Risk Factors Comparison 2025-03-26 to 2024-03-07 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to Our Financial Position and Capital Resources • We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. • We have incurred significant losses since our inception and anticipate that we will incur continued losses in the future. We may never achieve or maintain profitability, and will likely require additional capital to fund our operations. • Our failure to comply with the covenants or other terms of the A & R Note Purchase Agreement, including as a result of events beyond our control, could result in a default under the A & R Note Purchase Agreement that could materially and adversely affect the ongoing viability of our business. • The A & R Note Purchase Agreement contains restrictions that limit our flexibility in operating our business. • Provisions of the Pharmakon Senior Secured Notes and the 2022 Warrants could impede a sale of the Company. • The 2022 Warrants contain anti- dilution provisions that may result in the reduction of their exercise prices in the future. Risks Related to Commercialization of XHANCE • If we are unable to successfully commercialize XHANCE, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline. • The commercial success of XHANCE will depend upon its acceptance by multiple stakeholders, including physicians, patients and third- party payors. • If third- party payors do not reimburse patients for XHANCE or if reimbursement levels are set too low for us to sell XHANCE at a profit, our ability to successfully commercialize XHANCE and our results of operations will be harmed. • If we are unable to differentiate XHANCE from current and future products or existing methods of treatments, our ability to successfully commercialize XHANCE would be adversely affected. • If the market opportunities for XHANCE are smaller than we believe, our revenue potential may be adversely affected. • We rely on HUB and PPN partners for distribution of XHANCE in the U. S., and the failure of those HUB and PPN partners to distribute XHANCE effectively would adversely affect sales of XHANCE. • If we cannot implement and maintain effective patient affordability programs or improve formulary access for XHANCE in the face of increasing pressure to reduce the price of medications, the adoption of XHANCE by physicians and patients may decline. • If the U. S. Food and Drug Administration (FDA) or other applicable regulatory authorities approve generic or similar products that compete with XHANCE, or if the FDA or other applicable regulatory authorities change or create new pathways that may expedite approval of such products, it could decrease our expected sales of XHANCE. • Even though we have obtained regulatory approval for XHANCE, we still face extensive FDA regulatory requirements and may face future regulatory difficulties. • Our relationships with physicians, patients, payors and pharmacies in the U. S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions. • Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated. Risks Related to Clinical Development and Regulatory Approval ~~of XHANCE for the Treatment of Chronic Sinusitis and Our Other Product Candidates~~ • **Delays in** ~~The design and execution of~~ clinical trials ~~to support FDA- approval of XHANCE for the treatment of chronic sinusitis is subject to substantial risk and uncertainty. • The clinical development and regulatory approval processes of the FDA~~ are **common** ~~lengthy, time consuming~~ and ~~inherently unpredictable~~ **have many causes** , and ~~if we are ultimately unable~~ **any delay could result in increased costs to us and jeopardize or delay our ability** to obtain regulatory approval ~~for our~~ **and commence** product ~~candidates~~ **sales, or** ~~or~~ **our ability to** maintain regulatory approval ~~for our approved products, our business may be substantially harmed~~ . Risks Related to Our Reliance on Third Parties • If we encounter difficulties in maintaining commercial manufacturing and supply agreements with our third- party manufacturers and suppliers of XHANCE or if we encounter issues with the performance of our contract manufacturers or suppliers, our ability to commercialize and manufacture XHANCE would be impaired. Risks Related to Our Business Operations and Industry • Our long- term growth depends on our ability to develop and commercialize additional ENT and allergy products. • Our sales force and other employees, PPN and other distribution partners, CMOs, CROs, principal investigators, collaborators, independent contractors, consultants and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. Risks Related to Our Intellectual Property • If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology, XHANCE or our other product candidates, our competitors could develop and commercialize technology similar to ours, and our competitive position could be harmed. • We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. • Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business. • Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. ~~• Changes in either U. S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.~~ Risks Related to Ownership of Our Common Stock • The price of our common stock may be volatile and you may lose all or part of your investment. • Future issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. **Risks Related to the Merger** • ~~Some provisions~~ **Failure to complete the Merger could negatively affect the price** of our ~~charter documents~~ **common stock, as well as our future business** and ~~Delaware law~~ **financial results. • Expenses related to the proposed Merger are significant and will adversely affect our operating results. • We are subject to business uncertainties and contractual restrictions while the Merger is pending, which could adversely affect our**

