Risk Factors Comparison 2024-03-06 to 2023-03-08 Form: 10-K

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Investing in our common stock involves a high degree of risk. Careful consideration should be given to the following risk factors, in evaluating us and our business. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized and described below are not intended to be exhaustive and are not the only risks facing us. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations. Risks Related to our Financial Position and Need for Financing Risks Related to Our Operating History As a company, we have a limited operating history and limited experience commercializing pharmaceutical products and have incurred significant losses since inception ~~. We expect to incur losses over the next few years and may not be able to achieve or sustain revenues or profitability in the future~~ . Historically, we have funded our operations primarily through private placements of convertible preferred stock, public offerings of common stock and convertible notes, and debt issuances. We have five pharmaceutical products that were commercially launched in the past six years, i. e., Keveyis (2017), Gvoke PFS (2019), Gvoke HypoPen (2020), Recorlev (2022) and Gvoke Kit (2022). We are in the early stages of commercializing our biopharmaceutical products and have a limited operating history. ~~Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies prior to and at the early stages of commercialization of any product candidates, especially biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to successfully execute our commercialization strategy and may not be successful in doing so. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.~~ We have incurred significant losses in every fiscal year since inception. For the years ended December 31, **2023,** 2022 and 2021, we reported a net loss of **$ 62. 3 million,** $ 94. 7 million and $ 122. 7 million, respectively. In addition, our accumulated deficit as of December 31, ~~2022~~ **2023** was $ ~~554~~ **617** . ~~8~~ **0** million. We expect to continue to incur significant operating expenses as we continue the commercialization of Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ , develop, enhance and commercialize new products, and incur additional operational and reporting costs associated with being a public company. In particular, we anticipate that we will continue to incur significant expenses as we: < execute our Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ commercial strategies in the United States; < continue our research and development efforts; < seek regulatory approval for new product candidates and product enhancements; and < continue to operate as a public company. **Biopharmaceutical product development** ~~Our ability to generate revenue to transition to profitability and generate positive cash flows~~ is **a highly speculative undertaking and involves a substantial degree of risk. Accordingly, you should consider our prospects in light of the costs,** ~~uncertain~~ **uncertainties , delays** and ~~depends on~~ **difficulties frequently encountered by companies prior to and at** the ~~successful~~ **early stages of** commercialization of ~~Gvoke, Keveyis and Recorlev and~~ any ~~of our~~ product candidates **, especially biopharmaceutical companies such as** ~~for which we obtain marketing approval. Many of our~~ **ours** ~~product candidates are still in development~~ . **Any predictions you make about** ~~Successful development and commercialization will require achievement of key milestones, including completing clinical trials and obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of~~ our future **success** ~~collaborators, may obtain marketing approval, satisfying any post- marketing requirements and obtaining reimbursement for~~ - **or viability** ~~our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are sufficient enough for us to achieve profitability. Even if we do achieve profitability, we~~ may not be ~~able to sustain~~ **as accurate as they could be if we had a longer operating history or a history of successfully commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving** ~~or~~ **our** ~~increase profitability on~~ **business objectives. We will need to successfully execute our commercialization strategy and may not be successful in doing so. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to** a **variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any** quarterly or annual **periods** ~~basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses~~ as **indications of future operating performance** ~~we have in the past, investors may not receive any return on their investment and may lose their entire investment~~ . We may never be profitable **or be able to sustain revenues or, if achieved, sustain profitability in the future** and we may not be able to continue operations without additional fundings. Our ability to generate revenue from Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ , and our product candidates, if successfully developed and approved, depends on a number of factors, including, but not limited to, our ability to: < obtain commercial quantities of our products at acceptable cost levels; < successfully manage

inventory; < sell and distribute our products on terms acceptable to us; < achieve an adequate level of market acceptance of our products in the medical community and with third- party payors, including placement in accepted clinical guidelines for the conditions for which our product candidates are intended to target; < obtain and maintain third- party coverage and adequate reimbursement for our products; **< compete effectively against our competitors;** and < launch and commercialize our products utilizing our own sales force or by entering into partnership or co- promotion arrangements with third parties. We have incurred and expect to continue to incur significant sales and marketing costs as we commercialize Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ . Regardless of these expenditures, our products and our product candidates, if developed and approved, may not be commercially successful. Although we generate revenue from Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ , if we are unable to generate sufficient product revenue, we will not become profitable **. Our failure** ~~and may be unable~~ to **become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or** continue **our** operations ~~without additional funding~~ **. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment** . Risks Related to Future Financial Condition We may require additional capital to sustain our business, and this capital may cause dilution to our stockholders and might not be available on terms favorable to us, or at all, which ~~would~~ **could** force us to delay, reduce or eliminate our product development programs or commercialization efforts. Biopharmaceutical development is a time consuming, expensive and uncertain process that takes years to complete. We are incurring significant commercialization expenses related to product sales, marketing, manufacturing, packaging and distribution of Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ and expect to continue to incur such expenses for our products, as well as for any of our product candidates, if approved. We expect to require additional capital to complete the clinical trials associated with our product candidates and begin commercialization efforts, if approved. Accordingly, we may need additional funding in connection with our continuing operations. In the future, if we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs and / or sales and marketing activities. Market volatility **, including due to** ~~resulting from the ongoing COVID- 19 pandemic and~~ geopolitical instability ~~resulting from the ongoing military conflict between Russia and Ukraine~~ , rising interest rates, **fluctuations in inflation rates,** the tightening of lending standards **, any further deterioration in the macroeconomic economy or financial services industry resulting from actual or potential bank failures,** or other factors could also **materially and** adversely impact our ability to access capital as and when needed and increase our cost of capital even if available. We may be required to or choose to obtain further funding through public equity offerings, debt financings, royalty- based financing arrangements, collaborations and licensing arrangements or other sources. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing obtained by us would be senior to our common stock, would likely cause us to incur **significant** interest expense **or other costs** , and could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may increase our expenses and make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions and in- licensing opportunities. Under our existing credit facility dated March 8, 2022, ~~with the lenders from time to time parties thereto (the" Lenders"), Hayfin Services LLP, as administrative agent for the Lenders, Xeris Pharmaceuticals, Inc. and Xeris Biopharma Holdings, Inc.,~~ as amended ~~by Amendment No. 1 to Credit Agreement and Guaranty dated September 29, 2022 and Amendment No. 2 to Credit Agreement and Guaranty dated January 19, 2023~~ (the" Hayfin Loan Agreement") **, with the lenders from time to time parties thereto (the" Lenders"), Hayfin Services LLP, as administrative agent for the Lenders, Xeris Pharmaceuticals, Inc., Xeris Biopharma Holdings, Inc. and our subsidiaries party thereto** , we are restricted in our ability to incur additional indebtedness and to pay dividends. Any additional debt financing that we may secure in the future could include similar or more restrictive covenants relating to our capital raising activities, buying or selling assets and other financial and operational matters, which may make it more difficult for us to obtain additional capital, manage our business and pursue business opportunities. We may also be required to secure any such debt obligations with some or all of our assets. For example, our Hayfin Loan Agreement is secured by substantially all of our property and assets, including our intellectual property assets, subject to certain exceptions. If we raise additional funds through collaborations or marketing, distribution or licensing, or royalty- based financing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. Securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect our management' s ability to oversee the commercialization of our products and development and commercialization, if approved, of our product candidates. It is also possible that we may allocate significant amounts of capital toward solutions or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. Any of these negative developments could have a material adverse effect on our business, operating results, financial condition and common stock price. We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due, or to repurchase our Convertible Notes for cash following a fundamental change, if required, and our existing and future indebtedness may limit our ability to repurchase the Convertible Notes. On June 30, 2020, we completed a public offering of $ 86. 3 million aggregate principal amount of our 5. 00 % Convertible Senior Notes due 2025 (the" **2025** Convertible Notes"), including $ 11. 3 million pursuant to the underwriters' option to purchase additional notes which was exercised in July 2020. A total principal amount of $ 39. 1 million of Convertible Notes converted into equity in the second half of 2020. **On September 29, 2023, we completed the exchange of $ 31, 975, 000 in aggregate principal amount of the 2025 Convertible Notes for $ 33, 574, 000 in aggregate principal amount of new 8. 00 % Convertible Senior Notes due 2028 (the" 2028 Convertible Notes" and together with the 2025 Convertible Notes, the" Convertible Notes").** As of December 31, ~~2022~~ **2023** , the outstanding balance of **the 2025**

Convertible Notes was $ ~~47~~ **15** . 2 million **and the outstanding balance of the 2028 Convertible Notes was $ 33. 6 million** . The **2025** Convertible Notes are governed by the terms of a base indenture for senior debt securities dated June 30, 2020 (the" **2025** Base Indenture"), as supplemented by the first supplemental indenture thereto dated June 30, 2020 and the second supplemental indenture thereto dated October 5, 2021 (**collectively, the** " ~~the~~ **2025** Supplemental Indentures" and together with the **2025** Base Indenture, the" **2025** Indenture"), each between us and ~~United States~~ **U. S. Bank Trust Company, National Association (f / k / a U. S.** Bank National Association **) (" U. S. Bank"), as trustee. The 2028 Convertible Notes are governed by the terms of an indenture for senior debt securities dated September 29, 2023 (the" 2028 Indenture" and together with the 2025 Indenture, the" Indentures") between us and U. S. Bank** , as trustee. Failure to satisfy our current and future debt obligations under the ~~Indenture~~ **Indentures** could result in an event of default and, as a result, all of the amounts outstanding could immediately become due and payable. In the event of an acceleration of amounts due under the ~~Indenture~~ **Indentures** as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. Noteholders may require us to repurchase their Convertible Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change includes certain acquisition transactions and the failure of our common stock to be listed on the Nasdaq Global Select Market or certain similar national securities exchanges. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Convertible Notes. In addition, applicable law, regulatory authorities and the agreements governing our existing and future indebtedness may restrict our ability to repurchase the Convertible Notes. Our failure to repurchase the Convertible Notes when required will constitute a default under the ~~Indenture~~ **Indentures** that ~~governs~~ **govern** the Convertible Notes. A default under the ~~Indenture~~ **Indentures** or the fundamental change itself could also lead to a default under agreements governing our other existing or future indebtedness, which may result in that other indebtedness becoming immediately payable in full. For instance, a fundamental change without lender consent would constitute an event of default under our Hayfin Loan Agreement. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Convertible Notes. In addition, we have $ 150. 0 million **of term loans** outstanding under our Hayfin Loan Agreement as of December 31, ~~2022~~ **2023** . All obligations under our Hayfin Loan Agreement are secured by substantially all of our property and assets, including our intellectual property assets, subject to certain limited exceptions. The term loans and the Convertible Notes may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. Failure to satisfy our current and future debt obligations under our Hayfin Loan Agreement could result in an event of default **thereunder** and, as a result, our lenders could accelerate all amounts due. Events of default also include our failure to comply with customary affirmative and negative covenants as well as a default under any indenture or other agreement governing convertible indebtedness permitted by the Hayfin Loan Agreement, including the ~~Indenture~~ **Indentures** . The Hayfin Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict our ability to incur additional indebtedness, grant liens, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. In the event of an acceleration of amounts due under our Hayfin Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness. Our PPP Loan, which we repaid in full in June 2020, was subject to the terms and conditions applicable to loans administered by the SBA under the CARES Act, and we may be subject to an audit or enforcement action related to the PPP Loan. On April 21, 2020, we entered into the United States Small Business Administration (the" SBA") PPP Note (the" Note") with Silicon Valley Bank (the" PPP Lender") for a loan in the amount of $ 5. 1 million (the" PPP Loan") enabled by the Coronavirus Aid, Relief and Economic Security Act of 2020 (the" CARES Act"). We received the full amount of the PPP Loan on April 22, 2020. On May 4, 2020, we repaid $ 0. 9 million of the PPP Loan. In June 2020, we repaid the remaining amount outstanding under the PPP Loan in connection with the concurrent **2025** Convertible Notes and equity offerings. We may be subject to CARES Act- specific lookbacks and audits until May of 2026 that may be conducted by other federal agencies, including several oversight bodies created under the CARES Act. These bodies have the ability to coordinate investigations and audits and refer matters to the Department of Justice for civil or criminal enforcement and other actions. Complying with such SBA audit could divert management resources and attention and require us to expend significant time and resources, which could have an adverse effect on our business, financial condition and results of operations. Greater than expected product returns may exceed our reserve for returns. We use various factors to estimate the provision for returns, including the launch date of products, historical customer return rates, third- party industry data for comparable products in the market and estimated channel inventory data. In a reporting period, we may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels, inventory dating, prescription data, the expiration dates of product, price changes of competitive products and introductions of generic products. Any significant increase in returns that exceeds our reserves could adversely affect our revenue and operating results. We use data from third parties as part of our return reserves calculation. We are reliant on these third parties to ensure that the data they provide is accurate. Inaccurate data could cause us to estimate our return reserves incorrectly and could have an adverse impact on our results of operations and financial condition. Risks Related to the Commercialization and Marketing of our Products and Product Candidates Risks Related to Commercialization and Marketing Our business depends entirely on the commercial success of our products and product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed. To date, we have expended significant time, resources **,** and effort on the development of our product candidates, and a substantial portion of our resources recently has been and will continue to be focused on ~~launching,~~ marketing and commercializing our approved products, Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ ,

