Risk Factors Comparison 2024-02-29 to 2023-02-28 Form: 10-K

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The Company is subject to a number of risks that if realized could affect its business, financial condition, results of operations, cash flows and access to liquidity materially. The Company' s business is subject to uncertainties and risks including: • RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® face substantial competition for their intended uses in the targeted markets from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies, which could cause the royalties payable to us pursuant to the GSK Agreements to be less than expected, which in turn would harm our business and cause the price of our securities to fall. • We are dependent on GSK for the successful commercialization and development of the products developed under the GSK Agreements. If GSK does not devote sufficient resources to the commercialization and development of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, our business would be materially harmed. • Our debt including our convertible subordinated notes and convertible senior notes are senior in capital structure and cash flow, respectively, to our common stockholders. Satisfying the obligations relating to our debt could adversely affect our liquidity or the amount or timing of potential distributions to our stockholders. • GSK has indicated to us that it believes its consent may be required before we can engage in certain royalty monetization transactions with third parties, which may inhibit our ability to engage in these transactions. • If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of that product candidate. • We rely on collaborations with third parties for the development of **both** our product **and commercial** candidates, and we may seek additional collaborations in the future. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product **or commercial** candidates. • Even if any of our product candidates receives marketing approval, such product candidate may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. • ~~We might not~~ **Our operations could** be **disrupted by failure** ~~able to successfully integrate our operations with those~~ of ~~Entasis and / or~~ **our information systems or cyber- attacks** ~~La Jolla and other assets that we may acquire~~ . • If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks. • Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate. Risks Related to our Business Currently, we derive most of our revenues from GSK and our near- term success depends in large part on GSK' s ability to successfully develop and commercialize the products in the respiratory programs partnered with GSK. Pursuant to the GSK Agreements, GSK is responsible for the development and commercialization of products in the partnered respiratory programs. Royalty revenues from RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® are expected to represent the majority of our foreseeable future revenues from GSK. The amount and timing of revenue from such royalties are unknown and highly uncertain. Our near- term success depends in large part upon the performance by GSK of its commercial obligations under the GSK Agreements and the commercial success of RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ®. We have no control over GSK' s marketing and sales efforts, and GSK might not be successful, which would harm our business and cause the price of our securities to fall. Our quarterly royalty revenues may fluctuate due to a variety of factors, many of which are outside of our control. The amount of royalties and milestone payments, if any, we receive will depend on many factors, including **but not limited to** the following: • the extent and effectiveness of the sales and marketing and distribution support GSK provides to our partnered products; • market acceptance and demand for our partnered products; • changes in the treatment paradigm or standard of care for COPD or asthma, for instance through changes to the GOLD (Global Initiative for Chronic Obstructive Lung Disease) guidelines; • the competitive landscape of generic and branded products and developing therapies that compete with our products owned by GSK (such as Advair ®) but which are not partnered with us and pricing pressure in the respiratory markets targeted by our partnered products; • the size of the market for our partnered products; • the mix of sales of our partnered products; • decisions as to the timing of product launches, pricing and discounts; • reprioritization of GSK' s commercial efforts on other products owned by GSK ~~(such as Advair ®)~~ , which are not partnered with us; • GSK' s ability to expand the indications for which our partnered products can be marketed; • a satisfactory efficacy and safety profile as demonstrated in a broad patient population; • acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third- party payors; • timing and amounts of payor rebate adjustments and prior period rebate adjustments; • seasonal fluctuations of demand; • the ability of patients to be able to afford our partnered products or obtain health care coverage that covers our partnered products; • safety concerns in the marketplace for respiratory therapies in general and with our partnered products in particular; • regulatory developments relating to the manufacture or continued use of our partnered products; • the requirement to conduct additional post - approval studies or trials for our partnered products; • GSK' s ability to obtain regulatory approval of our partnered products in additional countries; • the unfavorable outcome of any potential litigation relating to our partnered products; • general economic conditions in the jurisdictions where our partnered products are sold, including microeconomic disruptions or slowdowns; or • if our royalty revenue or operating results fall below the expectations of investors or securities analysts or below any guidance we may

provide to the market, the price of our common stock could decline substantially. When the FDA or other applicable regulatory authorities approve generic products, including but not limited to generic forms of Advair, that compete with RELVAR ® / BREO ® ELLIPTA ®, and ANORO ® ELLIPTA ® or a generic form of RELVAR ® / BREO ® ELLIPTA ®, the royalties payable to us pursuant to the GSK Agreements will be less than anticipated, which in turn would harm our business and the price of our securities could fall. Once an NDA or marketing authorization application outside the United States is approved, the product covered thereby becomes a " listed drug " that can, in turn, be cited by potential competitors in support of approval of an ANDA in the United States. Agency regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non- infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes in the United States and in nearly every pharmaceutical market around the world. Numerous companies have brought to market generic forms of the ICS / LABA drug Advair ® since certain patents covering the Advair ® delivery device expired in 2016. In general, these manufactures are required to conduct a number of clinical efficacy, pharmacokinetic and device studies to demonstrate equivalence to Advair, per FDA' s September 2013 draft guidance document. These studies are designed to demonstrate that the generic product has the same active ingredient (s), dosage form, strength, exposure and clinical efficacy as the branded product. These generic equivalents, which must meet the same exacting quality standards as branded products, may be significantly less costly to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product and products that may compete with such branded product is typically lost to the generic product. In January 2019, Mylan announced that the FDA approved Wixela ™ Inhu ™ (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of ADVAIR DISKUS ®. In that same month, Teva announced that the FDA approved two of their products for adolescent and adult patients with asthma, one of which is AirDuo ™ RespiClick ® (fluticasone propionate and salmeterol inhalation powder), a non- AB substitutable generic version of Advair ®. In January 2020, Astra Zeneca launched an authorized generic version of Symbicort. In December 2020, Hikma / Vectura announced that it received FDA approval and launched its generic version of GSK' s Advair Diskus ®. In April 2016, the FDA issued draft guidance documents covering Fluticasone Furoate / Vilanterol Trifenatate (FF / VI), the active ingredients used in RELVAR ® / BREO ® ELLIPTA ®. Introduction of generic products that compete against ICS / LABA products, like RELVAR ® / BREO ® ELLIPTA ®, would materially adversely impact our future royalty revenue, profitability and cash flows. We cannot yet ascertain what impact these generic products and any future approved generic products will have on any sales of RELVAR ® / BREO ® ELLIPTA ® or ANORO ® ELLIPTA ®, if approved. Reduced prices and reimbursement rates due to the actions of governments, payors, or competition or other healthcare cost containment initiatives such as restrictions on use, may negatively impact royalties generated under the GSK Agreements. The continuing efforts of governments, pharmaceutical benefit management organizations (" PBMs "), insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care has adversely affected the price, market access, and total revenues of RELVAR ® / BREO ® ELLIPTA ®, and ANORO ® ELLIPTA ® and may continue to adversely affect them in the future **. These organizations, together with governments, have increasingly imposed utilization management tools favoring the use of generic products. As these practices expand, we may face difficulty in obtaining or maintaining timely or adequate pricing or formulary placement of our products** . In addition, we have experienced and expect to continue to experience increased competitive activity, which has resulted in lower overall prices for our products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, " PPACA ") and other legislative or regulatory requirements or potential legislative or regulatory actions regarding healthcare and insurance matters, along with the trend toward managed healthcare in the U. S., could adversely influence the purchase of healthcare products and reduce demand and prices for our partnered products. This could harm GSK' s ability to market our partnered products and significantly reduce future revenues. For example, when GSK launched RELVAR ® / BREO ® ELLIPTA ® for the treatment of COPD in the U. S. in October 2013, GSK experienced significant challenges gaining coverage at some of the largest PBMs, healthcare payors, and providers and lower overall prices than expected. Recent actions by U. S. PBMs in particular have increased discount levels for respiratory products resulting in lower net sales pricing realized for products in our collaboration. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures will continue and may increase. This may make it difficult for GSK to sell our partnered products at a price acceptable to us or GSK or to generate revenues in line with our analysts' or investors' expectations, which may cause the price of our securities to fall. More recently, presidential administrations and the U. S. Congress have taken actions in an effort to modify or replace PPACA and to implement or pass other reforms to the healthcare system, including proposed legislation related to the pricing of pharmaceuticals. There is uncertainty with respect to any potential changes that may be proposed and what the impact, if any, will be on our business, including the impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. We expect that additional state and federal healthcare reform measures will be considered and potentially adopted, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures and may adversely affect our operating results. A portion of our current revenues are from royalties derived from sales of our respiratory products partnered with GSK, RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ®. If the treatment paradigm for the indications our partnered products are approved for change or if GSK is unable to, or does not devote sufficient resources to, maintain or continue increasing sales of these products, our results of operations will be adversely affected. We currently depend, in part, on royalties from sales of our products partnered with GSK to support our existing operations. The treatment paradigm for COPD and asthma constantly evolves. For instance, in November 2018, the GOLD guidelines were revised to favorably position