business. • Uncertainties associated with the Merger may ~~have anti- takeover effects that~~ **cause a loss of management and other key employees and disrupt our business relationships, which** could **adversely affect our business. • The Merger Agreement limits our ability to pursue alternatives to the Merger and may** discourage ~~an acquisition of~~ **other companies from trying to acquire** us ~~by others~~ **for greater consideration than what Paratek has agreed to pay** . MARKET, INDUSTRY AND OTHER DATA This Annual Report on Form 10- K contains estimates, projections, market research and other information concerning our industry, our business, markets for XHANCE and the size of those markets, the prevalence of certain medical conditions, XHANCE market access, prescription data and other physician, patient and payor data. Unless otherwise expressly stated, we obtain this information from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as from our own internal estimates and research and from publications, research, surveys and studies conducted by third parties on our behalf. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are reflected in this information. As a result, you are cautioned not to give undue weight to such information. PART I ITEM 1. BUSINESS Overview We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. Our first commercial product, XHANCE ® (fluticasone propionate) nasal spray, 93 microgram (mcg), is a therapeutic utilizing our proprietary Exhalation Delivery System ™ (EDS ®) that delivers a topically- acting corticosteroid for the treatment of chronic rhinosinusitis with ~~nasal polyps~~ and ~~, if approved, chronic rhinosinusitis~~ without nasal polyps ~~(also known as chronic sinusitis)~~ . Chronic rhinosinusitis is a serious nasal inflammatory disease that is treated using therapies, such as intranasal steroids (INS), which have significant limitations. We believe XHANCE has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by conventional INS. **Additionally, we believe the current practice of postoperative INS use could support XHANCE' s adoption as a maintenance therapy to improve outcomes following sinus surgery.** In September 2017, the U. S. Food and Drug Administration (FDA) approved XHANCE for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was made widely available through commercial channels in April 2018. **In March** ~~We revised our operating strategy in 2023~~ **2024** ~~to focus on increasing efficiency~~ **, the FDA approved XHANCE for the treatment of chronic rhinosinusitis without nasal polyps in patients 18 years of age and older** . ~~We reduced expenses~~ **XHANCE is the first and only drug therapy approved** by ~~$ 38 million and stabilized revenue while preparing our organization to seize~~ the **FDA for** ~~opportunity created by potential approval of XHANCE as~~ the ~~first prescription~~ treatment ~~for~~ **of** chronic rhinosinusitis without nasal polyps (also referred to **by the medical community and payers** as **,** chronic sinusitis), which is one of the most common diseases diagnosed in adult outpatient medicine. ~~We completed two Phase 3b clinical trials (which we refer to as ReOpen1 and ReOpen2) of XHANCE for a follow- on indication for the treatment of chronic sinusitis. We submitted a supplemental new drug application (sNDA) for XHANCE as a treatment for adults with chronic rhinosinusitis. The sNDA has a Prescription Drug User Fee Act (PDUFA) goal date of March 16, 2024. If the sNDA is approved, XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment of patients suffering from chronic sinusitis. Although the term chronic rhinosinusitis is often used in medical literature and medical practice, the FDA did not historically recognize chronic rhinosinusitis as an indication for drug development purposes. Instead, the FDA recognized chronic sinusitis and nasal polyps as indications for drug development purposes rather than the terminology chronic rhinosinusitis with or without nasal polyps. Recently, the FDA has approved drug products for the treatment of chronic rhinosinusitis with nasal polyps and issued a guidance document in November 2021 for clinical trial programs for nasal polyps in which it adopted the different terminology " treatment of chronic rhinosinusitis with nasal polyps " to replace the terminology " treatment of nasal polyps. " Subsequent to issuance of that guidance, FDA requested that previously approved labels for multiple drugs, including XHANCE, with an indication for " treatment of nasal polyps " be changed to reflect the new terminology, and accordingly the XHANCE indication was changed from " nasal polyps " to " chronic rhinosinusitis with nasal polyps. " This modification is the result of a change in terminology and was not based on new XHANCE clinical trial data. As a result of the FDA' s evolving view on the terminology to be applied to what was historically labeled " chronic sinusitis " and " nasal polyps ", the additional indication we are seeking under the sNDA may, if approved, use the language " for the treatment of chronic sinusitis ", " for the treatment of chronic rhinosinusitis ", " for the treatment of chronic rhinosinusitis without nasal polyps ", or other similar language.