in the United States. Our business and future success are substantially dependent on our ability to generate and increase product revenue in the near term. Our estimates of the potential market opportunity for Gvoke, **Recorlev,** Keveyis, ~~Recorlev~~ and our product candidates include several key assumptions of the current market size and current pricing for commercially available products and are based on industry and market data obtained from industry publications, studies conducted by us, our industry knowledge, third- party research reports and other surveys. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, the actual market for our product and product candidates could be smaller than our estimates of our potential market opportunity. Our product candidates are in various stages of development and subject to the risks of failure inherent in developing drug products. Any delay or setback in the regulatory approval, product launch, commercialization or distribution of any of our product candidates will adversely affect our business. The infrastructure, systems, processes, policies, relationships and materials we have built for the commercialization of Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ may not be sufficient for us to achieve success at the levels we expect. Further, our products may contain undetected manufacturing defects, including mislabeling, which might require product replacement, re- labeling or product recalls, which could further harm our business. For more information, see the section entitled," Business — Coverage and Reimbursement". Even if all regulatory approvals are obtained, the commercial success of our products and product candidates will depend on gaining **and maintaining** market acceptance among physicians, patients, patient advocacy groups, healthcare payors and the medical community. The degree of market acceptance of our products and product candidates will depend on many factors, including **whether our products and product candidates are** : < ~~the scope of regulatory approvals, including limitations or warnings contained in~~ a **covered benefit under health plans** ~~product' s regulatory- approved labeling~~ ; < **safe** ~~our ability to produce~~ , **effective and medically necessary** ~~through a validated process, sufficiently large quantities of our products to permit successful commercialization~~ ; < **appropriate for the specific patient** ~~our ability to establish and maintain commercial manufacturing arrangements with third- party manufacturers~~ ; < ~~our ability to build and maintain sales, distribution and marketing capabilities sufficient to launch commercial sales of our products; < the acceptance in the medical community of the potential advantages of the products, including with respect to our efforts to increase adoption of our products by patients and healthcare providers; < the incidence, prevalence and severity of adverse side effects of our products; < the willingness of physicians to prescribe our products and of the target patient population to try these therapies; < the price and~~ cost- ~~effectiveness~~ ---- **effective** ~~of our products~~ ; **and** < **neither experimental** ~~the availability of sufficient third- party coverage and reimbursement, including the extent to which each product is approved for use at, or~~ **nor investigational** ~~included on formularies of, hospitals and managed care organizations; < any negative publicity related to our or our competitors' products or other formulations of products that we administer, including as a result of any related adverse side effects; < alternative treatment methods and potentially competitive products; < the potential advantages of our products over existing and future treatment methods; and < the strength of our sales, marketing and distribution support~~ . Additionally, if, after obtaining marketing approval of any of our products or product candidates, we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including: < regulatory authorities may withdraw approvals of such product, require us to take our approved product off the market or ask us to voluntarily remove the product from the market; < regulatory authorities may require the addition of labeling statements, specific warnings, contraindications or the issuance of field alerts to physicians and pharmacies; < regulatory authorities may impose conditions under a risk evaluation and mitigation strategy (" REMS") including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions; < we may be required to change the way a product is administered, conduct additional clinical trials or change the labeling of the product; < we may be subject to limitations on how we may promote the product; < sales of the product may decrease significantly; < we may be subject to litigation or products liability claims; and < our reputation may suffer. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, patients and third- party payors, we may never generate significant revenue from these product candidates, and our business, financial condition and results of operations may be materially harmed. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new therapeutics are introduced that are more favorably received than our products or that render our products obsolete, or if significant adverse events occur. If our products do not achieve and maintain market acceptance, we will not be able to generate sufficient revenue from product sales to attain profitability. We operate in a competitive business environment **, which may have** ~~and~~ **an** ~~,~~ **if adverse impact on our revenue. If** we are unable to compete successfully against our existing or ~~potential~~ **future** competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our products or product candidates, even if approved. The pharmaceutical and biotechnology industries are characterized by intense competition and significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Any product candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future. While we believe that our product and product candidate platform, development expertise and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Many of our current and potential competitors are major pharmaceutical companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. Our ability to compete successfully will depend on our ability to develop future products that reach the market in a timely manner, are well adopted by patients and healthcare providers and receive adequate coverage and reimbursement from third- party payors. **Competitors may also develop and patent processes or products earlier than we can or obtain regulatory clearance or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes, or products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products or product**

candidates, if approved, could be negatively affected and our results of operations could suffer. Because of the size of the potential market **for certain of our products and product candidates** , we anticipate that companies will dedicate significant resources to developing products competitive to ~~our~~ **such products and** product candidates. For example, Gvoke has numerous competitors in the severe hypoglycemia market, which currently include **Amphastar** ~~Eli Lilly~~ ' s Baqsimi, an intranasal glucagon dry powder ~~, Eli Lilly' s GEK~~ , Zealand Pharma' s Zegalogue, a dasiglucagon outlicensed to Novo Nordisk, Novo Nordisk' s GlucaGen HypoKit ~~and ,~~ Fresenius Kabi' s glucagon emergency kit for low blood sugar ~~.~~ **, and** Amphastar ~~'~~ **'** s ~~ANDA for~~ generic Glucagon for Injection Emergency Kit ~~was approved by the FDA on December 29, 2020 for the treatment of severe hypoglycemia~~ . At any time, these or other industry participants may develop alternative treatments, products **,** or procedures for the treatment of severe hypoglycemia that compete directly or indirectly with Gvoke. ~~Competitors may also develop and patent processes or products earlier than we can or obtain regulatory clearance or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products or product candidates, if approved, could be negatively affected and our results of operations could suffer. The widespread acceptance of currently available therapies with which our products and product candidates compete or will compete may limit market acceptance of Gvoke or our product candidates even if approved and commercialized. For example, traditional glucagon kits currently available for hypoglycemia are widely accepted in the medical community and have a long history of use. These treatments compete with Gvoke and may limit the potential for Gvoke to receive widespread acceptance. In addition,~~ Keveyis **(dichlorphenamide)** is an oral carbonic anhydrase inhibitor ~~,~~ that was approved in the United States to treat hyperkalemic, hypokalemic **,** and related variants of PPP **for which orphan drug exclusivity ended on August 7, 2022** . Torrent Pharmaceuticals Limited' s ANDA for generic dichlorphenamide was approved on December 29, 2022 and ~~will~~ **now** ~~compete~~ **competes** with Keveyis **, which may adversely impact our revenue** . In addition, due to the end of orphan drug exclusivity, **we expect that** additional generic ~~competition~~ **competitors could emerge which** may ~~compete with~~ **also contribute to the erosion of** Keveyis ~~and~~ sales ~~of Keveyis could be negatively affected and our results of operations could suffer~~ . Acetazolamide, another oral carbonic anhydrase inhibitor, is used frequently off- label for the prophylactic and sometimes acute treatment of PPP. Potassium supplements are indicated for use in hypokalemic periodic paralysis in the United States and are frequently used either chronically or for emergency treatment of episodes in that form of PPP. Several other types of drugs have been reported to have benefits for chronic or acute use in one or more than one PPP variant, including potassium- sparing diuretics, beta receptor agonists, mexelitine and other sodium channel blockers, and others. We are not aware of drugs currently in development for prophylactic chronic treatment of PPP. We are **also** currently aware of various companies that are marketing existing drugs that may compete with Recorlev **,** such as Corcept Therapeutics and Recordati. The treatment of endogenous Cushing' s syndrome patients who fail or are ineligible for surgery in the United States and Europe are: Korlym (mifepristone) marketed by Corcept Therapeutics in the United States; Signifor LAR (pasireotide) and Isturisa (osilodrostat), both marketed by Recordati in the United States and EU; and ketoconazole, metyrapone and mitotane marketed by HRA in the EU. Corcept is developing relacorilant, a second- generation glucocorticoid receptor modulator; currently in Phase 3. Ketoconazole is used off- label for treatment of Cushing' s syndrome in the United States. Regulatory approval of ketoconazole for the treatment of endogenous Cushing' s syndrome in the United States, which is not currently being sought by any sponsor to our knowledge, could significantly increase competition for Recorlev due to the similar mechanisms of action between the drug products. If we are unable to establish or do not maintain sufficient marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our products on terms acceptable to us, we may not be able to generate product revenue and our business, results of operations, and financial condition will be materially adversely affected. We have developed our commercial infrastructure for the sales, marketing and distribution of Gvoke, **Recorlev and** Keveyis ~~, and Recorlev~~ . In order to successfully commercialize our product candidates, we will need to maintain and may need to expand our marketing, sales, distribution, managerial and other non- technical capabilities and / or make arrangements with third parties to perform some or all of these services. We have established our sales force to market our products in the United States. In order to maintain **and, if needed, expand** our sales force, we will compete with other companies to recruit, hire, train and retain sales and marketing personnel. There are significant expenses and risks involved with maintaining **and, if needed, expanding,** our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, obtain access to an adequate number of physicians and persuade them to prescribe our products and any product candidates that receive regulatory approval, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in our ability to maintain or expand, if needed, our internal sales, marketing and distribution capabilities would adversely impact the commercialization of Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ and the launch and commercialization of our product candidates, if approved. Even if we are able to recruit, hire and retain a sufficient number of sales representatives, they may not be effective at promoting our products ~~. For example, as a result of the COVID- 19 pandemic, from time to time we have had to limit in- person interactions and engage with many healthcare professionals remotely, which may be less effective~~ . We intend to leverage the sales and marketing capabilities that we have established for our approved products to commercialize additional product candidates for the management of other conditions, if approved by the FDA, in the United States. If we are unable to do so for any reason, we would need to expend additional resources to establish commercialization capabilities for those product candidates, if approved. In the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of our product candidates could be delayed which would negatively impact our ability to generate product revenue. In addition, we intend to continue to establish collaborations to commercialize our product candidates outside the United States, if approved by the relevant regulatory authorities. Therefore, our future success **outside the United States** will depend, in part, on our ability to enter into and maintain collaborative relationships ~~for such efforts~~ , the