bronchodilator monotherapy and LABA / LAMA treatment ahead of ICS / LABA for the treatment of COPD unless the patient has frequent exacerbations, or an eosinophil count greater than 300 per cubic microliter. The use of ICS in COPD is also recommended for patients requiring triple therapy (LABA, LAMA, ICS). If the treatment paradigms were to change further, causing our partnered products to fall out of favor, or if GSK were unable, or did not devote sufficient resources, to maintain or continue increasing RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® sales, our results of operations would likely suffer, and the price of our securities could fall. If the commercialization of RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® in the countries in which they have received regulatory approval encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage does not meet investors', analysts', or our expectations, our business will be harmed, and the price of our securities could fall. Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ®. GSK has launched RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® in a number of countries, including the United States, Canada, Japan, the United Kingdom, and Germany, among others. The commercialization of the products in countries where they are already launched and the commercialization launch in new countries are still subject to fluctuating overall pricing levels and uncertain timeframes to obtain payor coverage. Any delays or adverse developments or perceived additional delays or adverse developments with respect to the commercialization of RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® including if sales or payor coverage does not meet investors', analysts', or our expectations, would significantly harm our business and the price of our securities could fall. We are dependent on GSK for the successful commercialization and development of products under the GSK Agreements. If GSK does not devote sufficient resources to the commercialization or development of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, our business would be materially harmed. GSK is responsible for all clinical and other product development, regulatory, manufacturing and commercialization activities for products developed under the GSK Agreements, including RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ®. Our royalty revenues under the GSK Agreements may not meet our, analysts', or investors' expectations, due to a number of important factors. GSK has a substantial respiratory product portfolio in addition to the partnered products that are covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For instance, GSK has wide discretion in determining the efforts and resources that it will apply to the development and commercialization of our partnered products. In addition, GSK may determine to focus its commercialization efforts on its own products. For example, in January 2015, GSK launched Incruse ® (UMEC) in the U. S., which is a LAMA for the treatment of COPD. GSK may determine to focus its marketing efforts on Incruse, which could have the effect of decreasing the potential market share of ANORO ® ELLIPTA ® and lowering the royalties we may receive for such product. Alternatively, GSK may decide to market to eventually compete directly against sales of RELVAR ® / BREO ® ELLIPTA ®. In the event GSK does not devote sufficient resources to the commercialization of our partnered products or chooses to reprioritize its commercial programs, our business, operations and stock price would be negatively affected. Any adverse change in FDA policy or guidance regarding the use of LABAs to treat asthma could significantly harm our royalty revenues and the price of our securities could fall. On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and it will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA now requires that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, in March 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as " clinical trial design ") to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it required the manufacturers of currently marketed LABAs to conduct additional randomized, double blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. These post - marketing studies have been completed and the FDA stated that treating asthma with LABAs in combination with ICS did not result in significantly more serious asthma- related side effects than treatment with ICS alone. The FDA subsequently removed the black box warning from the ICS / LABA package inserts. Although this concern appears to be resolved, it is unknown at this time what, if any, future concerns could impact the use of ICS / LABA and its potential impact on the prospects for FF / VI. Any adverse change in FDA policy or guidance regarding the use of LABAs to treat asthma could significantly harm our business and the price of our securities could fall. Any adverse developments to the regulatory status of either RELVAR ® / BREO ® ELLIPTA ® or ANORO ® ELLIPTA ® in the countries in which they have received regulatory approval, including labeling restrictions, safety findings, or any other limitation to usage, would harm our business and may cause the price of our securities to fall. Although RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® are approved and marketed in a number of countries, it is possible that adverse changes to the regulatory status of these products could occur in the event new safety issues are identified, treatment guidelines are changed, or new studies fail to demonstrate product benefits. A number of notable pharmaceutical products have experienced adverse developments during commercialization that have resulted in the product being withdrawn, approved uses being limited, or new warnings being included. In the event that any adverse regulatory changes were to occur to any of our products, our business would be harmed, and the price of our securities could fall. Any adverse developments or results or perceived adverse developments or results with respect to the ongoing studies for FF / VI in asthma or COPD, for UMEC / VI in COPD, or any future studies would significantly harm our business and the price of our securities could fall, and if regulatory authorities in

those countries in which approval has not yet been granted determine that the ongoing studies for FF / VI in asthma or COPD or the ongoing studies for UMEC / VI for COPD do not demonstrate adequate safety and efficacy, the continued development of FF / VI or UMEC / VI or both could be significantly delayed, they might not be approved by these regulatory authorities, and even if approved they may be subject to restrictive labeling, any of which might harm our business, and the price of our securities could fall. Although we have announced the completion of, and reported certain top - line data from, the Phase 3 registrational program for FF / VI in COPD and asthma, additional studies of FF / VI are underway or may commence in the future. Any adverse developments or perceived adverse developments with respect to any prior, current or future studies in these programs could significantly harm our business and the price of our securities could fall. Although the FDA, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare and Health Canada and other jurisdictions have approved ANORO ® ELLIPTA ®, it has not yet been approved in all jurisdictions. Any adverse developments or results or perceived adverse developments or results with respect to other pending or future regulatory submissions for the FF / VI program or the UMEC / VI program might significantly harm our business and the price of our securities could fall. Examples of such adverse developments include, but are not limited to: • not every study, nor every dose in every study, in the Phase 3 programs for FF / VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required; • safety, efficacy or other concerns arising from clinical or non - clinical studies in these programs having to do with the LABA VI, which is a component of FF / VI and UMEC / VI; • analysts adjusting their sales forecasts downward from previous projections based on results or interpretations of results of prior, current or future studies; • safety, efficacy or other concerns arising from clinical or non - clinical studies in these programs; • regulatory authorities determining that the Phase 3 programs in asthma or in COPD raise safety concerns or do not demonstrate adequate efficacy; or • any change in FDA (or comparable foreign regulatory agency) policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD. RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® face substantial competition for their intended uses in the targeted markets from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies, which could cause the royalties payable to us pursuant to the LABA Collaboration Agreement to be less than expected, which in turn would harm our business and cause the price of our securities to fall. GSK has responsibility for obtaining regulatory approval, launching and commercializing RELVAR ® / BREO ® ELLIPTA ®, and ANORO ® ELLIPTA ® for their intended uses in the targeted markets around the world. While these products have received regulatory approval and have been launched and commercialized in the U. S. and certain other targeted markets, the products face substantial competition from existing products previously developed and commercialized both by GSK and by other competing pharmaceutical companies and can expect to face additional competition from new products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward. For example, sales of generic Advair ®, GSK' s approved medicine for both COPD and asthma, continue to have a negative impact on sales of RELVAR ® / BREO ® ELLIPTA ®. Many of the pharmaceutical companies competing in respiratory markets are international in scope with substantial financial, technical and personnel resources that permit them to discover, develop, obtain regulatory approval and commercialize new products in a highly efficient and low- cost manner at competitive prices to consumers. In addition, many of these competitors have substantial commercial infrastructure that facilitates commercializing their products in a highly efficient and low- cost manner at competitive prices to consumers. The market for products developed for treatment of COPD and asthma continues to experience significant innovation and reduced cost in bringing products to market over time. There can be no assurance that RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® will not be replaced by new products that are deemed more effective at lower cost to consumers. The ability of RELVAR ® / BREO ® ELLIPTA ®, and ANORO ® ELLIPTA ® to succeed and achieve the anticipated level of sales depends on the commercial and development performance of GSK to achieve and maintain a competitive advantage over other products with the same intended use in the targeted markets. If sales of RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ® are less than anticipated because of existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, our royalty payments could be less than anticipated, which in turn would harm our business and cause the price of our securities to fall. We may not be able to utilize all of our net operating loss carryforwards. We have net operating loss carryforwards and other significant U. S. tax attributes that we believe could offset otherwise taxable income in the U. S. ~~As a part of the overall Spin- Off transaction, the transfer of certain assets by us to Theravance Biopharma and our distribution of Theravance Biopharma ordinary shares resulted in taxable transfers pursuant to applicable provisions of the Internal Revenue Code of 1986, as amended (the " Code ") and Treasury Regulations. The taxable gain recognized by us attributable to the transfer of certain assets to Theravance Biopharma generally equaled the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although we did not recognize any gain with respect to the cash we transferred to Theravance Biopharma, we may recognize substantial gain based on the fair market value of the other assets (other than cash) transferred to Theravance Biopharma. The determination of the fair market value of these assets is subjective and could be subject to adjustments or future challenge by the Internal Revenue Service (" IRS "), which could result in an increase in the amount of gain realized by us as a result of the transfer. Our U. S. federal income tax resulting from any gain recognized upon the transfer of our assets to Theravance Biopharma (including any increased U. S. federal income tax that may result from a subsequent determination of higher fair market values for the transferred assets), may be reduced by our net operating loss carryforward.~~ The net operating loss carryforwards available in any year to offset our net taxable income will be reduced following a more than 50 % change in ownership during any period of 36 consecutive months (an " ownership change ") as determined under the Code. Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. We have conducted an analysis to determine whether an ownership change had occurred since inception through December 31, ~~2022~~ **2023** and concluded that it is more likely than not that the Company did not experience an ownership change during the