** It is our view that ~~these variations in terminology are synonymous from a promotional perspective and that all are distinct from XHANCE' s current indication. In this Annual Report on Form 10- K, we use~~ the terms" chronic sinusitis" and" chronic rhinosinusitis without nasal polyps" **are synonymous from a promotional and medical prospective, and therefore, use the terms interchangeable in this Annual Report on Form 10- K. We are relaunching XHANCE to focus on the comparatively larger market opportunity that we believe is created by the new chronic rhinosinusitis without nasal polyps indication. We plan to continue to focus our commercial efforts primarily on the ENT and allergy specialist audience while seeking partnerships to extend the commercialization of XHANCE into primary care. Net product revenues from XHANCE sales and the average net revenue per prescription from XHANCE sales for the years ended December 31, 2024, 2023 and 2022 were** as ~~being synonymous~~ **follows: In accordance with the Pediatric Research Equity Act, and as part of the FDA approvals of XHANCE for the treatment of chronic rhinosinusitis with and without nasal polyps in patients 18 years of age and older, we are required to conduct clinical trials of XHANCE for these conditions in adolescents. Under these post- marketing requirements, we are required to complete a study of XHANCE in adolescent patients 12 to 17 years of age with chronic rhinosinusitis with nasal polyps by March 2026 and submit a final report to the FDA by September 2026, and complete a study of XHANCE in adolescent patients 12 to 17 years of age with chronic rhinosinusitis without nasal polyps by March 2028 and submit a final report to the FDA by October 2028. Our study of XHANCE in adolescent**

patients with chronic rhinosinusitis with nasal polyps is ongoing, and we expect to commence the required study of XHANCE in adolescent patients with chronic rhinosinusitis without nasal polyps in 2025 . Our Growth Strategy Our goal is to become a leading specialty pharmaceutical company dedicated to developing proprietary products that become a part of the standard of care for diseases in the ENT and allergy segments. The key elements of our strategy are to: • Continue to commercialize XHANCE in the ENT and allergy specialty segments in the U. S. We believe that approximately 15, 000 targeted physicians treat an estimated 3. 5 million chronic rhinosinusitis patients, an estimated 1. 2 million of whom have chronic rhinosinusitis with nasal polyps. We have a sales force of approximately 75 territory managers who target approximately 7, 000 ENT and allergy specialists and" specialty- like" primary care physicians. **• Explore** ~~• Obtain regulatory approval of XHANCE for the treatment of chronic sinusitis and~~ expansion into ~~the~~ primary care segment **and direct- to- patient promotion** to broaden our market opportunity. We ~~completed two Phase 3b clinical trials in pursuit of a follow- on indication for XHANCE for the treatment of chronic sinusitis. We announced positive top- line results from these trials and~~ believe ~~XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment of chronic sinusitis. In addition to increasing the number of patients for whom the product can be promoted within the currently targeted physician segment, we believe approval of the new indication by FDA could be a catalyst for us to enter into one or more collaborations to broaden the marketing of XHANCE to additional~~ primary care physicians ~~that we believe~~ treat an additional estimated 6. 25 million patients in the U. S. with chronic rhinosinusitis, an estimated two ~~–~~ thirds of whom have chronic sinusitis but do not have nasal polyps. **At** ~~In addition, at~~ some point in the future, we, together with any potential partner secured for the primary care segment, intend to consider ~~directing~~ --- **direct** promotional resources to an additional estimated 20 million adult chronic rhinosinusitis sufferers who are not regularly under the care of physicians for this disease using programs such as direct- to- consumer and direct- to- patient promotion. ▪ Seek additional development candidates or approved therapies focused on the ENT and allergy specialty segments. We continue to evaluate strategic licensing, acquisition, development and commercial partnerships. These targeted opportunities could increase our growth and leverage our existing infrastructure and capabilities. ▪ Explore business development activities for the EDS outside of the ENT and allergy segments. We evaluate potential opportunities for additional uses of the EDS to support development and commercialization outside of ENT and allergy. ▪ Expand XHANCE into international markets. We intend to remain opportunistic in pursuit of select international opportunities in order to maximize the commercial potential and the availability of