collaborator' s strategic interest in the product and such collaborator' s ability to successfully market and sell the product. We may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, such collaborators may not have effective sales forces ~~. To~~ **or exert** the ~~extent~~ **level of effort** that we **would if we were** ~~depend on third parties for~~ marketing and **selling** ~~distribution, any revenues we receive will depend upon~~ the **product ourselves** ~~efforts of such third parties, and such efforts may not be successful~~. Risks Related to Third- Parties Actions and Market Acceptance Our reliance on third- party suppliers, including single- source suppliers, ~~and~~ **together with** a limited number of ~~options~~ **possible suppliers and long development lead- times** for alternate sources for Gvoke, **Recorlev and** Keveyis ~~, and Recorlev~~ or our product candidates could harm our ability to develop our product candidates or to continue to commercialize Gvoke, **Recorlev,** Keveyis, ~~Recorlev~~ or any product candidates that are approved. We do not currently own or operate any manufacturing facilities for the production of Gvoke, **Recorlev, or** Keveyis ~~or Recorlev~~ for commercial supply or our product candidates for use in clinical trials. We rely on third- party suppliers to manufacture and supply our products and our product candidates. For Gvoke, we currently rely on a number of single- source suppliers, such as Bachem Americas, Inc. **and certain of its affiliates** (" Bachem") for active pharmaceutical ingredient (" API"), Pyramid Laboratories Inc. (" Pyramid") for drug product and SHL Pharma, LLC (" SHL Pharma") for auto- injector and final product assembly, and we have entered into several supply agreements including with Bachem, Pyramid and SHL Pharma. Taro produces all of our requirements for Keveyis pursuant to a supply agreement. If the agreement were to be terminated by Taro prior to the next renewal **in March of 2027**, we will need to find a new third party to manufacture Keveyis or manufacture the product ourselves. Similarly **,** for Recorlev, we rely on a number of single- source suppliers, such as Regis Technologies, Inc. for API and Xcelience, LLC (" Lonza") for finished drug product. We rely on other third parties to manufacture our product candidates for use in clinical trials. If any of these vendors ~~is~~ **are** unable or unwilling to meet our future requirements, we may not be able to manufacture and / or supply our products in a timely manner. Our current arrangements with these manufacturers are terminable by such manufacturers, subject to certain notice provisions. In addition, Taro maintains certain reversion rights in the purchased assets, including the regulatory approval for Keveyis, enabling Taro to elect to have **the** ~~purchases~~ **purchased** assets returned to it and to terminate its agreement with us should we be materially in non- compliance with any reversion condition such as breaching certain of the assignment restrictions or failing to meet our marketing commitments ~~for Keveyis~~ after receiving notice thereof and failing to cure such material non- compliance. Our third- party suppliers may not be able to produce sufficient inventory to meet commercial demand in a timely manner, or at all, and we ~~are~~ **continue to** ~~experiencing~~ **experience** ~~significantly longer~~ -- **long** lead times for certain components and materials used in the production of our products and product candidates. Our third- party suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our products. As a result, we may not obtain sufficient quantities of products, components or other key materials in the future, which could have a material adverse effect on our business as a whole ~~. For example, the COVID- 19 pandemic and the resulting impacts to global supply chains could continue to impact our and our suppliers' ability to procure sufficient supplies for the manufacture of our commercial products or our product candidates~~. Any disruption to the facilities or operations of our third- party suppliers resulting from weather- related events, epidemics, including ~~the~~ global health concerns ~~such as the COVID- 19 pandemic~~, fire, acts of terrorism, political instability **, war, labor or geopolitical issues,** or any other cause could materially impair our ability to manufacture our products and to distribute our products to customers. **We** ~~For example, we~~ have a global supply chain and manufacture some components of our products outside the United States, including without limitation, Taiwan **and Israel. The current war between Israel and Hamas could directly and indirectly affect our operations. For example, the Israel- Hamas war could result in damage, destruction or disruptions to the facilities or operations of our third- party suppliers, including, but not limited to, our supplier of Keveyis, longer lead times for ours products or product candidates, export delays or restrictions or other adverse events which adverse events we cannot predict with any certainty**. Any interruption or other delay in the production or delivery of our supplies could reduce sales of our products and increase our costs and any negative impact of such matters on our third- party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition. Gvoke and some of our product candidates are drug- device combination products that are regulated under the drug regulations of the **Federal Food, Drug, & Cosmetic Act ("** FDCA **")** based on their primary mode of action as a drug. Third- party manufacturers may **fail** ~~not be able~~ to comply with the current Good Manufacturing Practice (" CGMP") regulatory requirements applicable to drug- device combination products, including applicable provisions of the FDA' s drug CGMP regulations, device CGMP requirements embodied in the Quality System ~~Regulations~~ **Regulation** (**the** " ~~QSRs~~ **QSR** ") or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our products and product candidates, re- labeling or re- packaging of our products, operating restrictions and criminal prosecutions, any of which could significantly affect the supply of our products and product candidates. The facilities used by our contract manufacturers to manufacture our products and product candidates must be registered with the FDA and are subject to inspections conducted by the FDA to ensure compliance with CGMPs. ~~The FDA and other~~ **Other** foreign regulatory authorities **may also** require manufacturers to register manufacturing facilities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with CGMPs and **the** ~~QSRs~~ **QSR**. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or **circumstances** ~~a situation~~ where the contractor may not be able to maintain compliance with the applicable CGMP or **the** QSR ~~requirements~~. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications, CGMP and / or **the** ~~QSRs~~ **QSR** and the strict regulatory requirements of the FDA or others, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA

or such foreign regulatory authorities do not approve these facilities for the manufacture of our products or product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to market our products or develop, obtain regulatory approval for or market our product candidates, if approved. There are a limited number of third- party suppliers that are compliant with CGMP and / or **the** ~~QSRs~~ **QSR** , as required by the FDA, the EU, and other regulatory authorities, and that also have the necessary expertise and capacity to manufacture our materials and products. As a result, it may be difficult for us to locate third- party suppliers for our anticipated future needs, and our anticipated growth could strain the ability of our current third- party suppliers to deliver products, raw materials **,** and components to us. If we are unable to arrange for third- party suppliers for our materials and products, or to do so on commercially reasonable terms, we may not be able to complete development of or market our products. The introduction of new CGMP or QSR regulations or product specific requirements by a regulatory body may require that we source alternative materials, modify existing manufacturing processes **,** or implement design changes to our products that are subject to prior approval by the FDA or other regulatory authorities. We may also be required to reassess a third- party supplier' s compliance with all applicable new regulations and guidelines, which could further impede our ability to manufacture and supply products in a timely manner. As a result, we could incur increased production costs, experience supply interruptions, suffer damage to our reputation and experience an adverse effect on our business and financial results. **On February 23, 2022, the FDA proposed to amend its Quality System Regulation (" QSR ") requirements to align more closely with the international consensus standards for medical devices. Specifically, the FDA proposed to do so primarily by incorporating by reference the 2016 edition of the International Organization of Standardization (" ISO "), ISO 13485 standard. We do not have certainty on when or if the proposed rule will be finalized or even if it is finalized, whether it will be finalized in its current proposed form. While the ISO 13485 standard and the FDA' s QSR requirements are similar in certain aspects, it is possible that we may need to revise our compliance system and processes to be in line with the requirements established by any final rule to amend the QSR requirements.** In addition, our reliance on third- party suppliers involves a number of additional risks, including, among other things: < our suppliers may fail to comply with regulatory requirements or make errors in manufacturing raw materials, components or products that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products; < we may be subject to price fluctuations due to terms within long- term supply arrangements with suppliers or lack of long- term supply arrangements for key materials and products; < given the long lead times to change suppliers, existing suppliers may utilize that as leverage in negotiations with us in a manner that is adverse to our business; < our suppliers may lose access to critical services or sustain damage to a facility, including losses due to natural disasters, **accidents, terrorism,** geo- political events, or epidemics that may result in a sustained interruption in the manufacture and supply of our products; < fluctuations in demand for our products or a supplier' s demand from other customers may affect their ability or willingness to deliver materials or products in a timely manner or may lead to long- term capacity constraints at the supplier; < we may not be able to find new or alternative sources or reconfigure our products and manufacturing processes in a timely manner if necessary raw materials or components become unavailable; < our suppliers may encounter financial or other hardships unrelated to our demand for materials, products and services, which could inhibit their ability to fulfill our orders and meet our requirements; and < the possibility of breach or termination of a manufacturing agreement or purchase order by the third party. In addition, we could be forced to secure new materials or develop alternative third- party suppliers, which can be difficult given our product complexity, long development lead- times and global regulatory review processes. If any CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our products or product candidates **which license we may not be able to obtain on favorable terms or at all** . In addition, in the case of the CMOs that supply our products or product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Additionally, under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted. Reimbursement decisions by third- party payors and consolidation within the healthcare industry and among competitors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used and pricing pressure may impact our ability to sell our products at prices necessary to support our current business strategies. Our future revenues and profitability will be adversely affected if the United States and foreign governmental, private third- party insurers and payors and other third- party payors,

including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products on behalf of patients. If these entities do not provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for some patients to afford and physicians may not prescribe them. In addition, limitations on the amount of reimbursement for our products may also reduce our profitability. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. There have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any of our products or product candidates for which we obtain marketing approval. As the healthcare industry consolidates, competition to provide products and services to industry participants has become more intense and may intensify as the potential purchasers of our products or third- party payors use their purchasing power to exert competitive pricing pressure and other terms favorable to them. We expect that market demand, government regulation, third- party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our potential purchasers. If competitive **or other** forces drive down the prices we are able to charge for our products, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business. For more information, see the sections entitled," Business — Coverage and Reimbursement" and" Business — Healthcare Reform". Government and other third- party payors are also challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree ~~. Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost- effective; and (v) neither experimental nor investigational~~ . New requirements by third- party payors include: (i) net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States ~~;~~ and (ii) third- party payors are increasingly requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement; and many pharmaceutical manufacturers must calculate and report certain price metrics to the government, such as average manufacturer price, or AMP, and Best Price. Penalties may apply when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could negatively 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 and / or expanding access to healthcare. 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 to experience pricing pressures in connection with the sale of our products that we develop due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, these factors may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our products and our product candidates. Some patients may require health insurance coverage to afford our products or product candidates, and if we are unable to obtain adequate coverage and reimbursement by third- party payors, our ability to successfully commercialize our products or product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price, including through increased discounting, of our products will have a material adverse effect on our ability to achieve profitability. The success of Gvoke, **Recorlev,** Keveyis ~~, Recorlev~~ and our ~~other~~ product candidates will be dependent on ~~its~~ **their** proper use by patients, healthcare practitioners and caregivers. Additionally, individual devices may fail. We have designed our products to be operable by patients, caregivers **,** and healthcare practitioners. We cannot control the successful use of the product by patients, caregivers **,** and healthcare practitioners. If we are not successful in promoting the proper use of our products by patients, healthcare practitioners **,** and caregivers, we may not be able to achieve market acceptance or effectively commercialize our products. In addition, even in the event of proper use of our products such as Gvoke, individual devices may fail. Increasing the scale of production inherently creates increased risk of manufacturing errors, and we may not be able to adequately inspect every tablet or device that is produced, and it is possible that individual product may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of any of our products, result in negative press coverage, or increase the risk that we may be sued **. A small number of major customers account for a high percentage of our revenue, thus, the loss of any of these customers and our inability to enter into new customer relationships could negatively impact our business. We depend**

on a relatively small number of customers for the majority of our revenue. As further discussed in" Note 2- Basis of presentation and summary of significant accounting policies and estimates" to our consolidated financial statements, for the years ended December 31, 2023, 2022 and 2021, four customers accounted for over 90 % of the Company' s gross product revenue. At December 31, 2023 and December 31, 2022, the same four customers accounted for over 90 % of the trade accounts receivable, net. We expect to continue to depend upon a relatively small number of customers for a high percentage of our revenue. If we lose any of these customers and are unable to establish new customer relationships of similar magnitude, our business, prospects, financial condition and results of operations could be materially and adversely affected. Additionally, if one or more of our major customers experiences financial difficulties, the adverse impact on us could be substantial . Risk Related to our Dependence on Third Parties for Clinical Trials We depend on third parties to conduct the clinical trials for our product candidates, and any failure of those parties to fulfill their obligations could harm our development and commercialization plans. We depend on independent clinical investigators, clinical research organizations (" CROs"), academic institutions and other third- party service providers to conduct clinical trials with and for our product candidates. Although we rely heavily on these parties for successful execution of our clinical trials, we are ultimately responsible for the results of their activities and many aspects of their activities are beyond our control. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, but the independent clinical investigators may prioritize other projects over ours or may fail to timely communicate issues regarding our products to us. Further, conducting clinical trials in foreign countries, as we have done and may do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. The delay or early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials, or our reliance on results of trials that we have not directly conducted or monitored could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition. We maintain compliance programs related to our clinical trials through our clinical operations and development personnel. Our clinical trial vendors are required to monitor and report to us issues with the conduct of our clinical trials, and we monitor our clinical trial vendors through our clinical, regulatory , and quality assurance staff and other service providers. Our clinical trial vendors or personnel may not timely and fully discover and report any fraud or abuse or other issues that may occur in connection with our clinical trials to us. Such fraud or abuse or other issues, if they occur and are not successfully remediated, could have a material adverse effect on our research, development, and commercialization activities and results ~~. Risk Related to the Impact of the COVID- 19 Pandemic Our business may continue to be adversely affected by the ongoing COVID- 19 pandemic. The COVID- 19 pandemic continues to affect many businesses, including ours. We may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including: < If restrictive measures to reduce the spread of the virus are reintroduced, our sales and marketing personnel' s access to customers may be adversely impacted. Remote interactions, if required, may be less effective than in- person interactions and could adversely impact demand for our products. < We currently rely on third- party suppliers and contract manufacturing organizations (" CMOs") for the manufacturing of Gvoke, Keveyis, and Recorlev, as well as to perform third- party logistics functions, including warehousing and distribution of Gvoke, Keveyis, and Recorlev. In addition, we rely on third parties to perform quality testing and supply other goods and services to run our business. Certain of our third party suppliers in our supply chain for materials have been adversely impacted by restrictions resulting from the COVID- 19 pandemic or supply chain issues, including staffing shortages, production slowdowns and disruptions in delivery systems, and may continue to be impacted such that our supply chain may be disrupted, limiting our ability to manufacture commercial quantities of our products. < Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID- 19 pandemic. The FDA and comparable foreign regulatory agencies had and may again have slower response times or be under- resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. Any elongation or deprioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. < The trading prices for our common shares have been volatile in the past few years. As a result, we may face difficulties raising further capital through sales of our common shares or convertible debt or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common shares. The COVID- 19 pandemic and its effects continue to impact our business. The ultimate impact of the COVID- 19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the emergence of new variants, the efficacy, acceptance and availability of vaccines in various geographies, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID- 19 and the actions taken to contain the coronavirus or address its impact in the short and long term, among others. We do not yet know the full extent of potential impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely~~ . Risks Related to the Product Development and Regulatory Approval of Our Product Candidates Risks Related to Regulatory Approval We cannot be certain that our product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our product candidates. We have devoted significant financial resources and business efforts to the development of our product candidates. We cannot be certain that any of our product candidates will receive marketing approval. The development of a product candidate and issues relating to its approval and marketing are