testing period. Subsequent changes in our ownership or sale of our stock could have the effect of limiting the use of our net operating losses in the future. There may be certain annual limitations for utilization based on the above- described ownership change provisions. In addition, we may not be able to have sufficient future taxable income prior to their expiration because net operating losses have carryforward periods. Future changes in federal and state tax laws pertaining to net operating loss carryforwards may also cause limitations or restrictions from us claiming such net operating losses. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U. S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced. If any product candidates in any respiratory program partnered with GSK were not approved by regulatory authorities or are determined to be unsafe or ineffective in humans, our business would be adversely affected and the price of our securities could fall. The FDA must approve any new medicine before it can be marketed and sold in the U. S. Our partner GSK must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that the product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. GSK will not obtain this approval for a partnered product candidate unless and until the FDA approves an NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to market medicines in foreign countries, separate regulatory approvals must be obtained in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more country may make approval in other countries more difficult. Clinical studies involving product candidates partnered with GSK may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they have other unacceptable side effects. In addition, the results of preclinical studies do not necessarily predict clinical success, and larger and later - stage clinical studies may not produce the same results as earlier - stage clinical studies. Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical or non - clinical studies. In addition, clinical and non - clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of product candidates in development partnered with GSK, GSK may not receive regulatory approval for such product candidates and our business and financial condition could be materially harmed and the price of our securities might fall. Several well - publicized Complete Response letters issued by the FDA and safety - related product withdrawals, suspensions, post - approval labeling revisions to include boxed warnings and changes in approved indications over the last several years, as well as growing public and governmental scrutiny of safety issues, have created a conservative regulatory environment. The implementation of new laws and regulations and revisions to FDA clinical trial design guidance have increased uncertainty regarding the approvability of a new drug. Further, there are additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal risk evaluation and mitigation strategy at the FDA' s discretion. These laws, regulations, additional requirements and changes in interpretation could cause non - approval or further delays in the FDA' s review and approval of any product candidates in any respiratory program partnered with GSK. Even if product candidates in any respiratory program partnered with GSK receive regulatory approval, as is the case with RELVAR ® / BREO ® ELLIPTA ® and ANORO ® ELLIPTA ®, commercialization of such products may be adversely affected by regulatory actions and oversight. Even if GSK receives regulatory approval for product candidates in any respiratory program partnered with GSK, this approval may include limitations on the indicated uses for which GSK can market the medicines or the patient population that may utilize the medicines, which may limit the market for the medicines or put GSK at a competitive disadvantage relative to alternative therapies. These restrictions make it more difficult to market the approved products. For example, at the joint meeting of the Pulmonary - Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA regarding the sNDA for BREO ® ELLIPTA ® as a treatment for asthma, the advisory committee recommended that a large LABA safety trial with BREO ® ELLIPTA ® should be required in adults and in children ages 12 - 17, similar to the ongoing LABA safety trials being conducted as an FDA Post - Marketing Requirement by each of the manufacturers of LABA containing asthma treatments. The FDA did not concur with the recommendation. A pediatric program including patients 5 - 17 years of age is currently ongoing. In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we or GSK become aware of previously unknown problems with an approved product in the U. S. or overseas or at contract manufacturers' facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on GSK, including requiring it to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities. GSK is also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U. S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which any of the product candidates in any respiratory program partnered with GSK are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non - clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post - market surveillance, advertising, dissemination of information and promotion. Any failure to maintain regulatory approval would limit GSK' s ability to commercialize the product candidates in any respiratory program partnered with GSK, which could materially and adversely affect our business and

financial condition, and which may cause the price of our securities to fall. **Pharmaceutical research and development are very costly and highly uncertain; we may not succeed in developing, licensing, or acquiring commercially successful products. There are many difficulties and uncertainties inherent in pharmaceutical research and development, the introduction of new products, and business development activities to enhance our product pipeline. There is a high rate of failure inherent in new drug discovery and development. Failure can occur at any point in the process, including in later stages after substantial investment. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payer reimbursement or coverage, the application of pricing controls, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of new or better competitive products, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Regulatory agencies establish high hurdles for the efficacy and safety of new products and indications. Delays, uncertainties, unpredictability, and inconsistencies in drug approval processes across markets and agencies can result in delays in product launches, lost market opportunity, potential impairment of inventories, and other negative impacts. In addition, it can be very difficult to predict revenue growth rates of or variability in demand for new products and indications. We cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful. Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company' s business, results of operations, cash flow, financial condition and prospects.** Acquisitions or strategic investments we have made or may make could turn out to be unsuccessful. As part of our strategy, we frequently monitor and analyze acquisition or investment opportunities that we believe will create value for our shareholders. Existing or future acquisitions and investments could involve numerous risks that may prevent us from fully realizing the benefits that we anticipated as a result of the transaction. These risks include the failure to derive any commercial value from the acquired technology, products and intellectual property including as a result of the failure to obtain regulatory approval or to monetize products once approved, as well as risks from lengthy product development and high upfront development costs without guarantee of successful results. Patents and other intellectual property rights covering acquired technology and / or intellectual property may not be obtained, and if obtained, may not be sufficient to fully protect the technology or intellectual property. We may be subject to liabilities, including unanticipated litigation costs, that are not covered by indemnification protection we may obtain. As we pursue or consummate a strategic acquisition or investment, we may value the acquired or funded company incorrectly, fail to successfully manage our operations as our asset diversity increases, expend unforeseen costs during the acquisition or integration process, or encounter other unanticipated risks or challenges. Once an investment is made, we may fail to value it accurately, properly account for it in our consolidated financial statements, or successfully divest it or otherwise realize the value which we originally invested or have subsequently reflected in our consolidated financial statements. Any failure by us to effectively limit such risks as we implement our acquisitions or strategic investments could have a material adverse effect on our business, financial condition or results of operations and may negatively impact our net income and cause the price of our securities to fall. We have a significant amount of debt including our convertible subordinated notes and convertible senior notes that are senior in capital structure and cash flow, respectively, to our common stockholders. Satisfying the obligations relating to our debt could adversely affect our liquidity or the amount or timing of potential distributions to our stockholders. As of December 31, ~~2022~~ **2023**, we had $ ~~549~~ **453**. ~~7~~ **5** million in total debt outstanding, comprised primarily of ~~$ 96. 2 million in principal that remains outstanding under our convertible subordinated notes due 2023 (the " 2023 Notes "),~~ $ 192. 5 million in principal outstanding under our convertible senior notes due 2025 (the " 2025 Notes ") and $ 261. 0 million in principal outstanding under our convertible notes due 2028 (the " 2028 Notes ") (the ~~2023 Notes,~~ 2025 Notes and 2028 Notes, hereinafter, the " Notes "). The Notes are unsecured debt and, with the exception of the 2028 Notes, are not redeemable by us prior to the maturity date. Holders of the Notes may require us to purchase all or any portion of their Notes at 100 % of their principal amount, plus any unpaid interest, upon a fundamental change. A fundamental change is generally defined to include a merger involving us, an acquisition of a majority of our outstanding common stock ~~, and, under the 2023 Notes, the change of a majority of our board of directors without the approval of the board of directors~~. In addition, to the extent we pursue and complete a monetization transaction or a transaction that modifies our corporate structure, the structure of such transaction may qualify as a fundamental change under the Notes, which could trigger the put rights of the holders of the Notes, in which case we would be required to use a portion of the net proceeds from such transaction to repurchase any Notes put to us. Satisfying the obligations of this debt could adversely affect the amount or timing of any distributions to our stockholders. We may choose to satisfy, repurchase, or refinance this debt through public or private equity or debt financings if we deem such financings available on favorable terms. If any or all of the Notes are not converted into shares of our common stock before the maturity date, we will have to pay the holders the full aggregate principal amount of the Notes then outstanding. Any of the above payments could have a material adverse effect on our cash position. If we fail to satisfy these obligations, it may result in a default under the indenture, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall. If we lose key management personnel, or if we fail to retain our key employees, our ability to manage our business may be impaired. Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in our business. None of our employees have employment commitments for any fixed period of time and all may leave our employment at will. If we fail to retain our qualified personnel or to replace them when they leave, our ability to manage our business may be impaired, which may cause the price of our securities to fall **. To continue to commercialize our products, and advance the research, development, and commercialization of additional**