XHANCE to patients. Chronic Rhinosinusitis and Market Opportunity Chronic rhinosinusitis (CRS) is a serious nasal inflammatory disease significantly impacting patients' quality of life and daily functioning. CRS, unlike allergic rhinitis, is characterized by chronic inflammation affecting tissues high and deep in the nasal passages, including the area where the openings from the sinuses normally ventilate and drain, causing symptoms that persist for a period of 8 to 12 weeks or longer. CRS patients typically suffer from these symptoms four to six months a year, with symptoms often persisting for many years. In medical literature and medical practice, CRS is commonly divided into two subgroups: CRS with nasal polyps (CRSwNP) and CRS without nasal polyps (CRSsNP). CRS patients with and without nasal polyps suffer from chronic inflammation of the lining of the deep nasal passages and sinuses. Patients with CRSwNP also develop non- cancerous polyps on these chronically inflamed surfaces, typically originating in the deep crevices or sinus cavities on both sides of the nose. We estimate that up to 10 million adults in the U. S. have CRSwNP. Both subgroups of CRS share the same four defining diagnostic symptoms: (1) nasal congestion / obstruction; (2) facial pain and pressure; (3) purulent runny nose, and postnasal drip; and (4) loss of sense of smell and taste. Additional symptoms may include headaches, chronic sleep problems, fatigue, frequent episodes of acute rhinosinusitis and mood disorders. There is evidence suggesting that the harm to a sufferer' s quality of life from CRS, as measured in multiple domains, such as bodily pain, social functioning and mental health, is comparable to or worse than other serious diseases, including chronic obstructive pulmonary disease, congestive heart failure and angina. As a result, many patients eventually seek surgery for symptom relief. The American Academy of Otolaryngology- Head and Neck Surgery estimates that approximately 30 million adults in the U. S. have CRS, and it is estimated that up to 10 million adults have CRSwNP. CRS imposes a significant healthcare burden on insurers and employers. It has been reported that the U. S. healthcare system spends approximately $ 60 billion annually in direct costs treating patients with CRS and its associated symptoms, including an estimated $ 5 billion on sinus surgeries. In the U. S., physicians perform over 500, 000 sinus surgeries each year, and we estimate that as of 2017, over seven million adults had undergone sinus surgery to treat CRS with and without nasal polyps. CRS has been reported to account for an aggregate of 73 million restricted activity days per year. Additionally, people with CRS have been reported to be absent from work because of this disease 6. 5 % of the time and to suffer a 38 % loss of productivity. U. S. Market Opportunity We estimate that approximately 9. 75 million CRS patients are currently being treated in physician offices in the U. S. We derived this estimate from a large patient claims database that reflects actual treatment patterns of CRS over a two- year period from 2010 to 2012. We also estimate that approximately 10, 000 ENT and allergy specialists, as well as approximately 5, 000" specialty- like" primary care physicians, treat approximately 36 % of all CRS patients in the U. S., or approximately 3. 5 million patients, an estimated 1. 2 million of whom have CRSwNP. In accordance with multiple published clinical practice guidelines, physicians typically medically manage CRS patients by prescribing INS despite the fact that there are no FDA- approved products for the treatment of CRSsNP. **We** ~~If we obtain FDA approval for the follow- on indication for the treatment of chronic sinusitis (CS), we~~ intend to broaden, through potential collaborations, our marketing outreach to additional primary care physicians that treat an additional estimated 6. 25 million U. S. patients with CRS ~~, an estimated one- third of whom have CRSwNP~~ . We expect to execute this expansion primarily through one or more collaborations with third parties that already have a sales force calling on primary care physicians. We may also direct promotional resources to an additional estimated 20 million CRS sufferers who are not regularly under the care of physicians for this disease using programs such as direct- to- consumer and direct- to- patient promotion. Based on internal estimates, we believe the total annual U. S. market opportunity for XHANCE in the specialty segment is over $ 3. 4 billion ~~, of which approximately one- third consists of patients with CRSwNP~~ . Based on these same estimates, we believe the total