subject to extensive regulation by the FDA **and other regulatory authorities** in the United States and by comparable regulatory authorities in other countries. We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application (" NDA") or Biologics License Application (" BLA") from the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, **conditions for** approval ~~policies~~, regulations **, standards of care** , or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. NDAs and BLAs must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety and effectiveness for each desired indication. NDAs and BLAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. Any delay or setback in the regulatory approval or commercialization of any of our product candidates will adversely affect our business. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA: < could determine that we cannot rely on the Section 505 (b) (2) regulatory pathway or other pathways we have selected, as applicable, for our product candidates; < could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidates for any indication; < may not find the data from bioequivalence studies and / or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval ~~in the United States~~, including any findings that the clinical and other benefits of our product candidates **do not** outweigh their safety risks; < may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and / or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials; < may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505 (b) (2) application for any of our product candidates is blocked by patent or non- patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as any of our product candidates (as applicable); < may identify deficiencies in the manufacturing processes or facilities of third- party manufacturers with which we enter into agreements for the manufacturing of our product candidates; < may audit some or all of our clinical research and human factors study sites to determine the integrity of our data and may reject any or all of such data; < may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post- approval clinical trials **or implementation of a REMS** ; < may change its **criteria for** approval **,** policies or adopt new regulations; or < may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling **(e. g., boxed warnings)** or require expensive and time- consuming clinical trials and / or reporting as conditions of approval. Regulators ~~of~~ **in** other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn. Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates. If our clinical trials fail to demonstrate efficacy and safety to the satisfaction of the FDA or other regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product ~~candidate~~ **candidates** . We cannot be certain that existing clinical trial results will be sufficient to support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Moreover, success in clinical trials in a particular indication does not ensure that a product candidate will be successful in other indications. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials or successful later- stage trials in other related indications. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any of our product candidates. Any delay in, or termination of, our clinical trials will delay the submission of the applicable NDA or BLA to the FDA, the **Marketing Authorisation Application ("** MAA **")** to the **European Medicines Agency ("** EMA **")** or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate revenue. We intend to utilize the 505 (b) (2) pathway for the regulatory approval of certain of our product candidates. If the FDA does not conclude that such product candidates meet the requirements of Section 505 (b) (2), final marketing approval of our product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues. We are pursuing a regulatory pathway pursuant to Section 505 (b) (2) of the FDCA for the approval of certain of our product candidates, which allows us to rely on submissions of existing clinical data for the drug. Section 505 (b)

(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505 (b) (2) of the FDCA to permit the applicant to rely upon the FDA' s previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval. If the FDA determines that our product candidates do not meet the requirements of Section 505 (b) (2), we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. In March 2010, former President Obama signed into law legislation creating an abbreviated pathway for approval under the Public Health Service Act, or PHS Act, of biological products that are similar to other biological products that are approved under the PHS Act. The legislation also expanded the definition of biological product to include proteins such as insulin. The law contains transitional provisions governing protein products such as insulin, that, under certain circumstances, might permit companies to seek approval for their insulin products as biologics under the PHS Act. Specifically, on March 23, 2020, a small subset of ~~" "~~ biological products ~~" "~~ approved under the **FDCA** ~~Federal Food, Drug, and Cosmetic Act~~, such as insulin, which historically were approved as drugs, transitioned to being regulated as biological products. Being regulated as biological products enables transition products to serve as the reference product for biosimilar or interchangeable products approved through the abbreviated licensure pathway. The transition is a regulatory action in which the approved drug application for a transition biological product will be ~~" "~~ deemed ~~" "~~ to be a biologics license application ~~. Thus our XeriSol pramlintide- insulin co- formulation which would have previously been reviewed through a 505 (b) (2) NDA was instead required to be approved under the PHS Act~~. If our other product candidates do not meet the requirements of Section 505 (b) (2) or are otherwise ineligible or become ineligible for approval via the Section 505 (b) (2) pathway, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505 (b) (2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, our product candidates may not receive the requisite approvals for commercialization. Some pharmaceutical companies and other actors have objected to the FDA' s interpretation of Section 505 (b) (2) to allow reliance on the FDA' s prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505 (b) (2), or if the FDA' s interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505 (b) (2) application that we submit. Moreover, the FDA has adopted an interpretation of the three- year exclusivity provisions whereby a 505 (b) (2) application can be blocked by exclusivity even if it does not rely on the previously approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA' s interpretation, the approval of one or more of our product candidates may be blocked by exclusivity awarded to a previously- approved drug product that shares certain innovative features with our product candidates, even if our 505 (b) (2) application does not identify the previously- approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues. Additional time may be required to obtain regulatory approval for certain of our product candidates because they are combination products. Certain of our product candidates are drug and device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as ~~" "~~ combination products ~~" "~~ in the United States and Europe. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e. g., drug / device, device / biologic, drug / biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre- market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre- market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process and the lack of a well- established review process and criteria. The EMA has a parallel review process in place for combination products, the potential effects of which in terms of approval and timing could independently affect our ability to market our combination products in Europe. Gvoke, **Recorlev,** Keveyis ~~, Recorlev~~ and our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to include safety warnings, require them to be taken off the market or otherwise limit their sales. **Patients treated in** ~~Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt~~ clinical trials ~~and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The range and potential severity of possible side effects from systemic therapies are significant. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings. Recent developments in the pharmaceutical industry have prompted heightened government focus on safety reporting during both pre- and post- approval time periods and pharmacovigilance. Global health authorities may impose regulatory requirements to monitor safety that may burden our ability to commercialize our drug products. To date, patients treated~~ with our ready- to- use glucagon have experienced drug- related side effects typically

observed with glucagon products, including nausea, vomiting and headaches. In our clinical trials of Recorlev, the most common adverse reactions (incidence > 20 %) were nausea / vomiting, hypokalemia, hemorrhage / contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain / dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia / sleep disturbances, and peripheral edema. In the Keveyis clinical trial, the most common adverse reactions (incidence > 10 %) were paresthesia, cognitive disorder, dysgeusia, and confusional state. These adverse events can be dose- dependent and may increase in frequency and severity if we increase the dose to increase efficacy. ~~It is possible that there may be~~ **For our product candidates in development, undesirable** side effects ~~associated with~~ **that may be caused by** our product candidates ~~' use. In such an event, our trials~~ could ~~be suspended~~ **cause us** or ~~terminated and the FDA or comparable foreign~~ regulatory authorities ~~could order us~~ to **interrupt, delay** ~~cease further development of~~ or ~~deny~~ **halt clinical trials, and result in delay of, or failure to obtain, marketing** approval ~~of~~ **from the FDA and other regulatory authorities,** ~~our~~ **or** ~~product candidates~~ **result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings, and** for ~~any or~~ **our approved products, the emergence of new or more serious side effects may cause regulatory authorities to impose additional requirements on our marketing and monitoring of these products. The range and potential severity of possible side effects from systemic therapies are significant. Recent developments in the pharmaceutical industry have prompted heightened government focus on safety reporting during both pre- and post- approval time periods and pharmacovigilance. For example, at the request of the FDA we are conducting an enhanced pharmacovigilance program for** all ~~targeted indications~~ **cases of hepatotoxicity reported with patients taking Recorlev tablets, for a period of 5 years from the date of approval . Global health authorities may impose regulatory requirements to monitor safety that may burden our ability to commercialize our** ~~Drug~~ **drug products. In addition, drug** - related side effects of our product candidates could affect patient recruitment or the ability of enrolled patients to complete the trial or could also adversely affect physician or patient acceptance thereof. Any of these occurrences may harm our business, financial condition and prospects. Even if our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by ~~such~~ **one of our** products: < regulatory authorities may require the addition of labeling statements, including ~~“~~ **"** black box ~~”~~ **"** warnings, contraindications or dissemination of field alerts to physicians and pharmacies; < we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product; < we may be subject to limitations on how we may promote the product; < sales of the product may decrease significantly; < regulatory authorities may require us to take our approved product off the market; < we may be subject to litigation or products liability claims; and < our reputation may suffer. Any of these events could also prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products. We have received orphan drug designation for Keveyis, Recorlev and certain of our product candidates with respect to certain indications and may pursue such designation for others, but we may be unable to obtain such designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted. We have received orphan drug designation from the FDA for five indications for our products and product candidates, which are our ready- to- use glucagon for **post- bariatric hypoglycemia (" PBH ")** and Congenital Hyperinsulinism (" CHI") ~~, our ready- to- use diazepam for acute repetitive seizures and Dravet syndrome~~ , and for Recorlev, for the treatment of adult patients with endogenous Cushing' s syndrome for whom surgery is not an option or has not been curative. We ~~have also received orphan drug designation from the EMA for our ready- to- use glucagon for CHI and Noninsulinoma Pancreatogenous Hypoglycaemia Syndrome (" NIPHS") which includes patients with PBH. We~~ may pursue such designation for others in specific orphan indications in which there is an unmet medical need. We relied on orphan drug exclusivity in the marketing and ~~sales~~ **sale** of Keveyis until it expired on August 7, 2022 and **with respect to the marketing and sale of Recorlev,** intend to rely on orphan drug exclusivity ~~and~~ **through December 30 , 2028** ~~if granted, new chemical entity (" NCE") exclusivity in the marketing and sale of Recorlev~~ . Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200, 000 individuals in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Although we may seek orphan drug designation for certain additional indications, we may never receive such designation. Moreover, obtaining orphan drug designation for one indication does not mean we will be able to obtain such designation for another indication. If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective or makes a major contribution to patient care. In assessing whether a drug provides a ~~“~~ **"** major contribution to patient care ~~”~~ **"** over and above the currently approved drugs, which is evaluated by the FDA on a case- by- case basis, there is no one objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug

administration, longer periods between doses, and potential for self- administration. However, such a demonstration to overcome the seven- year market exclusivity may be difficult to establish with limited precedents and there can be no assurance that we will be successful in these efforts if and where we pursue them. Even with respect to the indications for which we have received orphan designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of our product candidates could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity for the same drug and same condition. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off- label in our approved indication, and different drugs for the same condition may already be approved and commercially available. In **the** ~~Europe~~ **European Union** , the period of orphan ~~drug~~ **market** exclusivity is ten years, although it may be reduced to six years if, at the end of the fifth year, it is established that the criteria for orphan ~~drug~~ designation are no longer met, **including if** ~~in other words, when~~ it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. **Legislation has been proposed by the European Commission that, if implemented, has the potential in some cases to shorten the ten- year period of orphan market exclusivity.** We have received orphan ~~drug~~ designation from the EMA for our ready- to- use glucagon for the treatment of CHI and NIPHS, which includes patients with PBH. Even with the FDA approval of Gvoke, **Recorlev and** Keveyis ~~and Recorlev~~ in the United States **,** and the EMA and MHRA approval of Ogluo in the European Union (" EU") and the United Kingdom (" UK"), we may not be able to obtain or maintain foreign regulatory approvals to market our products in other countries. We do not have any products other than Gvoke, **Recorlev, and** Keveyis ~~and Recorlev~~ approved for sale in the United States, nor any products or product candidates other than Ogluo approved for sale in any international markets, and we do not have experience in obtaining regulatory approval in international markets outside of the EU and the UK. In order to market products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain clearance or approval in the United States. In addition, some countries only approve or certify a product for a certain period of time, and we are required to re- approve or re- certify our products in a timely manner prior to the expiration of our prior approval or certification. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, or if we fail to have our products re- approved or re- certified, our business, results of operations and financial condition could be adversely affected. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. In addition, the clinical standards of care may differ significantly such that clinical trials conducted in one country may not be accepted by healthcare providers, third- party payors or regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any drug we develop will be unrealized. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our products and product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any products or product candidates for which we obtain marketing approval. For more information, see the section entitled," Business — Healthcare Reform" ~~. 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 and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives~~ . The cost of prescription pharmaceuticals in the United States has also been the subject of considerable debate, and members of Congress have indicated that they will address such costs through new legislative measures. To date, there have been several recent United States congressional inquiries and proposed state and federal legislation designed to, among other things, improve transparency in drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. There has recently been intense publicity regarding the pricing of pharmaceutical products generally, including publicity and pressure resulting from the prices charged for new products as well as price increases for older products that the government and public deem excessive. We may experience downward pricing pressure on the price of our products due to social or political pressure to lower the cost of drugs, which could reduce our revenue and future profitability. Many companies in our industry have received governmental requests for documents and information relating to drug pricing and patient support programs. We could incur significant expense and experience reputational harm as a result of these or other similar future inquiries, as well as reduced market acceptance and demand for our