modalities, indications, and product candidates, we have expanded, and may need to further expand, our workforce. Our failure to compete effectively for talent could negatively affect sales of our current and any future approved products, and could result in material financial, legal, commercial, or reputational harm to our business . Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business. The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a lingering economic downturn or significant increase in our expenses could require additional financing at less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans. Sales of our partnered products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of negative trends in the general economy in the U. S. or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our or our partners' product sales and revenue. In addition, we rely on third parties for several important aspects of our business. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third - party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected. Our success in preclinical studies or clinical trials may not be indicative of results in current or future clinical trials. Our success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Certain product candidates may fail to show the necessary safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier- stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections because of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects. We, or our potential collaborators, may not commercialize, market, promote, or sell any product candidate without obtaining marketing approval from the FDA, the EMA or other comparable regulatory authority, and we may never receive such approvals. Even if our product candidates appear sufficiently effective and / or safe in patients in well- controlled clinical trials, it is impossible to predict if or when these product candidates will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events prior to, during, or because of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including **but not limited to** : • the FDA, the EMA or other comparable regulatory authority may change from the views they have expressed to us as to the design, implementation, and / or interpretation of our clinical trials; • the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program; • regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • clinical trials of product candidates may produce negative or inconclusive results; • we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • we may not be able to complete our clinical trials in a timely manner, if at all, for example because the number of patients required for clinical trials of our product candidates may be larger than we anticipate; • enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, or we may fail to recruit suitable patients to participate in a trial; • we may fail to comply with regulatory requirements applicable to them, to the FDA' s or other comparable regulatory authority' s, satisfaction; • third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; • the cost of clinical trials of our product candidates may be greater than we anticipate; • the FDA, the EMA or other comparable regulatory authorities may fail

to approve the manufacturing processes or facilities of third- party manufacturers with whom we enter into agreements for clinical and commercial supplies; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; • our product candidates, once exposed to greater numbers of patients, may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials or cause regulatory authorities to refuse to approve our product candidates or approve them only with significant restrictions on distribution or use; • even if our clinical trials are successful, the FDA, the EMA or other comparable regulatory authorities may determine that the overall risk- benefit profiles of our product candidates are insufficient to support marketing authorization; and • the approval policies or regulations of the FDA, the EMA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of those product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, such as black box warnings or a REMS program; • be subject to additional post- marketing testing requirements; or • be required to remove the product from the market after obtaining marketing approval. Our product development costs may also increase if we experience delays in testing and we may be required to obtain additional funds to complete clinical trials. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of a product candidate. If we are not successful in discovering, developing, and commercializing additional product candidates, our ability to expand and achieve our strategic objectives would be impaired. ~~Although~~ **We have chosen to devote** a substantial amount of our effort ~~will focus~~ on the continued clinical testing and potential regulatory approval of our product candidates **. However** , an element of our strategy ~~is to~~ **may include the** ~~develop~~ **development of** ~~and commercialize, either by ourselves or with a collaborator, our product candidates and discover and develop~~ novel product candidates in other therapeutic areas. **Our** ~~We are seeking to do so by utilizing our discovery research experience and capabilities to design active new compounds that target causative mechanisms of disease. Research~~ efforts to identify and develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including **but not limited to** the following: • the research methodology used may not be successful in identifying potential product candidates; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; • a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; • a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors, if applicable; and • the FDA, the EMA or other regulatory authorities may not approve or agree with the intended use of a new product candidate. If we fail to develop and successfully generate revenue from other current and future product candidates, our future prospects may be harmed, and we will be more vulnerable to any problems that we or potential collaborators may encounter in developing and commercializing our current product candidates. If we or our collaborators experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate, continue or complete clinical trials of our product candidates that we develop if we and our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other comparable regulatory authority. We have limited experience enrolling patients in our clinical trials and cannot predict how successful we will be in enrolling patients in future clinical trials. For instance, patients involved in our clinical trials are often in the hospital setting and the decision to participate can be made by the caregiver or doctor. Accordingly, seeking consent for patient participation may become difficult when the family and / or the patient may not be available to consider participation in a clinical trial and the providers / investigators seeking the consent often have no established relationship with the family or patient. ~~The challenges of obtaining consent for patient participation have increased during the COVID- 19 pandemic as hospitals have imposed restrictions on visitation by friends or family members who may be able to provide consent on behalf of patients. The COVID- 19 pandemic may make patients less willing to seek medical attention or return for follow- up visits post- treatment.~~ In addition, some of our competitors have ongoing clinical trials to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. If we are not successful at enrolling patients in one clinical trial, it may affect when we are able to initiate the next clinical trial, which could result in significant delays in our efforts to pursue regulatory approval of and commercialize our product candidates. Patient enrollment is affected by other factors including **but not limited to** : • the size and nature of the patient population; • the severity of the disease under investigation; • the proximity and availability of clinical trial sites for prospective patients; • the eligibility criteria for participation in the clinical trial; • the design of the clinical trial; • the perceived risks and benefits of the product candidate under study; • our ability to recruit clinical trial investigators with appropriate experience; • the availability of drugs approved to treat the diseases under study; • the patient referral practices of physicians; • our ability to obtain and maintain patient consents; • the ability to monitor patients adequately

during and after treatment; • the risk that patients enrolled in clinical trials will drop out of the trials before completion; and • the impact of public health epidemics, such as the COVID- 19 pandemic. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would reduce the capital we have available to support current and future product candidates and may result in the need to raise additional capital earlier than planned and could cause the value of our common stock to decline and limit our ability to obtain additional financing. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts (generally referred to as adverse events), to their doctor. We are required to report adverse events to the FDA and other regulatory authorities. Often, it is not possible to determine whether the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm or refute these observations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational drugs are tested in large- scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current product candidates or any future product candidates, have side effects or causes serious or life- threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which could harm our business, prospects, operating results and financial condition. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may significantly harm our business, financial condition and prospects. Additionally, if any of our product candidates receive marketing approval, regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication, or the adoption of a REMS program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners, and / or significant restrictions on distribution or use of the drug. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several potentially significant negative consequences could result, including **but not limited to** : • regulatory authorities may suspend or withdraw approvals of such product candidate; • regulatory authorities may require additional warnings on the label or impose distribution or use restrictions; • we may be required to change the way a product candidate is administered or conduct additional clinical trials, including one or more post-market studies; • we could be sued and held liable for harm caused to patients; • we may be required to implement a REMS, including the creation of a medication guide outlining the risks of such side effects for distribution to patients, and / or other elements to assure safe use; • we may need to conduct a recall; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations. Interim " top- line " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may announce interim top- line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and / or more patient data become available. Preliminary or top- line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. on entities handling personal data of consumers or households.Having gone into effect January 1,2020,the CCPA requires covered companies to provide new disclosures to California consumers,provide such consumers new ways to opt- out of certain sales of personal information,and allow for a new cause of action for data breaches.The CCPA may significantly impact our business activities and require substantial compliance costs that adversely affect business,operating results,prospects and financial condition. **Thus** ~~Any breach of our security measures or the accidental loss~~ , ~~inadvertent~~ **any access,** disclosure ~~,unapproved dissemination,misappropriation or misuse of trade secrets,proprietary information~~ or other ~~confidential~~ **loss of** information, ~~whether as a~~ **including our data being breached at our partners or third- party providers,could** result **in legal claims or proceedings and liability under laws that protect the privacy** of ~~theft~~ **personal information** , ~~hacking~~ **disrupt our operations and damage our reputation** , **which** ~~fraud,trickery or other forms of deception,or for any other cause,~~ could adversely affect our **business** If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal

fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials **. Increased scrutiny of our environmental, social or governance responsibilities will likely result in additional costs and risks and may adversely impact our reputation, employee retention and willingness of customers and suppliers to do business with us. There is an increasing focus from certain customers, consumers, employees and other stakeholders concerning environmental, social and governance (" ESG ") matters, including corporate citizenship and sustainability. Additionally, public interest and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet regulatory requirements or stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted, and customers and suppliers may be unwilling to do business with us. The standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. The disclosure frameworks we choose to align with, if any, may change from time- to- time and may result in a lack of consistent or meaningful comparative data from period to period. Ensuring there are systems and processes in place to comply with various ESG tracking and reporting obligations will require management time and expense. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, fail, or be perceived to fail, in our achievement of such initiatives or goals, or fail in fully and accurately reporting our progress on such initiatives and goals, our reputation, business, financial performance and growth may be adversely impacted. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business** . Risks Related to Our Dependence on Third Parties We rely on third parties to conduct the clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements. We have engaged contract research organizations, or CROs, to conduct our ongoing and planned clinical trials. We also expect to engage CROs for any of our other product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on government- sponsored, publicly accessible databases, such as ClinicalTrials. gov, within specified timeframes. Failure to do so by us or by third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the results of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates. We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure or regulatory noncompliance on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, resulting in additional losses and depriving us of potential product revenue. We have limited capabilities for drug development, and our product development programs and the commercialization of our product candidates will require substantial additional cash to fund expenses. As a result of these factors, we are, and expect to continue to be, dependent on collaborations relating to the development of our existing and future product candidates. We have had and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. In addition, we may seek third- party collaborators for the development and commercialization of

