to expend~~

~~a significant amount of resources to investigate such allegations and / or defend themselves, including shareholder suits against the company that may be prompted by such allegations. We may in the future be the subject of shareholder suits that we believe were prompted by allegations made by short sellers.~~