products, which could harm our ability to market our products in the future. These factors could also result in changes in our product pricing and distribution strategies, reduced demand for our products and / or reduced reimbursement of products, including by federal health care programs such as Medicare and Medicaid and state health care programs. **We cannot predict** ~~On August 16, 2022~~ the ~~Inflation Reduction Act~~ **initiatives that may be adopted in the future. The continuing efforts** of **the government** ~~2022 was passed~~ , ~~which among~~ **insurance companies, managed care organizations and** other ~~things, allows~~ **payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: < the demand** for ~~CMS to negotiate prices for certain single- source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or~~ **our product candidates** ~~Part D drugs in 2028~~ , ~~and 20 Part B~~ **if we obtain regulatory approval; <** ~~or~~ **our ability** ~~Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers~~ to **set** ~~civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering~~ a price that **we believe** is ~~not equal to or less than the negotiated " maximum~~ fair ~~price " under the law or~~ for ~~taking price increases~~ **our approved products; < our ability to generate revenue and achieve or maintain profitability; < the level of taxes** that **we are** ~~exceed inflation. The legislation also requires~~ **required** ~~manufacturers~~ to pay **;** ~~rebates for drugs in Medicare Part D whose price increases exceed inflation. Further, the legislation caps Medicare beneficiaries' annual out- of- pocket drug expenses at $ 2, 000. The effect of Inflation Reduction Act of 2022 on our business~~ and **<** the **availability of capital** ~~healthcare industry in general is not yet known~~ . The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these other countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for approved products. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products and product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA' s approval process may significantly delay or prevent marketing approval of those product candidates for which we seek marketing approval, as well as subject us to more stringent labeling and post- marketing testing and other requirements. Risks Related to Product Development Our failure to successfully identify..... other regulatory authorities. Risks Related to our Industry and Ongoing Legal and Regulatory Requirements Risks Related to Ongoing Regulatory Obligations Even after approval of our products and product candidates, we may still face future development and regulatory difficulties. If we fail to comply with continuing United States and non- United States regulations or new adverse safety data arise, we could lose our marketing approvals and our business would be seriously harmed. Our approved products and product candidates, if approved, will also be subject to ongoing regulatory requirements for manufacturing, distribution, sale, labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market information. Approved products, third-party suppliers and their facilities are required to comply with extensive FDA requirements and requirements of other ~~similar agencies~~ **regulatory authorities** even after approval, including ensuring that quality control and manufacturing procedures conform to CGMPs and applicable QSRs and applicable product tracking and tracing requirements. As such, we and our third-party suppliers are subject to continual review and periodic inspections, both announced and unannounced, to assess compliance with CGMPs and **the** ~~QSRs~~ **QSR** . Accordingly, we and our third- party suppliers must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse ~~reactions~~ **events** and production problems, if any, to the FDA and other ~~similar agencies~~ **regulatory authorities** and to comply with certain requirements concerning advertising and promotion ~~for~~ **of** our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. Accordingly, we may not promote our approved products for indications or uses for which they are not approved. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. These unknown problems could be discovered as a result of any post- marketing follow- up studies, routine safety surveillance or other reporting required as a condition to approval. Regulatory agencies may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed. The FDA, the Federal Trade Commission and other agencies and government entities, including the Department of Justice (" DOJ") and the Office of Inspector General of the United States Department of Health and Human Services, closely regulate and monitor the post- approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use, and if we, or any future collaborators, do not market any of our products for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to ~~warnings~~ **warning** or enforcement action for off- label marketing, government investigations, or

litigation. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. **On June 7, 2023, we received an untitled letter from FDA' s Office of Prescription Drug Promotion (" OPDP") regarding specific sections of the Recorlev consumer website. The letter raised concerns that the webpages made false or misleading claims about the safety and efficacy of Recorlev that misbrand Recorlev within the meaning of the FDCA. We submitted a response to the FDA regarding our plan to revise those sections of the webpages at issue. The FDA completed evaluation of our response and issued a close- out letter in August 2023 stating that it appears that we have addressed all the concerns contained in the untitled letter.** If our products or product candidates fail to comply with applicable regulatory requirements, or if a problem with one of our products or third- party suppliers is discovered, a regulatory agency may: < restrict the marketing or manufacturing of such products; < restrict or require modification of or revision to the labeling of a product; < issue warning letters or untitled letters which may require corrective action; < mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; < require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for **third party** inspection **and / or monitoring** costs, **corrective action plans with** required due dates for specific actions and penalties for noncompliance; < impose other administrative or judicial civil or criminal penalties including fines, imprisonment and disgorgement of profits; < suspend or withdraw regulatory approval; < refuse to approve pending applications or supplements to approved applications filed by us; < close the facilities of our third- party suppliers; < suspend ongoing clinical trials; < impose restrictions on operations, including costly new manufacturing requirements; or < seize or detain products or recommend or require a product recall. The FDA' s and foreign regulatory agencies' policies are subject to change, and additional federal, state, local or non- United States governmental regulations may be enacted that could affect our ability to maintain compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that may arise from future legislation or administrative action, either in the United States or abroad. Our relationships with customers and payors are subject to applicable anti- kickback, fraud and abuse, transparency, privacy, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, physicians and third- party payors ~~will~~ play a primary role in the recommendation and prescription **use** of any products for which we obtain marketing approval. Our arrangements with investigators, healthcare practitioners, consultants, third- party payors and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. For more information, see the section entitled," Business — Other Healthcare Laws and Compliance Requirements". Efforts to ensure that our business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom may receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement **, deferred prosecution agreement** or other agreement to resolve allegations of non- compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. Defending against any such actions can be costly and time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business ~~is~~ **are** found **not** to be ~~not~~ in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. The United States government has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide copay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first- come basis according to consistent financial criteria and do not link aid to use of a donor' s product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, copay, and co- insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which

we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance. Further, it is possible that changes in insurer policies regarding copay coupons and / or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition. ~~Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current United States presidential administration may reverse or otherwise change these measures, both the current United States presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict how the implementation of and any further changes to this rule will affect our business.~~ If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We participate in the Medicaid Drug Rebate Program, the 340B program, the ~~United States~~ **U. S.** Department of Veterans Affairs, Federal Supply Schedule ~~, or~~ **("** FSS **")** , pricing program, and the Tricare Retail Pharmacy program, **which require us to disclose average manufacturer pricing,** and ~~have obligations~~ **, in the future may require us** to report the average sales price for certain of our drugs to the Medicare program. ~~For calendar quarters beginning January 1, 2022, manufacturers will need to start reporting the average sales price for drugs under the Medicare program regardless of whether they are enrolled in the Medicaid Drug Rebate Program. Currently, only manufacturers participating in the Medicaid Drug Rebate Program are obligated to do so.~~ Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts **. Furthermore** , ~~which can~~ **regulatory and legislative** ~~change~~ **changes ,** and ~~evolve over~~ **judicial rulings relating to these programs and policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be** time **- consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation** . ~~In~~ **For example, in** the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter ~~was incorrect, or~~ has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the ~~corrected~~ **revised** data for up to three years after those data originally were due. Such restatements ~~and recalculations~~ increase our costs ~~for complying with the laws and regulations governing the Medicaid Drug Rebate Program~~ and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our **government** ~~average sales price~~ **prices** , if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. **Additionally** ~~The Centers for Medicare & Medicaid Services~~ , ~~or~~ **our agreement** ~~CMS, could also decide~~ to ~~terminate~~ **participate in the 340B program or** our Medicaid drug rebate agreement **could be terminated** , in which case federal payments may not be available under Medicaid or Medicare Part ~~B~~ **D** for our covered outpatient drugs. ~~We cannot assure you that~~ **Additionally, if we overcharge the government in connection with our arrangements with FSS** ~~our~~ **or** ~~submissions will not~~ **Tricare Retail Pharmacy, we are required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would** be **expensive** ~~found by CMS to be incomplete or incorrect. Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results. CMS issued a final regulation, which became effective in April 2016, to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. In December 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value- based purchasing arrangements (beginning in 2022); and provided definitions for " line extension, " " new formulation, " and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an~~ **and** ~~alternative rebate formula (beginning in 2022). Regulatory and legislative changes, and judicial rulings relating to the Medicaid Drug Rebate Program and related policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be~~ time- consuming ~~to implement~~ , and could have a material adverse effect on our **business, financial condition,** results of operations ~~, particularly if CMS or another agency challenges the approach we take in our implementation. The HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective in January 2019. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated this regulation or other requirements of the program could negatively impact our financial results. Moreover, HRSA newly established an~~ **and growth prospects** ~~administrative dispute resolution, or ADR, process under a final regulation effective January 2021, for claims by covered entities that a manufacturer engaged in overcharging, including claims that a manufacturer limited the ability of a covered entity to purchase the manufacturer' s drugs at the 340B ceiling price, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. This ADR regulation has~~

~~been challenged in separate litigation instituted by PhRMA and by pharmaceutical manufacturers in multiple federal courts. Under the ADR final rule which became effective in January 2021, an ADR proceeding could potentially subject us to discovery by covered entities and other onerous procedural requirements and could result in additional liability. HRSA could also decide to terminate a manufacturer' s agreement to participate in the 340B program for a violation of that agreement or other good cause shown, in which case the manufacturer' s covered outpatient drugs may no longer be eligible for federal payment under the Medicaid or Medicare Part B program. In November 2022, HRSA issued a proposed rule to revise the ADR procedures contained in its January 2021 final regulation for disputes arising under the 340B drug pricing program between covered entities and manufacturers~~ . Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid **unit** rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, certain pharmaceutical manufacturers are involved in ongoing litigation regarding contract pharmacy arrangements under the 340B ~~Program~~ **program** . The outcome of those judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain ~~. We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations. Pursuant to applicable law, knowing provision of false information in connection with price reporting under the United States Department of Veterans Affairs, FSS or Tricare Retail Pharmacy, or Tricare, programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time- consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects~~ . Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside the United States and require us to develop and implement costly compliance programs. We currently have operations in the United States and in Ireland, and we maintain relationships with CMOs in certain parts of Europe, Asia and the United States for the manufacture of our products and product candidates. The Foreign Corrupt Practices Act (" FCPA") prohibits any United States individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti- bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission (" SEC") is involved with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from having its securities traded on United States exchanges for violations of the FCPA' s accounting provisions. Various laws, regulations and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non- United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside the United States, we are required to dedicate additional resources to comply with laws and regulations in each new jurisdiction in which we are operating or plan to operate, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates ~~outside~~ **in** ~~the~~ **these jurisdictions** ~~United States~~ , which could limit our growth potential and increase our development costs. The creation and implementation of international business practices compliance programs, particularly FCPA compliance, are costly and such programs are difficult to enforce, especially in countries in which corruption is a recognized problem and where reliance on third parties is required. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Indictment alone under the FCPA can lead to suspension of the right to do business with the United States government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long- term disqualification as a government contractor. Accordingly, our failure to comply with the FCPA or other export control, anti- corruption, anti- money laundering and anti- terrorism laws or regulations and other similar laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under such laws would have a negative impact on our operations and harm our reputation and ability to procure government contracts. We cannot assure you that our compliance policies and procedures are or will be sufficient or that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its 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. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low- priced and high- priced countries can further reduce prices. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidates to other available therapies, which is time consuming and costly. A Member State may approve a specific price for the medicinal product 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. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Risks Related to Industry Competition If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the sales of our products and product candidates, if approved, could be adversely affected. Once an NDA, including a Section 505 (b) (2) application, is approved, the product covered becomes a ~~“~~ **"** listed drug ~~”~~ **"** which can be cited by potential competitors in support of approval of an abbreviated new drug application (" ANDA"). FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient (s), dosage form, strength, route of administration, and conditions of use, or labeling, as our products or product candidates, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our products or product candidates. In some cases, even this limited bioequivalence testing can be waived by the FDA. Laws have also been enacted to facilitate the development of generic drugs and biologics based off recently approved NDAs and BLAs. The Creating and Restoring Equal Access to Equivalent Samples Act (~~“~~ **"** CREATES Act ~~”~~ **"**) was enacted in 2019 requiring sponsors of approved NDAs and BLAs to provide sufficient quantities of product samples on commercially reasonable, market- based terms to **eligible** ~~entities developing generic drugs and biosimilar biological products~~ **product developers** . The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. **Providing** ~~If we are required to provide~~ product samples ~~or~~ **and** ~~allocate~~ **allocating** additional resources to ~~responding~~ **respond** to such requests or any legal challenges under this law, **could adversely impact** our business ~~could be adversely impacted~~ . Competition from generic equivalents to our products or product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products or product candidates. For example, Amphastar' s ANDA for generic Glucagon for Injection Emergency Kit was approved by the FDA on December 29, 2020 for the treatment of severe hypoglycemia and while we previously relied on orphan drug exclusivity in the marketing and ~~sales~~ **sale** of Keveyis through the expiration of orphan drug exclusivity, Torrent Pharmaceuticals Limited’ s ANDA for generic dichlorphenamide was approved on December 29, 2022. We intend to rely on orphan drug exclusivity and if available, NCE exclusivity in the marketing and sale of Recorlev. While we applied for NCE exclusivity for Recorlev under section 505 (u) of the FDCA, the FDA may determine that the Recorlev application does not meet the eligibility criteria under 505 (u) for NCE exclusivity ~~.Risks Related to~~ Product Development Our failure to successfully identify,develop and market additional product candidates,or acquire additional product candidates or enter into collaborations or other commercial agreements could impair our ability to grow.As part of our growth strategy,we intend to identify,develop and market additional product candidates leveraging our formulation science,and evaluate other commercial relationships through collaborations or other strategic agreements.We are exploring various therapeutic opportunities for our pipeline programs.We may spend several years completing our development of any particular current or future internal product candidates,and failure can occur at any stage.The product candidates to which we allocate our resources may not end up being successful.Gvoke,which delivers ready- to- use glucagon via a pre- filled syringe or auto- injector,was approved by the FDA in 2019 for the treatment of severe hypoglycemia in pediatric (aged two years and above) and adult patients with diabetes.While we have identified several additional potential applications of our ready- to- use glucagon,there is no guarantee that we will be able to utilize our formulation science to obtain approval of additional product candidates.In the future,we may be dependent upon other pharmaceutical companies,academic scientists and other researchers to sell or license product candidates,approved products or the underlying technology to us.The process of proposing,negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex.Other companies,including some with substantially greater financial,marketing and sales resources,may compete with us for the license or acquisition of product candidates and approved products.In addition,we expect to seek one or more collaborators for the development and commercialization of one or more of our products or product candidates,particularly with respect to our pipeline product candidates or foreign geographies.We face significant competition in seeking appropriate collaborators.We have limited resources to identify and execute the acquisition or in- licensing of third- party products,businesses and technologies or enter into collaborations or other strategic arrangements and integrate them into our current infrastructure.Moreover,we may devote resources to potential acquisitions or in- licensing opportunities that are never completed,or we may fail to realize the anticipated benefits of such efforts.We may not be able to acquire the rights to additional product candidates or approved products on terms that we find acceptable,or at all.In addition,future acquisitions may entail numerous operational and financial risks,including:< exposure to unknown liabilities;< disruption of our business and diversion