our product candidates, particularly for the commercialization of our product candidates outside the United States. Likely collaborators for any collaboration arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies and we may face significant competition in seeking appropriate collaborators. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future product candidates could be delayed, the commercial potential of our products could change, and our costs of development and commercialization could increase. If we enter into any future collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Our collaborations and any future collaborations we might enter into may pose a number of risks, including **but not limited to** : • collaborators often have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected or contractually obligated; • collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • collaborators may be subject to geo- political actions, natural disasters or other occurrences, including public health epidemics such as the COVID- 19 pandemic; • collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and • collaborators' decisions may limit the availability of the product supplies required for development, clinical and commercial activities. Collaboration agreements may not lead to development or **successful** commercialization of product **or commercial** candidates in the most efficient manner or at all. If a present or future collaborator were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated. Our reliance on third parties to manufacture our product candidates increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not own or operate manufacturing facilities to produce clinical or commercial supplies of the product candidates that we are developing or evaluating. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates and approved products, if any, to third parties. To conduct clinical trials of our product candidates, we will need to identify suitable manufacturers with the capabilities to manufacture our compounds in large quantities in a manner consistent with existing regulations. Our third- party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities and at any other time. If our manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed, or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business. Even if we can establish and maintain arrangements with third- party manufacturers, reliance on third- party manufacturers entails risks, including **but not limited to** : • reliance on the third party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and • supply chain disruptions due to geo- political actions, natural disasters or public healthy crises, including epidemics such as the COVID- 19 pandemic. Third- party manufacturers may not be able to comply with cGMP regulations 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 fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis. We may not be able to win government or non- profit contracts or grants to fund our product development activities. Historically, we have relied in part on funding from contracts or grants from government agencies and

non- profit entities and it is part of our strategy to continue to do so. Such contracts or grants can be highly attractive because they provide capital to fund the ongoing development of our product candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for or to otherwise be eligible to receive certain contracts or grants that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded, and the size of the contracts or grants to each awardee. Even if we can satisfy the award requirements, there is no guarantee that we will be selected to receive any contract or grant. If we are not successful in achieving this form of funding for our clinical trials, we will need to seek alternative means of funding which may not be available to the same extent, if at all. Our reliance on government funding for certain of our programs adds uncertainty to our research, development and commercialization efforts with respect to those programs and may impose requirements that increase the costs of the research, development and commercialization of product candidates developed under those government- funded programs. Aspects of certain of our development programs are currently being supported, in part, with funding from the NIH, NIAID, CARB- X and the DOD. Contracts and grants awarded by the U. S. government, its agencies and its partners, including our awards from the NIH, NIAID, CARB- X, and the DOD, include provisions that reflect the government' s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to: • terminate agreements, in whole or in part, for any reason or no reason at all; • provide grant support to potential competitor programs; • reduce or modify the government' s obligations under such agreements without the consent of the other party; • claim rights, including intellectual property rights, in products and data developed under such agreements; • audit contract- related costs and fees, including allocated indirect costs; • suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations; • impose U. S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements; • suspend or debar the contractor or grantee from doing future business with the government; • control and potentially prohibit the export of products; • pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and • limit the government' s financial liability to amounts appropriated by the U. S. Congress on a fiscal- year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period. We may not have the right to prohibit the U. S. government from using certain technologies developed by us, and may not be able to prohibit third- party companies, including our competitors, from using those technologies in providing products and services to the U. S. government. The U. S. government generally takes the position that it has the right to royalty- free use of technologies that are developed under U. S. government contracts. In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example: • specialized accounting systems unique to government awards; • mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent; • adhering to stewardship principles imposed by CARB- X as a condition of the award; • public disclosures of certain award information, which may enable competitors to gain insights into our research program; and • mandatory socioeconomic compliance requirements, including labor standards, non- discrimination and affirmative action programs and environmental compliance requirements. As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and termination of our contracts. As a U. S. government contractor, we are subject to financial audits and other reviews by the U. S. government of our costs and performance on our contracts, as well as our accounting and general business practices related to these contracts. Based on the results of its audits, the government may adjust our contract- related costs and fees, including allocated indirect costs. Risks Related to the Commercialization of Our Product Candidates Even if we obtain approvals from the FDA, the EMA or other comparable regulatory agencies and can initiate commercialization of a product candidate we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third- party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including **but not limited to**: • the efficacy and potential advantages compared to alternative treatments; • the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments; • the convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • acceptance by physicians, patients, operators of hospitals, including in- hospital formularies, and treatment facilities and parties responsible for coverage and reimbursement of the product; • the availability of coverage and adequate reimbursement by third- party payors and government authorities; • the ability to manufacture our product in sufficient quantities and yields; • the strength and effectiveness of marketing and distribution support; • the prevalence and severity of any side effects; • limitations or warnings, including distribution or use restrictions, contained in the product' s approved labeling or an approved REMS; • whether the product is designated under physician treatment guidelines as a first- line therapy or as a second- or third- line therapy for particular infections; • the approval of other new products for the same indications; • the timing of market introduction of the approved product as well as competitive products; • the emergence of bacterial resistance to the product; and • the rate at which resistance to other drugs in the target infections grow. Any failure by any of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success could have a material adverse effect on our business prospects. We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. We face competition from major multi- national pharmaceutical companies, biotechnology

companies, specialty pharmaceutical companies and generic drug companies with respect to our current and future product candidates. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of drug- resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, more effectively marketed and sold or less costly than our product candidates, which could render our product candidates non- competitive and obsolete. If our competitors obtain marketing approval from the FDA, the EMA or other comparable regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market **. Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, health authority guidelines and legislative actions could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. In the U. S., the FDA has issued several" interchangeability" designations for biosimilar products, and is expected to continue doing so in the future. These designations could – subject to state law requirements – enable pharmacies to substitute biosimilars for innovator biological products** . Many of such our competitors have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do as an organization. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA, the EMA or other comparable regulatory agencies for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or the EMA, or our competitors establish a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic drugs. Additional drugs may become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic drugs **. Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business. Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured- often in unregulated, unlicensed, uninspected and unsanitary sites- as well as the lack of regulation of their contents. The industry' s failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability** . Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved. Market acceptance and sales of any product candidates that we or our collaborators commercialize will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third- party payors, including government health care programs (such as Medicare and Medicaid), government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor- by- payor basis. One payor' s determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third- party payor' s decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor' s formulary generally determines the co- payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third- party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs, and providers are unlikely to prescribe our drugs, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our drugs and their administration. A primary trend in the United States healthcare industry and elsewhere is cost containment. Third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand, or the price of, any drug for which we obtain marketing approval for. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully

commercialize our current and any future product candidates that we develop. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • reduced resources of our management to pursue our business strategy; • decreased demand for any product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • significant costs to defend the resulting litigation; • substantial monetary awards paid to clinical trial participants or patients; • loss of revenue; and • the inability to commercialize any drugs that we may develop. We currently hold product liability insurance coverage in an amount that may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. There are a variety of risks associated with marketing our product candidates internationally, which could affect our business. We or our collaborators may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including **but not limited to** : • differing regulatory requirements in foreign countries; • the potential for so- called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • reduced level of reimbursement, pricing and insurance regimes compared to the United States; • potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geo- political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, fires, and public health epidemics, such as the COVID- 19 pandemic. These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability. Risks Related to ~~Our Business and~~ Managing Our Growth We have pursued and may continue to pursue acquisitions. Acquisitions could be difficult to integrate, divert the attention of key personnel, disrupt our business, dilute stockholder value and impair our financial results. As part of our business strategy, we have pursued and intend to continue to pursue acquisitions of complementary businesses, products, services or technologies that we believe could accelerate our ability to compete in our existing markets or allow us to enter new markets. Any of these transactions could be material to our financial condition and results of operations. If we fail to properly evaluate or integrate acquisitions, we may not achieve the anticipated benefits of any such acquisitions, and we may incur costs in excess of what we anticipate. The failure to successfully evaluate and execute acquisitions or otherwise adequately address these risks could materially harm our business and financial results. Acquisitions also frequently result in the recording of goodwill and other intangible assets which are subject to potential impairments which could harm our financial results. As a result, if we fail to properly evaluate acquisitions or investments, we may not achieve the anticipated benefits of any such acquisitions, and we may incur costs in excess of what we anticipate. The failure to successfully evaluate and execute acquisitions or investments or otherwise adequately address these risks could materially harm our business and financial results. ~~We completed the acquisition of Entasis on July 11, 2022, pursuant to which Entasis became a wholly owned subsidiary of Innoviva and the acquisition of La Jolla, on August 22, 2022, pursuant to which La Jolla became a wholly owned subsidiary of Innoviva. Our integration of the operations and personnel of each of Entasis and La Jolla and any other assets we may acquire may require significant efforts, including significant amounts of management' s time, and result in additional expenses. Factors that will affect the success of the acquisitions include the strength of our combined product pipelines, our ability to execute our business strategy, our ability to adequately fund research and development and retain key employees, and results of clinical trials, regulatory approvals and reimbursement levels of any approved product. In addition, we cannot be certain that any technology or assets we acquire will be successfully developed, become profitable or remain so.~~ Failure to realize the anticipated benefits from our acquisition of Entasis and La Jolla may affect our future results of operations and financial operations. In connection with our acquisition of Entasis and La Jolla, we have integrated the research and development, commercial operations and personnel into our existing infrastructure. If there are unexpected difficulties in our integration of these acquired businesses, the anticipated benefits of the transaction may not be realized or may take longer to realize than expected. The anticipated benefits of the acquisition could be materially reduced by a number of factors, including **but not limited to** the following: • the future revenue and gross margins of the acquired products may be materially different from those we originally anticipated; • we could incur material unanticipated expenses; • claims or lawsuits may arise from the acquisition transaction or from their previous business operations; • we may experience difficulties in implementing effective internal controls over financial reporting as part of our integration actions; and • potential growth, expected financial results, perceived synergies and anticipated opportunities may not be realized through the ongoing integration actions. The occurrence of any or all of these events may have an adverse effect on our business and results of operations. From time to time, we may evaluate various

acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including **but not limited to** : • increased operating expenses and cash requirements; • the assumption of additional indebtedness or contingent liabilities; • assimilation of operations, intellectual property and drugs of an acquired company, including challenges associated with integrating new personnel; • the diversion of our management' s attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition; • retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and • our inability to generate revenue from acquired technology and / or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technology and product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process are expensive and time- consuming. We, our current licensees, or any future licensors and licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with our best interests. 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, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensees, or any future licensors or licensees, 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, and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and / or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Any of these outcomes could impair our ability to prevent competition from third parties. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. 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 as the laws of the United States. 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. For example, European patent law currently restricts the patentability of methods of treatment of the human body more than United States law does. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies 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. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. We may not be aware of all third- party intellectual property rights potentially relating to our current and future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and Trademark Office, or USPTO, or become involved in derivation, ex- parte reexamination, or inter partes review proceedings in the USPTO or similar proceedings elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may seek to market

generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and / or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and / or assert our patents, 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 and / or unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate, a patent being held unenforceable, and / or in one or more or in patent claims being narrowed or invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the U. S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest filing date of a non- provisional application to which the patent claims priority. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our candidates might expire before or shortly after our candidates are commercialized. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union, as discussed above. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed. We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed. If we are unable to obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could materially harm our business, financial condition, results of operations, and prospects. 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 and other third parties may infringe our issued patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, 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, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable or that one or more claims of a patent are invalid, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. 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 stop the other party from using the invention at issue on the basis that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our 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 invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price 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. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property

portfolios. 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 because of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in several areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we are found to infringe a third- party' s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license 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. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain licensed technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties prior to beginning research or disclosing proprietary information. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Despite these efforts and the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information due to our reliance on third parties, 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. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, our competitors may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be

lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post- market information, are subject to comprehensive regulation by the FDA, the EMA and other foreign regulatory agencies. Failure to obtain marketing approval for a product candidate will prevent us or a potential collaborator from commercializing the product candidate. We will rely on third parties to assist us in the process of filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. We may not be able to successfully manufacture our products in compliance with applicable requirements such as GMPs. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use more narrowly than we anticipate, which could limit sales of the product. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude us from obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. Any marketing approval that we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be impaired. Failure to obtain marketing approval in foreign jurisdictions would prevent certain of our product candidates from being marketed in these territories. Any approval we are granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions. To market and sell our products in the European Union, or EU, and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA. The regulatory approval process outside the United States generally includes all the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, denial of approval in one jurisdiction may impact the ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we or our collaborators manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue. Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirements to implement a REMS or to conduct costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. 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 labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and

documentation and reporting requirements, among other things. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP. We must also comply with FDA requirements for adverse event reporting for commercial products. Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post- approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. We could also be subject to other civil or criminal penalties. Thus, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. Any product candidate for which we obtain marketing approval could be subject to post- marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved. The FDA and other federal and state agencies, including the U. S. DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off- label use and if we market our products for indications other than their approved indications, we may be subject to enforcement action for off- label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including **but not limited to** : • litigation involving patients taking our products; • restrictions on our products, manufacturers or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approve applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • damage to relationships with any potential collaborators; • unfavorable press coverage and damage to our reputation; • refusal to permit the import or export of our products; • product seizure; or • injunctions or imposition of civil or criminal penalties. Non- compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Non- compliance with U. K. and EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the U. K.' s or EU' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid; • federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent; • HIPAA, which created additional federal criminal and civil statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; • HIPAA, as amended by the HITECH Act of 2009, and their respective implementing regulations, which

impose obligations on " covered entities, " including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective " business associates " that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal Physician Payments Sunshine Act, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, which created annual reporting requirements for manufacturers of drugs, devices, biologicals and medical supplies for certain payments and " transfers of value " provided to covered recipients, including physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and • analogous state and foreign laws, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and drug pricing; state and local laws requiring the licensure of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Further, the ACA, among other things, amended the intent requirement of the federal Anti- Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. 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, including, without limitation, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business. Future legislation, and / or regulations and policies adopted by the FDA, the EMA or comparable regulatory authorities, may increase the time and cost required for us or our collaborators to conduct and complete clinical trials of our current and future product candidates. The FDA and the EMA have each established regulations to govern the product development and approval process, as have other foreign regulatory authorities. The policies of the FDA, the EMA and other regulatory authorities may change. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but not all its provisions have yet been implemented. Additionally, in August 2017, the FDA issued final guidance setting forth its current thinking with respect to development programs and clinical trial designs for antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need. We cannot predict what if any effect the Cures Act or any existing or future guidance from the FDA or other regulatory authorities will have on the development of our product candidates. Recently enacted and future legislation, including relevant provisions of the Inflation Reduction Act, may increase the difficulty and cost for us and our collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. 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. Other federal health reform measures have been proposed and adopted in the United States. For example, the Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit- based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. It is unclear how payment reductions or the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. It is also unclear if changes in Medicare payments to providers would impact such providers' willingness to prescribe and administer our products, if approved. Further, there has been heightened governmental scrutiny over the way companies set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and patient programs, and reform government program reimbursement methodologies for drug products. In particular, the recently passed Inflation Reduction Act contains provisions designed to limit the prices paid by Medicare for various

prescription drugs. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us or our collaborators from being able to generate revenue, attain profitability, or commercialize our drugs. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities 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 product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Our product candidates may be subject to government price controls that may affect our revenue. There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the former Trump Administration' s budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low- income patients. The former Trump Administration also released a " Blueprint ", or plan, to lower drug prices and reduce out- of- pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out- of- pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS' s policy change that was effective January 1, 2019. On November 20, 2020, CMS issued an interim final rule through the CMS Innovation Center whereby Medicare Part B reimbursement for " certain high- cost prescriptions drugs " would be no more than most- favored- nation price (i. e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per- capita gross domestic product. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. While some of these and other measures may require additional authorization to become effective, members of Congress and the new Biden Administration have indicated that they will continue to seek new legislative and / or administrative measures to control drug costs. For example, the recently enacted Inflation Reduction Act contains provisions designed to limit the prices paid by Medicare for various prescription drugs. At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate 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 business could be harmed. Risks Related to our Alliance with GSK Because a portion of our current revenues and near- term projected revenues have historically been derived from products under the GSK Agreements, disputes with GSK could harm our business and cause the price of our securities to fall. Historically, all of our current and near- term projected revenues have been derived from products under the GSK Agreements. We expect royalties from such products will likely continue to comprise a portion of our revenues in the future. Any action or inaction by either GSK or us that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between the parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non - performance of contractual obligations and allegations of non - performance, disagreements over the relative marketing and sales efforts for our partnered products and other GSK respiratory products, disputes over public statements, and similar matters. Because GSK is a strategic partner, it may take actions that in certain cases are materially harmful to our business or to our stockholders. GSK is a strategic partner with rights and obligations under the GSK Agreements that cause its interests to differ from our interests and those of our stockholders. In particular, GSK has a substantial respiratory product portfolio in addition to the partnered products that are covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For example, GSK could promote its non - GSK / Innoviva respiratory products or a partnered product for which we are entitled to receive a lower percentage of royalties, delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements, or take other actions, such as making public statements, that have a negative effect on our stock price. In this regard and by way of example, sales of Advair ®, GSK' s approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR ® / BREO ® ELLIPTA ®, and GSK has indicated publicly that it intends to continue commercializing Advair ®. Also, given the potential future royalty payments which GSK may be obligated

to pay under the GSK Agreements, GSK may seek to acquire us in order to reduce those payment obligations. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in our best interest or the best interest of our stockholders. GSK has also indicated to us that it believes its consent may be required before we can engage in certain royalty monetization transactions with third parties, which may inhibit our ability to engage in these transactions. GSK indicated to us that it believes that its consent may be required before we can engage in certain transactions designed to monetize the future value of royalties that may be payable to us from GSK under the GSK Agreements. GSK has informed us that it believes that there may be certain covenants included in these types of transactions that might violate certain provisions of the GSK Agreements. Although we believe that we can structure royalty monetization transactions in a manner that fully complies with the requirements of the GSK Agreements without GSK' s consent, a third party in a proposed monetization transaction may nonetheless insist that we obtain GSK' s consent for the transaction or restructure the transaction on less favorable terms. We have obtained GSK' s agreement that (i) we may grant certain pre - agreed covenants in connection with monetization of our interests in RELVAR ® / BREO ® ELLIPTA ®, ANORO ® ELLIPTA ® and vilanterol monotherapy, and (ii) it will not unreasonably withhold its consent to our requests to grant other covenants, provided among other conditions, that in each case, the covenants are not granted in favor of a pharmaceutical or biotechnology company with a product either being developed or commercialized for the treatment of respiratory disease. If we seek GSK' s consent to grant covenants other than pre - agreed covenants, we may not be able to obtain GSK' s consent on reasonable terms, or at all. If we proceed with a royalty monetization transaction that is not otherwise covered by the GSK Agreement without GSK' s consent, GSK could request that its consent be obtained or seek to enjoin or otherwise challenge the transaction as violating or allowing it to terminate the GSK Agreements. Regardless of the merit of any claims by GSK, we would incur significant cost and diversion of resources in defending against GSK' s claims or asserting our own claims and GSK may seek concessions from us in order to provide its consent. Any uncertainty about whether or when we could engage in a royalty monetization transaction, the potential impact on the enforceability of the GSK Agreements or the loss of potential royalties from the respiratory programs partnered with GSK, could impair our ability to pursue a return of capital strategy for our stockholders ahead of our receipt of significant royalties from GSK, result in significant reduction in the market price of our securities and cause other material harm to our business.

General Risks Factors **Unfavorable global economic conditions, whether brought about by material global crises, health epidemics, military conflicts or war, geopolitical and trade disputes or other factors, may adversely affect our business and financial results.** Our **business is sensitive to global economic conditions, which can be adversely affected by epidemics and other public health crises, political and military conflict, trade and other** ~~internal~~ **international disputes** ~~computer systems~~ , **significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and** ~~or~~ **our business partners and suppliers. Further, military conflicts or wars (such as the ongoing conflicts between Russia and Ukraine and Israel and Palestine) can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter- sanctions, or retaliatory cyber- attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations, such as worldwide supply chain issues. It is not possible to predict the short and long- term implications of military conflicts or wars or geopolitical tensions which could include further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber- attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets. Additionally, the operations of our suppliers and manufacturers may be located in areas that are prone to earthquakes, wildfires and other natural disasters. Such operations and facilities are also subject to the risk of interruption by drought, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, labor disputes, public health crises, and other events beyond the Company' s control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. Such events can create delays or interruptions to the Company' s development efforts and inefficiencies in the Company' s supply and manufacturing chain. Significant delays in our development efforts could materially impact our ability to obtain regulatory approval and to commercialize our products. Any public health crisis may affect our operations and those of** third **parties on which we rely, including our business partners and suppliers. The COVID** - ~~parties~~ **19 pandemic has had an adverse impact on the global economy, including as a result of impacts associated with protective health measures** that we ~~work with~~ , **other businesses and governments are taking or might have to take again in the future to manage the pandemic. Without limiting the foregoing, we have experienced and / or** may ~~fail~~ **in the future experience: • delays in receiving authorization from regulatory authorities to initiate any planned clinical trials, inspections, reviews and approvals of products; • delays or difficulties enrolling patients in** ~~or our suffer security breaches~~ **clinical trials; • delays in or disruptions to the conduct of preclinical programs and clinical trials; • constraints on the movement of products and supplies through the supply chain** , which ~~could result~~ **can disrupt our ability to conduct clinical trials and develop our products; • price increases** in ~~a~~ **raw** ~~material~~ **materials** ~~disruption of our business. Despite the implementation of security measures, our internal computer systems~~ and **capital** ~~those of third- parties with whom we work (including our~~

~~collaborative partner) are vulnerable to damage or disruption from computer viruses, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication,~~ equipment ~~and electrical failures. In the event we~~ **, as well as increasing price competition in** ~~or~~ **our markets; •** ~~they were to experience any significant system failure, accident or security breach it could cause interruptions in our operations and adversely~~ -- **adverse** ~~affect~~ **impacts on our workforce and /** ~~our~~ - **or key employees;** ~~business, financial condition~~ and **• increased risk** ~~results of operations. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches~~ that **counterparties** ~~could lead~~ to ~~disruptions in systems, misappropriation of~~ our ~~confidential,~~ **contractual arrangements will become insolvent** or otherwise **unable to fulfill** ~~protected, information and corruption of data. Additionally, California recently enacted legislation that has been dubbed the~~ **their contractual** ~~first " GDPR- like " law in the United States. Known as the California Consumer Privacy Act (" CCPA "), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security~~ obligations on entities handling personal data of consumers....., which could adversely affect our business . If we fail to maintain proper and effective internal control over financial reporting or if the interpretations, estimates or judgments utilized in preparing our financial statements prove to be incorrect, our operating results and our ability to operate our business could be harmed. The Sarbanes- Oxley Act requires, among other things, that we establish and maintain effective internal control over financial reporting and disclosure controls and procedures. Under the SEC' s current rules, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes- Oxley Act. Our independent registered public accounting firm is also required to report on our internal control over financial reporting. Our testing and our independent registered public accounting firm' s testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses and render our internal control over financial reporting ineffective. We have and expect to continue to incur substantial accounting and auditing expense and to expend significant management time in complying with the requirements of Section 404. If we are not able to maintain compliance with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to investigations or sanctions by the SEC, FINRA, The Nasdaq Global Select Market or other regulatory authorities. In addition, we could be required to expend significant management time and financial resources to correct any material weaknesses that may be identified or to respond to any regulatory investigations or proceedings. We are also subject to complex tax laws, regulations, accounting principles and interpretations thereof. The preparation of our financial statements requires us to interpret accounting principles and guidance and make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated, and expenses incurred during the reporting periods. Our interpretations, estimates and judgments are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for the preparation of our financial statements. U. S. generally accepted accounting principles (" U. S. GAAP ") presentation is subject to interpretation by the SEC, the Financial Accounting Standards Board and various other bodies formed to interpret and create appropriate accounting principles and guidance. In the event that one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results. The need to restate our financial results could, among other potential adverse effects, result in our incurring substantial costs, affect our ability to timely file our periodic reports until such restatement is completed, divert the attention of our management and employees from managing our business, result in material changes to our historical and future financial results, result in investors losing confidence in our operating results, subject us to securities class action litigation, and cause our stock price to decline. Our employees or third party providers, or employees or third party providers of our portfolio companies may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by employees, third party providers, or employees or third party providers of our portfolio companies. Misconduct by employees, third party providers, or employees or third party providers of our portfolio companies could include intentional failures to comply with applicable regulations, provide accurate information to regulatory authorities, comply with federal and state fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, the health care industry is subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. It is not always possible to identify and deter misconduct by employees, third party providers, or employees or third party providers of our portfolio companies, 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 these laws or regulations. 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, including the imposition of significant fines or other sanctions. We have incurred litigation and may incur additional litigation. We have been subject to various legal proceedings, and, in the future, we may be exposed to, or threatened with, litigation, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. In addition, agreements entered into by us sometimes include indemnification provisions which may subject us to costs and damages in the event of a claim against an indemnified third party. Regardless of the merit of particular claims, litigation may be expensive, time- consuming, disruptive to our operations and distracting to management. In recognition of these considerations, we may enter into agreements or other arrangements to settle litigation and resolve such disputes. No assurance can be given that such agreements can be obtained on acceptable terms or that litigation will not occur. These agreements may also significantly increase our operating expenses. If one or more legal matters