of our management' s time and attention to develop acquired products or technologies;< incurrence of substantial debt,dilutive issuances of securities or depletion of cash to pay for acquisitions;< higher than expected acquisition and integration costs;< difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;< increased amortization expenses;< impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;and < inability to motivate or retain key employees of any acquired businesses.Further,any product candidate that we identify internally or acquire would require additional development efforts prior to commercial sale,including extensive clinical testing and approval by the FDA and other regulatory authorities **.Risks Related to** . Risks Related to Our Intellectual Property Risks Related to Protecting Our Intellectual Property Our success depends on our ability to protect our intellectual property and proprietary formulation science, as well as the ability of our collaborators to protect their intellectual property and proprietary formulation science. Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries with respect to the use, formulation and structure of our proprietary product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third- party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we may in the future also license or purchase patents or applications owned by others. The patent application and approval process is expensive and time consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords are limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non- infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our products or product candidates but that uses a formulation and / or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our products or product candidates is not sufficiently broad to exclude such competition, our ability to successfully commercialize our products or product candidates could be negatively affected, which would harm our business. Although we currently own all of our patents and our patent applications, similar risks would apply to any patents or patent applications that we may in- license in the future. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent or may prevent a patent from issuing from a pending patent application. For example, such patent

filings may be subject to a third- party pre- issuance submission of prior art to the USPTO and / or to other patent offices around the world. Alternately or additionally, we may become involved in post- grant review procedures, oppositions, derivations proceedings, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to exclude others from using or commercializing similar or identical technology and products, or may limit the duration of the patent protection of our technology and products. Pending and future patent applications may not result in patents being issued which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any future development partners will be successful in protecting our product candidates by obtaining, maintaining and defending patents. These risks and uncertainties include the following: < the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case; < patent applications may not result in any patents being issued; < patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; < our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates; < there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and < countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates in such countries. Issued patents that we have or may in the future obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our or our future licensors' patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or in the future licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. We have entered into a license agreement with a third party (and may, in the future, enter into additional such license agreements with other third parties) pursuant to which they have the right, but not the obligation, in certain circumstances to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of those ~~licensors~~ **licensees** and cannot guarantee that we would receive it and on what terms. We cannot be certain that those ~~licensors~~ **licensees** will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer. In addition, we rely on the protection of our trade secrets and proprietary know- how. Although we take steps to protect our trade secrets and unpatented know- how, including entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know- how, our business may be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair

our competitive position and may harm our business. The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. We have not conducted searches for third- party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, so we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patent applications and patents, in any future licensed patents or patent applications or in third- party patents. We cannot provide assurances that any claim (s) in any of our patent applications will be found to be patentable, including over our own prior art patents, or that any such patent applications will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings instituted by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and / or materially harm our business. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: < we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs; < it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent (s) will not: (a) be sufficient to protect our technology, (b) provide us with a basis for commercially viable products and / or (c) provide us with any competitive advantages; < if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under the United States or foreign laws; or < if issued, the patents under which we hold rights may not be valid or enforceable. In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost- effective to extend our portfolio by pursuing additional development of a product or product candidate for follow- on indications. We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators , and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third- party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods , and know- how. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Where available, we will seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Our unpatented trade secrets, know- how, confidential and proprietary information, and technology may be inadequately protected. We rely in part on unpatented trade secrets, know- how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants, and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. Thus, there is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us. If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know- how, we would not be able to assert our trade secret protections against them, which could have a material adverse effect on our business. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be

challenged, infringed, circumvented , or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such objections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and / or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Risks Related to Intellectual Property Litigation The pharmaceutical industry is characterized by frequent patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management' s time and efforts, require us to pay damages or prevent us from marketing our existing or future products. Our commercial success depends in part on our ability to develop, manufacture, market and sell our products that have been approved for sale, and to use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we will market products and are developing product candidates. Some claimants, who may include our competitors in both the United States and abroad, may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties. We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of Gvoke, **Recorlev,** Keveyis ~~, Recorlev~~ , or our product candidates. Generally, we do not conduct independent reviews of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and uncertainty of litigation increase the risk of business assets and management' s attention being diverted to patent litigation. Because patent applications can take up to 18 months after filing to become public, and many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement lawsuits, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to exclude the other party from making, using or selling the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to exclude the other party from making, using or selling the invention at issue on the grounds that our patent claims do not cover the invention or the other party' s manufacture, use or sale of it. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks. Others may challenge inventorship or claim an ownership interest in our intellectual property, which could expose it to litigation and have a significant adverse effect on its prospects. A third party or former employee or collaborator may claim an ownership interest in one or more of our patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and / or enjoin clinical testing, manufacturing , and marketing of the affected product or products. A third party could assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our

technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross- licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Furthermore, any potential intellectual property litigation also could force us to do one or more of the following: < stop selling products or using technology that contains the allegedly infringing intellectual property; < lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; < incur significant legal expenses; < pay substantial damages to the party whose intellectual property rights we may be found to be infringing; < redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and / or infeasible; or < attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. We may also be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products and product candidates, which could have an adverse effect on our business, results of operations and financial condition. An NDA submitted under Section 505 (b) (2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates. We expect to submit NDAs under Section 505 (b) (2) of the FDCA for most of our product candidates. Section 505 (b) (2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies and / or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. An NDA under Section 505 (b) (2) would enable us to reference published literature and / or the FDA' s previous findings of safety and effectiveness for a previously approved drug. For NDAs submitted under Section 505 (b) (2), the patent certification and related provisions of the Hatch- Waxman Act apply. Accordingly, if we rely for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, we will be required to include patent certifications in our 505 (b) (2) application regarding any patents covering the listed drug. If there are patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and we seek to obtain approval prior to the expiration of one or more of those patents, we will be required to submit a Paragraph IV certification indicating our belief that the relevant patents are invalid or unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of our 505 (b) (2) application. Otherwise, our 505 (b) (2) application cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. While we did not submit any Paragraph IV certifications in connection with our 505 (b) (2) NDA for Gvoke, and do not expect to submit any Paragraph IV certifications for our other current product candidates, there can be no assurance that we will not be required to submit a Paragraph IV certification in respect of any future product candidates for which we seek approval under Section 505 (b) (2). However, an NDA submitted under Section 505 (b) (2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates. If we submit any Paragraph IV certification that may be required, we will be required to provide notice of that certification to the NDA holder and patent owner shortly after our 505 (b) (2) application is accepted for filing. Under the Hatch- Waxman Act, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner' s or NDA holder' s receipt of notice (whichever is later), a one- time, automatic stay of the FDA' s ability to approve the 505 (b) (2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505 (b) (2) application will not be approved until any non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505 (b) (2) submissions and require us to submit traditional NDAs under Section 505 (b) (1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. In addition, the FDA could reject any future 505 (b) (2) application and require us to submit an ANDA if, before the submission of our 505 (b) (2) application, the FDA approves an

application for a product that is pharmaceutically equivalent to ours. These factors, among others, may limit our ability to commercialize our product candidates successfully. We may not be able to enforce our intellectual property rights throughout the world. We may not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products and product candidates. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Agreements through which we may license patent rights may not give us sufficient rights to permit us to pursue enforcement of those licensed patents or defense of any claims asserting the invalidity of these patents or the ability to control enforcement or defense of such patent rights in all relevant jurisdictions as requirements may vary. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Risk Related to Intellectual Property Laws Changes to the patent law in the United States and other jurisdictions could diminish the value of our patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and are therefore costly, time consuming and inherently uncertain. Changes in patent statutes, regulations promulgated under them, and court holdings interpreting the statutes and regulations could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition. Depending on future actions by the United States Congress, the United States courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Further, for a patent with an effective filing date of March 16, 2013 or later, a petition for post- grant review can be filed by a third party in a nine- month window from issuance of the patent. Alternatively, a petition for inter partes review can be filed after the nine- month period for filing a post- grant review petition has expired. Post- grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to the United States patents in lawsuits in the United States federal courts and uses a lower burden of proof than used in litigation in the United States federal courts. Therefore, it is generally considered easier and less costly for a competitor or third party to have a United States patent invalidated in a USPTO post- grant review or inter partes review proceeding than in a litigation in a United States federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which could result in a loss of the challenged patent right to us. Risks Related to Employee Matters, Managing Growth and Ongoing Operations Risks Related to Potentially Under- resourced Regulatory Authorities Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those

agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA **or other similar regulatory agencies** to review and approve new products can be affected by a variety of factors, including government budget and funding levels, global health concerns, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. ~~Average review times at the agency have fluctuated in recent years as a result.~~ In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable ~~. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business~~ . For example, over the last several years the United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. ~~Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold due to the COVID- 19 pandemic, the FDA has been working to resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic and may experience delays in their regulatory activities.~~ If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Risk Related to Employment Matters Our business could suffer if we lose the services of key members of our senior management or if we are not able to attract and retain other key employees and consultants. We are dependent upon the continued services of key members of our executive management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our executive management team, including Paul Edick, our Chief Executive Officer, Steven Pieper, our Chief Financial Officer, ~~Steven Prestrelski, our Chief Scientific Officer and Co- Founder,~~ John Shannon, our President and Chief Operating Officer, Ken Johnson, our Senior Vice President, Global Development and Medical Affairs, and Beth Hecht, our Chief Legal Officer and Corporate Secretary. The loss of any one of these individuals could disrupt our operations or our strategic plans. Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified scientific, technical **,** and managerial personnel, for whom we compete with numerous other companies, academic institutions **,** and organizations. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to commercialize our products and to develop and commercialize our product candidates will be limited. Risks Related to Our Common Stock Risks Related to Investment in Securities Our stock price has been and will likely continue to be volatile, and you may **lose part or all** ~~not be able to resell shares~~ of ~~our~~ **your investment** ~~common stock at or above the price you paid~~ . The trading price of our common stock historically has been highly volatile and could continue to be subject to large fluctuations in response to the risk factors discussed in this section, and others beyond our control, including: < our ability to successfully commercialize Gvoke, **Recorlev, and** Keveyis ~~and Recorlev~~ ; < regulatory actions with respect to our products and product candidates; < regulatory actions with respect to our competitors' products and product candidates; < the success of existing or new competitive products or technologies; < results of clinical trials of product candidates of our competitors; < announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; < the timing and results of clinical trials of our pipeline product candidates; < commencement or termination of collaborations for our development programs; < the results of our efforts to develop additional product candidates or products; < the level of expenses related to any of our product candidates or clinical development programs; < failure or discontinuation of any of our development programs; < the pricing and reimbursement of Gvoke, **Recorlev,** Keveyis ~~, Recorlev~~ or any of our product candidates that may be approved; < regulatory or legal developments in the United States and other countries; < developments or disputes concerning patent applications, issued patents or other proprietary rights; < the recruitment or departure of key personnel; < actual or anticipated changes in estimates as to financial results or development timelines; < announcement or expectation of additional financing efforts; < sales of our common stock by our insiders or other stockholders; < variations in our financial results or those of companies that are perceived to be similar to us; <