were resolved against us or an indemnified third party in a reporting period for amounts in excess of management' s expectations, our consolidated financial statements for that reporting period could be materially adversely affected. Further, such an outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against us that could materially adversely affect our financial condition and operating results. While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise. Failure to comply with the U. S. Foreign Corrupt Practices Act, or " FCPA ", as well as the anti- bribery laws of the nations in which we conduct business, could subject us to penalties and other adverse consequences. We are subject to the FCPA, which generally prohibits U. S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls. In addition, we are subject to the anti- bribery laws of other jurisdictions in which we conduct business. Our employees or other agents may engage in prohibited conduct without our knowledge under our policies and procedures and the FCPA and other anti- bribery laws that we may be subject to for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations. U. S. federal income tax reform could adversely affect us. On December 22, 2017, U. S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act (TCJA), was signed into law, significantly reforming the U. S. Internal Revenue Code. The TCJA, among other things, includes changes to U. S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, puts into effect the migration from a " worldwide " system of taxation to a territorial system and modifies or repeals many business deductions and credits. The TCJA is a complex revision to the U. S. federal income tax laws with disparate and, in some cases, countervailing impacts on different categories of taxpayers and industries, and will require subsequent rulemaking and interpretation in a number of areas. The long-term impact of the TCJA on the overall economy, the industries in which we operate and our partners business cannot be reliably predicted at this early stage of the new law' s implementation. There can be no assurance that the TCJA will not negatively impact our operating results, financial condition, and future business operations. The estimated impact of the TCJA is based on our management' s current knowledge and assumptions, following consultation with our tax advisors, and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. The impact of the TCJA on holders of common stock is uncertain and could be materially adverse. This Annual Report does not discuss any such tax legislation or the manner in which it might affect investors in common stock. Investors should consult with their own tax advisors with respect to such legislation and the potential tax consequences of investing in common stock. We are subject to evolving and complex tax laws, which may result in additional liabilities and affect our results of operations. We are subject to income taxes in the U. S. and other jurisdictions, and in the course of our business, we make judgments about the expected tax treatment of various transactions and events. Changes in tax laws, regulations, administrative practices, principles, and interpretations, as well as events that differ from our expectations, have affected and may adversely affect our effective tax rates, cash flows, and / or results of operations. Significant uncertainty currently exists regarding tax proposals introduced by the U. S., including modifications to certain aspects of the Tax Cuts and Jobs Act of 2017, such as the potential repeal or deferral of the provision requiring capitalization of research and development expenses. In addition, tax authorities in the U. S. and other jurisdictions in which we do business routinely examine our tax returns and are intensifying their scrutiny and examinations of profit allocations among jurisdictions, which could unfavorably impact our results of operations. Further actions taken with respect to tax- related matters by associations such as the Organization for Economic Co- operation and Development and the European Commission could influence tax laws in countries in which we operate. Modifications to key elements of the current U. S. or international tax framework could have a significant impact on our effective tax rate, results of operations, and cash flows. The widespread outbreak of an illness or any other communicable disease, or any other public health crisis, could adversely affect our business, results of operations and financial condition. The outbreak of ~~the novel coronavirus (" COVID- 19 ")~~ has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. The Company is closely monitoring developments related to the COVID- 19 pandemic to assess its impact on the Company' s business. It is possible that an extended period of global supply chain and economic disruption resulting from the COVID- 19 pandemic could materially affect our results of operations and financial condition. Under the Services Agreement with Sarissa Capital, we may rely on Sarissa Capital to assist in our strategic investing activity. On December 11, 2020, we entered into the Services Agreement pursuant to which Sarissa Capital provides substantial assistance to us in connection with our acquisition strategy. Pursuant to the terms of the Services Agreement, and subject to the limitations set forth therein, Sarissa Capital will, among other things: (i) assist Innoviva in the development of an overall acquisition and investment process and strategy; (ii) advise Innoviva on market trends, market dynamics and merger and acquisition activity; (iii) identify potential transaction targets; (iv) assist in due diligence of transaction targets and the negotiation and execution of transactions; (v) advise on the growth and operational plans, performance and integration of target companies once an investment or acquisition is made; and (vi) assist in the identification of director and officer candidates for target companies. The services are provided by Sarissa Capital personnel and we have limited or no ability to control the manner upon which the services are provided. In the event that Sarissa Capital fails to adequately perform the required services, our investment activity operations and financial performance may be negatively impacted. Our investment into the Partnership **, managed by Sarissa Capital,** could subject us to various risks and uncertainties, any of which could impact our investment results and could materially and adversely affect our business, financial condition and results of operations. Historically, we have invested our cash reserves in short- term investments and marketable securities, primarily corporate notes, government securities, government agencies, and commercial papers. On December 11, 2020, we entered into the Partnership Agreement and invested $ 300 million of our cash reserves to be managed by Sarissa Capital as the investment manager to the Partnership. While we expect that a portion of our

revenues will continue to be derived from our royalty management business **and the sales of our products** , as a result of this investment, we may derive a material portion of our income from assets managed by Sarissa Capital. The investment strategy of Sarissa Capital will focus on a concentrated portfolio of " long " positions in publicly or privately traded securities (debt or equity) and derivatives of, and other financial instruments related to, each of the foregoing, specifically in the areas of healthcare, pharmaceuticals and biotechnology. The risks associated with this investment strategy may be substantially greater than the risks associated with traditional fixed- income investment strategies or other low- yield strategies. We have limited rights to remove the general partner of the Partnership and do not have any right to participate in the management of the Partnership or the investment activity of Sarissa Capital. We are solely dependent on Sarissa Capital' s management of our investment in the Partnership. We cannot provide assurance that Sarissa Capital will be successful in meeting our investment objectives. Unexpected market volatility or losses in the Partnership' s securities portfolio could significantly and negatively affect our investment in the Partnership and therefore our investment results, financial condition or results of operations. The Partnership Agreement limits our ability to withdraw our invested funds from the Partnership. Under the terms of the Partnership Agreement, subject to limited exceptions, we are ~~not entitled to withdraw our funds invested in the Partnership until expiration of a " lock- up " period. Following the expiration of the lock- up period, we are~~ able to make annual withdrawals subject to 25 % gating provision such that we would receive our entire account in the Partnership over four fiscal quarters. Therefore, we are limited in our ability to obtain liquidity with respect to those funds and are further subjects to market fluctuations with respect thereto, particularly given the expected concentrated nature of the Partnership' s portfolio. Sarissa Capital intends to continue to manage other third party capital and is not required to dedicate any minimum amount of time to the Partnership. In addition to managing the Partnership, Sarissa Capital, its principals and their affiliates may engage in investment and trading activities for their own accounts and / or for the accounts of third parties and is not required to afford the Partnership exclusivity or priority with respect to investment or trading activities. Affiliates of Sarissa Capital manage and expect to continue to manage other client accounts which have objectives similar to the Partnership. The Partnership Agreement does not include any specific obligations or requirements concerning allocation of time, effort or investment opportunities to us or impose any restriction on the nature or timing of investments for accounts that Sarissa Capital or its affiliates may manage. The price of our securities has been volatile and may continue to be so, and purchasers of our securities could incur substantial losses. The price of our securities has been volatile and may continue to be so. Between January 1, ~~2022~~ **2023** and December 31, ~~2022~~ **2023** , the high and low sales prices of our common stock as reported on The Nasdaq Global Select Market varied between $ 10. ~~92~~ **64** and $ ~~18~~ **16** . ~~97~~ **43** per share. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years. We may be unable to or elect not to return capital to our stockholders. The payment of, or continuation of, capital returns to stockholders is at the discretion of our Board of Directors and is dependent upon our financial condition, results of operations, capital requirements, execution of our strategic initiatives, general business conditions, tax treatment of capital returns, potential future contractual restrictions contained in our credit agreement and other agreements and other factors deemed relevant by our Board of Directors. Future capital returns may also be affected by, among other factors: our views on potential future capital requirements for investments in acquisitions and our working capital and debt maintenance requirements; legal risks; stock or debt repurchase programs; changes in federal and state income tax laws or corporate laws; and changes to our business model. Our capital return programs may change from time to time, and we cannot provide assurance that we will continue to provide any particular amounts. Our announcement of future capital return programs does not obligate us to repurchase any specific dollar amount of debt or equity or number of shares of common stock. A reduction, suspension or change in our capital return programs could have a negative effect on our stock price. Anti - takeover provisions in our charter and bylaws and in Delaware law could prevent or delay a change in control of our company. Provisions of our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include: • requiring supermajority stockholder voting to effect certain amendments to our Certificate of Incorporation and Bylaws; • restricting the ability of stockholders to call special meetings of stockholders; • prohibiting stockholder action by written consent; and • establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at meetings. In addition, some provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us ~~. Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies are facing growing inflation, higher interest rates and potential recession. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the United States dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID- 19 pandemic or political disruption such as the war between Ukraine and Russia could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business~~ . The enactment of proposed or future tax legislation may adversely impact our financial condition and results of operations. On August 16, 2022, President Biden signed the Inflation Reduction Act, or the IRA. The IRA contains a number of tax related provisions including a 15 % minimum corporate income tax on certain large corporations as well as an exercise tax

on stock repurchases, both provisions are effective for tax years beginning after December 31, 2022. We are in the process of evaluating the IRA to determine any impact on our financial condition and results of operations in the future.