changes in estimates or recommendations by securities analysts, if any, that cover our stock; < changes in the structure of healthcare payment systems; < market conditions in the pharmaceutical and biotechnology sectors; < general economic, industry and market conditions, including impacts from inflation ~~and ~~**,** interest rate increases **, major bank failure or sustained financial market illiquidity** ; and < ~~global~~ **any public** health ~~concerns~~ **crisis** , such as **a resurgence of** the COVID- 19 pandemic. In recent years, the stock markets, and particularly the stock of smaller pharmaceutical and biotechnology companies, at times have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. Broad market and industry factors may significantly affect the market price of our common stock unrelated to our actual operating performance. Since shares of our common stock were sold in our IPO in June 2018 at a price of $ 15. 00 per share, our stock price has fluctuated significantly. In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us in connection with volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management' s attention and resources from our business. On March ~~6~~ **4** , ~~2023~~ **2024** , the closing price of a share of our common stock was $ ~~1~~ **3** . ~~45~~ **04** per share. The conversion of any of the Convertible Notes or other convertible securities into shares of common stock could have a material dilutive effect that could cause our share price to decline. We have a number of convertible securities outstanding, including Contingent Value Rights (" CVRs"), Convertible Notes and warrants, and the conversion of such securities into shares of our common stock could have a material dilutive effect that could cause our share price to decline. The Convertible Notes are convertible into shares of common stock at any time at the option of the holder subject to certain conditions. We have reserved a sufficient number of shares of common stock for issuance upon conversion of the Convertible Notes, CVRs and warrants. During the second half of 2020, $ 39. 1 million in principal amount of Convertible Notes were converted into 13, 171, 791 shares of our common stock. As of December 31, ~~2022~~ **2023** , the outstanding balance of Convertible Notes was $ ~~47~~ **48** . ~~2~~ **8** million. If any more or all of the Convertible Notes are converted into shares of common stock, our existing shareholders will experience immediate dilution of voting rights and the price of shares of our common stock may decline. Furthermore, the perception that such dilution could occur may cause the market price of our common stock to decline. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders of Convertible Notes may convert their Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then- applicable conversion rate. The conversion rate for the Convertible Notes **is** ~~will initially be~~ 326. 7974 shares of our common stock per $ 1, 000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $ 3. 06 per share of common stock, and is subject to adjustment under the terms of the Convertible Notes. In the event of certain circumstances, we will increase the conversion rate, provided that the conversion rate will not exceed 367. 6470 shares of our common stock per $ 1, 000 principal amount of Convertible Notes **in the case of the 2025 Convertible Notes and 549** . ~~Because~~ **4505 shares of our common stock per $ 1, 000 principal amount of Convertible Notes in the case of the 2028 Convertible Notes. As a result of** the conversion rates of the Convertible Notes ~~adjust~~ **adjusting** upward upon the occurrence of certain events, our existing shareholders may experience more dilution if any or all of the Convertible Notes are converted into shares of common stock after the adjusted conversion rate became effective. Each CVR is worth up to $ 1. 00, payable to CVR holders if future performance milestones are achieved, and settleable in cash, common stock, or a combination of cash and common stock, at our sole election. If the performance milestones are met and we elect to pay the CVR consideration in common stock, it could have a dilutive effect to our earnings per share and cause our share price to decline. **As of December 31, 2023, a performance milestone worth $ 0. 25 has been achieved, and performance milestones worth $ 0. 50 remain outstanding.** Upon completion of the ~~Acquisition~~ **acquisition of Strongbridge** , each outstanding and unexercised Strongbridge warrant (except private placement warrants) was assumed by the Company such that, upon exercise, the applicable holders will have the right to have delivered to them the reference property (as such term is defined in the Strongbridge assumed warrants). We also assumed the outstanding and unexercised Strongbridge private placement warrants and they expired in June 2022. The conversion of these assumed Strongbridge warrants (except the private placement warrants) into shares of our common stock could have a dilutive effect that could cause our share price to decline. We do not anticipate paying any cash dividends in the foreseeable future, and accordingly, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock. We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, under our Hayfin Loan Agreement, we are generally restricted from paying any dividends or making any distributions on account of our capital stock. Our ability to pay cash dividends also may be prohibited by future loan agreements. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Investors seeking cash dividends should not invest in our common stock. Risks Related to Tax We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards. As of December 31, ~~2022~~ **2023** , we had federal net operating loss carryforwards of $ ~~501~~ **494** . ~~4~~ **3** million and various state net operating loss carryforwards of $ ~~345~~ **352** . ~~3~~ **2** million. If not utilized, the federal net operating losses generated in taxable years beginning on or before December 31, 2017 will expire **in** ~~at various dates between 2025 and~~ 2037, and these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Federal net operating losses generated in taxable years beginning after December 31, 2017 can be carried forward indefinitely; however, such net operating losses may only offset up to 80 % of taxable income in taxable years beginning after December 31, ~~2022~~ **2023** . As of December 31, ~~2022~~ **2023** , we had $ 6. ~~7~~ **9** million and $ 3. ~~1~~ **7** million of federal and state income tax credits, respectively, to reduce future tax liabilities. If not utilized, the $ ~~5~~ **6** . ~~4~~ **9** million in federal income tax credits will begin to expire in ~~2025~~ **2038** , and the $ ~~2~~ **3** . ~~5~~ **7** million of state **economic development and** research and development credits will begin to expire in ~~2022~~ **2024** ~~, and these tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities~~ . In addition, under

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (" Code") 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 pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income may be limited. Our existing net operating losses or credits may be subject to limitations arising from previous ownership changes, and if we undergo future ownership changes, many of which may be outside of our control, our ability to utilize our net operating losses or credits could be further limited by Sections 382 and 383 of the Code. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits. Changes in tax law may adversely affect us or our investors. The rules dealing with the United States federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (" IRS") and the United States Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the United States will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Risks Related to our ~~Indenture~~ **Indentures** for our Convertible Notes, Charter and Bylaws Provisions in the ~~Indenture~~ **Indentures** for our Convertible Notes and corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us. Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: < establish a classified board of directors such that all members of the board are not elected at one time; allow the authorized number of our directors to be changed only by resolution of our board of directors; and limit the manner in which stockholders can remove directors from the board; < establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings; < require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; < limit who may call a special meeting of stockholders; < authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “ " poison pill ” " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; < require the approval of the holders of at least two- thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws; and < establish a Delaware Forum Provision (as defined below) or a Federal Forum Provision (as defined below). Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in our stockholders’ best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. In addition, certain provisions in the ~~Indenture~~ **Indentures** governing our Convertible Notes could make a third- party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their notes for cash. In addition, if a takeover constitutes a make- whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the notes and the ~~indenture~~ **indentures** could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that noteholders or holders of our common stock may view as favorable. Our bylaws designate certain courts as the sole and exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees and may discourage such lawsuits with respect to such claims. Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of or based on a fiduciary duty owed by any of our current or former directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the “ " Delaware Forum Provision ” "). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended. In addition, our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the “ " Federal Forum Provision ” "). This forum selection provision may limit a shareholder’ s ability to bring a claim in a judicial

forum that it finds favorable or cost- efficient for disputes with us or any of our directors, officers, employees or agents, which may discourage such lawsuits, or increase the costs to a shareholder of bringing such lawsuits, against us and such persons. The enforceability of forum selection provisions in other companies' articles of incorporation, bylaws or similar governing documents has been challenged in legal proceedings, and it is possible that in connection with any action a court could find the forum selection provisions contained in our bylaws to be inapplicable or unenforceable in such action. If a court were to find these forum selection provisions inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely impact our operating or financial condition or performance. General Risk Factors If we experience significant disruptions in our information technology systems, our business may be adversely affected. We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, compliance, purchasing and inventory management. Our current systems are not fully redundant. We may experience difficulties in implementing some upgrades which would impact our business operations or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions of our information technology systems, we may not be able to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows. We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Despite our implementation of security measures, our information systems are vulnerable to damages from computer viruses, natural disasters, unauthorized access, cyber **-** attack, including ransomware, and other similar disruptions. Any system failure, accident or ~~security~~ **cybersecurity incident, compromise, or** breach could result in disruptions to our operations. For example, third parties may attempt to hack into systems and may obtain our proprietary information or other sensitive information, which could cause significant damage to our reputation, lead to claims **or government enforcement action** against the Company and ultimately harm our business **. To the best of our knowledge, no risks from cybersecurity threats, including those resulting from any previous cybersecurity incidents, have materially affected, and we do not believe they are reasonably likely to materially affect, us, our business strategy, results of operations, or financial condition. We may expend significant resources to try to protect against these threats to our Systems. In addition, a cybersecurity incident involving one of our customers, including an incident involving their customers or vendors, could materially affect our business strategy, results of operations, or financial condition if our customers or their customers or vendors are unable to conduct their regular operations. For example, in February 2024, UnitedHealth Group announced that its Change Healthcare information technology systems that process payment claims for payors was being taken offline for an undefined period due to a cybersecurity incident, such incident could reduce demand for our products and harm our revenues as physician providers are unable to use such systems to submit electronic prescriptions and pharmacies are unable to fill electronic prescriptions for our products** . If products liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage. We may face liability claims related to the use or misuse of our products and product candidates. These claims may be expensive to defend and may result in large judgments against us. During the course of treatment, patients using our products and product candidates could suffer adverse medical effects for reasons that may or may not be related to our products and product candidates. Any of these events could result in a claim of liability. Any such claims against us, regardless of their merit, could result in significant costs to defend or awards against us that could materially harm our business, financial condition or results of operations. In addition, any such claims against us could result in a distraction to management, decreased demand for our products, an adverse effect on our public reputation, and / or difficulties in commercializing our products. To date, we have not received notice of any products liability claims against us. We maintain total products liability insurance coverage of $ 15. 0 million. Although we maintain products liability insurance for claims arising from the use of our products after FDA approval and for claims arising from the use of our product candidates in clinical trials prior to FDA approval at levels that we believe are appropriate, we may not be able to maintain our existing insurance coverage or obtain additional coverage on commercially reasonable terms for the use of our other products and product candidates in the future. Also, our insurance coverage and resources may not be sufficient to satisfy any liability resulting from products liability claims, which could materially harm our business, financial condition or results of operations. In addition, we have in the past and may in the future agree to indemnify counterparties from losses arising from claims relating to the products, processes or services made, used, sold or performed. Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage and the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected. Products liability claims could result in an FDA or other regulatory authority investigation into the safety or efficacy of our products, our manufacturing processes and facilities, our marketing programs, our internal safety reporting systems or our staff conduct. A regulatory authority investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval. Products liability claims could also result in investigation, prosecution or enforcement action by the DOJ or other federal or state government agencies. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to

implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. ~~However, for as long as we are an " emerging growth company " under the Jumpstart Our Business Startups Act (" JOBS Act") enacted in April 2012, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act. We could be an " emerging growth company " for up to five years from the date of our IPO.~~ An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. As a result of being a public company, we will continue to incur significant additional costs which may adversely affect our operating results and financial condition. We expect to continue to incur costs associated with corporate governance requirements, including requirements under the Sarbanes- Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, as well as rules implemented by the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd- Frank Act, the SEC and The Nasdaq Global Select Market. These rules and regulations have increased our accounting, legal and financial compliance costs and make some activities more time consuming and costly. In addition, we will continue to incur costs associated with our public company reporting requirements, and we expect those costs may increase in the future ~~. For example~~ **, particularly since we determined** we have **ceased** ~~devoted and expect~~ to **qualify** ~~continue to devote significant resources to complete the assessment and documentation of our internal controls over financial reporting under Section 404 of the Sarbanes- Oxley Act, including assessment of the design and effectiveness of our internal controls related to our information systems. During the course of our ongoing review and testing of our internal controls, we may identify deficiencies and may incur significant costs to remediate such deficiencies, including material weaknesses, if any, that we identify through these efforts. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. New laws and regulations,~~ as ~~well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes- Oxley Act, the Dodd- Frank Act and rules adopted by the SEC and The Nasdaq Global Select Market, would likely result in increased costs to us as we respond to their requirements, which may adversely affect our operating results and financial condition. Securities analysts may publish inaccurate or unfavorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline. The trading market for our common stock is influenced by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. Analysts who publish information about our common stock may have relatively little experience covering our company, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. If any of the analysts who cover us provide inaccurate or unfavorable research or issue~~ an **" ~~adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline. We are an"~~ emerging growth company ~~" and a" smaller reporting company~~ , ~~" and the reduced disclosure requirements applicable to " emerging growth companies~~ " ~~and" smaller reporting companies" may make our common stock less attractive to investors. We are an" emerging growth company,"~~ as defined in the Jumpstart Our Business Startups Act ~~of~~ **enacted in April** 2012 ~~(" JOBS Act")~~ , **as of December 31, 2023** and **as a " smaller reporting company " as of June 30, 2023. For example,** we ~~have elected~~ **are no longer able** to take advantage of certain exemptions and relief from various reporting requirements that are applicable to ~~other~~ public companies that are not " emerging growth companies ~~.~~ " **.** In particular **and amongst other requirements** , ~~while~~ we are ~~an " emerging growth company, " (i) we will not be~~ required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley **and are** ~~Act, (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor' s report on financial statements, (iii) we will be~~ subject to ~~reduced~~ **the full** disclosure obligations regarding executive compensation in our periodic reports and proxy statements **which rules** and ~~(iv) we~~ **regulations have increased our legal and financial compliance costs relative to prior years and** will **make some activities more time- consuming and costly** ~~not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. As a result, our public filings may not be comparable to companies that are not " emerging growth companies "~~ . We may **also need** ~~remain an " emerging growth company " until the fiscal year- end following the fifth anniversary of the completion of our IPO, though we may cease~~ to **hire** ~~be an " emerging growth company " earlier under certain circumstances, including the date on which we have issued~~ more **employees** ~~than $ 1. 0 billion~~ in ~~non- convertible debt during the previous three~~ -- **the** ~~years. In~~ **future or engage** ~~addition~~ **additional outside consultants** , ~~the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. In addition, we qualify as a " smaller reporting company, " which allows us to take advantage of many of the same exemptions from disclosure requirements, including not being required~~ to comply with ~~the~~ **these** ~~auditor attestation~~ requirements **, which will increase our costs and expenses. During the course** of ~~Section 404~~ **our ongoing review and testing of our internal controls, we may identify deficiencies and may incur significant costs to remediate such deficiencies, including material weaknesses, if any, that we identify through these efforts. We cannot**

predict or estimate the amount of additional costs we may incur or the timing of such costs. New laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes- Oxley Act **, the Dodd- Frank Act** and ~~reduced disclosure obligations regarding executive compensation~~ **rules adopted by the SEC and The Nasdaq Global Select Market, would likely result** in **increased costs to us as we respond to their requirements, which may adversely affect our operating results and financial condition. Securities analysts may publish inaccurate** ~~our~~ **or** ~~periodic~~ **unfavorable research or** reports **about our business or may publish** ~~and proxy statements. Even after we~~ no **information at all** ~~longer qualify as an " emerging growth company~~ , **which could cause** ~~" we may still qualify as a " smaller reporting company " if the market value of~~ our ~~common~~ stock **price** ~~that is held by non- affiliates is below $ 250 million (or $ 700 million if our~~ **or trading volume** ~~annual revenue is less than $ 100 million) as of June 30 in any given year, which would allow us~~ to **decline** ~~continue to take advantage of these exemptions~~ . **The** ~~Investors may find our common stock less attractive if we rely on these exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active~~ trading market for our common stock **is influenced by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. Analysts who publish information about our common stock may have relatively little experience covering our company, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. If any of the analysts who cover us provide inaccurate or unfavorable research or issue** ~~and~~ **an adverse opinion regarding** our stock price ~~may~~ **, our stock price could** decline ~~and /~~ **. If one** or ~~become~~ more ~~volatile~~ **of these analysts cease coverage of our company or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline** . Our data collection and processing activities are governed by restrictive regulations governing the use, processing and, in certain jurisdictions, cross- border transfer of personal information. We may be subject to the United States federal and state, European, UK and other foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). We have personnel located in Ireland and have conducted and may in the future conduct clinical trials in the ~~EU~~ **European Economic Area (" EEA")** and / or the UK subjecting us to additional privacy restrictions and data protection requirements. The collection and use of personal **data (including** health data **)** in the ~~EU~~ **EEA and the UK** are governed by the provisions of the EU General Data Protection Regulation (" EU GDPR") ~~,~~ as well as other national data protection legislation in force in relevant Member States **, with respect to the EEA, and the UK General Data Protection Regulation** (~~including~~ **the" UK GDPR," together with** the EU GDPR ~~as it forms part of~~ the **" GDPR"** ~~law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal~~) **and** ~~Act 2018 (~~ the ~~" UK GDPR ", together with the EU GDPR the " GDPR ") and the~~ Data Protection Act 2018 ~~in~~ **with respect to** the UK ~~)~~ . These laws impose a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the ~~European Economic Area, or~~ EEA ~~(~~ or ~~in the case of~~ the UK ~~GDPR, outside of the UK)~~ , providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals' requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record- keeping. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the ~~new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Although the UK is regarded as a third country under the EU' s GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the~~ EEA ~~to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European~~ and UK data protection ~~laws~~ **regimes** . ~~On June 4~~ **This may be onerous and adversely affect our business** , ~~2021~~ **financial condition** , **results** ~~the EC issued new forms~~ of ~~standard contractual clauses~~ **operations and prospects. The GDPR prohibits the international transfer of personal data to countries outside of the EEA or the UK (" third countries") which are not deemed as adequate** for **the transfers of personal** data ~~transfers from controllers~~ **by competent authorities, unless a derogation exists** or **adequate safeguards** ~~processors in the EEA~~ (~~or otherwise subject to the GDPR) to controllers or processors established outside the EU / EEA (and not subject to the GDPR). As of December 27, 2022, the new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive~~ for **example,** ~~all transfers outside of the EEA. The UK is not subject to~~ the European Commission **approved** ~~' s new standard~~ **Standard** ~~contractual~~ **Contractual** ~~clauses~~ **Clauses** ~~but has published~~ **(" EU SCCs") and** the UK International Data Transfer Agreement ~~/ and International Data Transfer~~ Addendum ~~to the new standard contractual clauses (the " IDTA "), which enable transfers from the UK. For new transfers, the IDTA already needs to be in place, and must be in place for all existing transfers from the UK from March 21, 2024. Following a ruling from the Court of Justice of the EU, in Data Protection Commissioner v Facebook Ireland Limited and Maximillian Schrems, Case C- 311 / 18~~ (" ~~Schrems II~~ **UK IDTA** ") ~~, companies~~ **) are implemented in compliance with EEA and UK data protection laws. Where** relying on ~~standard contractual clauses to govern~~ **the EU SCCs or UK IDTA for data** transfers ~~of personal~~ **, we may also be required to carry out transfer impact assessments on transfers made pursuant to the EU SCCs and the UK IDTA, on a case- by- case basis to ensure the law in the** data ~~to third~~ **importer' s** ~~countries~~ **country and** ~~(in particular the United States) will need to assess whether~~ the data

importer can ensure sufficient guarantees for safeguarding the personal data under GDPR. This assessment includes assessing whether third party vendors can also ensure these guarantees. The **international** ~~same assessment is required for transfers~~ **transfer obligations under** ~~governed by the IDTA. We will be required to implement these~~ -- **the EEA and UK** ~~new safeguards when conducting restricted~~ data **protection regimes** ~~transfers under the GDPR and doing so~~ will require significant effort and cost **Although** ~~the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK adequacy decision from the European Commission.The potential of the respective provisions and enforcement of~~ the EU GDPR and **the** UK GDPR ~~further diverging~~ **currently impose substantially similar obligations,it is possible that over time the UK GDPR could become less aligned with the EU GDPR.The UK government has announced plans to reform the data protection legal framework** in the ~~future creates additional regulatory challenges and uncertainties for us~~ **UK in its Data Reform Bill but those have been put on hold** . ~~The~~ **This** lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk,uncertainty,complexity and cost to our handling of ~~European~~ **EU** personal ~~data~~ **information** and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the ~~EEA~~ **EU** . ~~In~~ . If we are investigated by a European or UK data protection authority, we may face fines and other penalties, including bans on processing and transferring personal data. ~~EU~~ **EEA** and UK data protection authorities have the power to impose administrative fines for violations of the GDPR of up to a maximum of € 20 (£ 17. 5 **under the UK GDPR**) million or 4 % of ~~the data controller' s or~~ **our** ~~data processor' s~~ total worldwide global turnover for the preceding fiscal year, whichever is higher, and violations of the GDPR may also lead to damages claims by data controllers and data subjects. Such penalties are in addition to any civil litigation claims by data controllers, clients, and data subjects. As such, we will need to take steps to cause our processes to continue to be compliant with the applicable portions of the GDPR, but we cannot assure you that we will be able to implement changes in a timely manner or without significant disruption to our business, or that such steps will be effective, and we may face the risk of liability under the GDPR. Although the EU GDPR and the UK..... for the UK and the EU. Many jurisdictions outside of Europe where we may do business or conduct trials in the future are also considering and / or have enacted comprehensive data protection legislation. In addition, we also continue to see jurisdictions imposing data localization laws. These and similar regulations may interfere with our intended business activities, inhibit our ability to expand into those markets, require modifications to our products or services or prohibit us from continuing to offer services or conduct trials in those markets without significant additional costs **. Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data. Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business** . Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements, which could cause significant liability for us and harm to our reputation. We are exposed to the risk that our employees, independent contractors, consultants, collaborators and CROs may engage in fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non- United States regulatory authorities, to provide accurate information to the FDA or comparable non- United States regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non- United States regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the ~~conflict~~ **conflicts** between Russia and Ukraine **and Israel and Hamas** , **or other events** could adversely affect our business and financial performance. Economic uncertainty in various global markets caused by political instability and conflict and economic challenges ~~caused by the COVID- 19 pandemic~~ has **in the past** resulted, and may continue to result, in weakened demand for our products. Political developments impacting government spending and international trade, including potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-

economic conditions. The effects of these events may continue due to potential United States government shutdowns and the transition in administrations, and the United States' ongoing trade disputes with China and other countries. In addition, the current military ~~conflict~~ **conflicts** between Russia and Ukraine **and Israel and Hamas** could disrupt or otherwise adversely impact our operations and related sanctions, export controls or other actions that may be initiated by nations including the United States, the EU ~~or~~ **,** Russia **or countries or actors in the Middle East** (e. g., potential cyberattacks, disruption of energy flows, etc.) could adversely affect our business and / or our supply chain or those of our third party service providers. The United States and other countries could ~~impose wider sanctions and~~ take other actions **that may adversely affect our business** should the ~~conflict~~ **conflicts** further escalate. It is not possible to predict the broader consequences of ~~this~~ **these** ~~conflict~~ **conflicts** , which could include further sanctions, embargoes, regional instability, prolonged periods of higher inflation **, international trade disruptions, supply disruptions** , geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations. The continuing effect of any or all of these events could adversely impact demand for our products, harm our operations and weaken our financial results. Our operations are subject to the effects of a rising rate of inflation. The United States has recently experienced historically high **and fluctuating** levels of inflation. If the inflation rate continues to increase, for example due to increases in the costs of labor and supplies, or remain at a historically high rate, it will affect our expenses, such as employee compensation, supply costs and research and development expenses. ~~Additionally~~ **In addition** , **elevated** ~~the United States is experiencing an~~ **and fluctuating inflation and increasing interest rates** ~~acute workforce shortage, which in turn,~~ has **contributed to potential economic uncertainty in the larger economy** ~~created a very competitive wage environment that may increase our operating costs~~ . To the extent inflation **continues to** ~~results~~ **result** in rising interest rates and has other adverse effects on the market, it may adversely affect our financial condition and results of operations. **We maintain our cash at financial institutions, often in balances that exceed federally- insured limits. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect the Company' s current and projected business operations, ability to pay operational expenses or make other payments, and its financial condition and results of operations. Our cash held in non- interest bearing and interest- bearing accounts exceeds the Federal Deposit Insurance Corporation (" FDIC") limits and is predominantly held at one institution, Wells Fargo Bank, N. A. If such banking institution or any future banking institutions where we maintain our cash were to fail, we could lose all or a portion of those amounts held in excess of such insurance limits. For example, the recent closures of Silicon Valley Bank, where we maintained a portion of our cash, Signature Bank and First Republic Bank and their placement into receivership with the FDIC created bank- specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, future adverse developments with respect to specific financial institutions or the broader financial services industry, including concerns or rumors about any events of these kinds or similar risks, may lead to market- wide liquidity shortages and the FDIC may elect not to make all account holders whole. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds and could have a material adverse effect on our business and financial condition. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. Finally, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us or others, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. Any supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a supplier, or the loss of any significant supplier relationships, could result in material losses to the Company and may have a material adverse impact on our business. Our business could be negatively impacted by environmental, social and corporate governance matters or our reporting of such matters. There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning environmental, social and corporate governance (" ESG") matters. For instance, the SEC has recently proposed climate change and ESG reporting requirements, which, if approved, would significantly increase our costs, divert management resources and attention and require us to expend significant time and resources, which could have an adverse effect on our business, financial condition and results of operations. If our ESG practices fail to meet investor, customer, consumer, employee or other stakeholders' evolving expectations and standards in areas such as environmental stewardship, Board of Directors and employee diversity, human capital management, corporate governance and transparency, our reputation could be negatively impacted, which could have a material adverse effect on our business or financial condition.**