additional annual U. S. market opportunity for XHANCE in the primary care segment is over $ 6. 0 billion ~~, of which approximately one- third consists of patients with CRSwNP~~ . Therefore, we estimate the total annual U. S. market opportunity for the combined specialty and primary care segments is over $ 9. 5 billion, of which approximately one- third consists of patients with CRSwNP. Treatment Landscape The treatment of CRS with and without nasal polyps typically begins with medical management. In cases where patients remain symptomatic despite medical management, physicians often recommend various forms of sinus surgery to help restore normal sinus ventilation and drainage. The following is a brief description of the current treatment landscape and product candidates in development for CRS with and without nasal polyps: Current Therapies ▪ Intranasal Steroids. Multiple published clinical practice guidelines generally recommend topically- acting INS as the first line of prescription therapy for the treatment of CRS with and without polyps. As a result, physicians typically prescribe INS nasal sprays or nasal aerosols **,** despite the fact that **prior to the approval of XHANCE in March 2024,** there ~~are~~ **were** no FDA- approved products for the treatment of CRSsNP. Therefore, the majority of chronic rhinosinusitis sufferers being treated have tried INS. We estimate that physicians in the U. S. prescribe approximately 17 million INS prescriptions each year for the treatment of chronic rhinosinusitis, which includes, among other INS products, a generic fluticasone propionate nasal spray. The only other branded INS to receive an indication for the treatment of nasal polyps is Nasonex ™, which was marketed by Merck & Co., Inc. before being removed from the prescription market but is available over- the- counter without a prescription for other indications. Generic versions of Nasonex ™, mometasone furoate monohydrate, remain available as prescription drugs. Physicians not only prescribe INS as a standalone therapy, but also typically prescribe INS following sinus surgery as some third- party clinical trials suggest that INS treatment can improve symptoms and delay symptom recurrence. In lieu of prescription INS nasal sprays, physicians may recommend use of over- the- counter INS nasal sprays including over- the- counter products containing fluticasone propionate and mometasone furoate monohydrate. ▪ Oral steroids. Physicians may prescribe oral steroids on an episodic basis to patients who have not received sufficient symptomatic relief from INS. Oral steroids are often effective at treating the underlying inflammation associated with the disease and reducing postoperative scarring, but the benefit is temporary. As inflammation returns, many patients resume INS therapy. ▪ Monoclonal antibodies. In June 2019, the FDA approved DUPIXENT ™ as an add- on (to an INS) maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis. In November 2020, the FDA approved XOLAIR ™ **as an** add- on maintenance treatment of nasal polyps in adult patients with inadequate response to nasal corticosteroids. In July 2021, the FDA approved NUCALA ™ **as an** add- on maintenance treatment of chronic rhinosinusitis with nasal polyps in adult patients with inadequate response to nasal corticosteroids. In addition, these monoclonal antibodies may be studied as potential treatments for patients with chronic rhinosinusitis without nasal polyps. ▪ Other medical management. Physicians commonly employ a variety of other non- surgical treatments in the medical management of chronic rhinosinusitis, including nasal saline rinses, multi- week courses of antibiotics, leukotriene antagonists, decongestants, aspirin desensitization and antifungals. The recognized limitations of drug deposition with current INS cause some physicians to seek out alternative treatment regimens, such as high doses of locally compounded liquid budesonide in high- volume nasal rinses. Chronic rhinosinusitis is one of the most common reasons for adult outpatient antibiotic use in the U. S., comprised of approximately 37 million prescriptions per year. ▪ Sinus surgery and other procedures. Physicians generally recommend surgical treatment of chronic rhinosinusitis with and without nasal polyps only after patients fail medical management. The primary surgical alternative is Endoscopic Sinus Surgery (ESS), which attempts to open the sinus drainage pathways while preserving as much bone and sinus tissue lining as possible. The physician typically uses rigid steel instruments and powered cutting tools to remove inflamed tissue, including any nasal polyps, and underlying bone and cartilage to create a larger passage through the nasal anatomy to the sinuses. At the conclusion of the procedure, patients often have their nasal passages packed with a material that acts as a spacer to prevent surgical adhesions and control bleeding. Patients typically require one or more follow- up debridement treatments in which the physician may remove more tissue, crusting, scabs or scar tissue at the area of surgery in order to keep the sinus drainage pathway open and promote proper healing. Several companies have developed less invasive technologies for the treatment of chronic rhinosinusitis since the introduction of ESS, such as balloon sinus dilation devices and steroid- releasing sinus implants. Balloon sinus dilation employs a high pressure inflated balloon to open blocked sinus pathways to increase ventilation and mucus drainage. Steroid- releasing sinus implants are used to hold open the surgically enlarged sinus, while releasing a steroid over a period of time in order to reduce postoperative sinus inflammation and scarring. SINUVA ® (mometasone furoate) sinus implant is a commercially available corticosteroid- eluting implant indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. In the SINUVA clinical studies, patients were advised to use nasal steroid sprays and sinus rinses for the duration of the study. Potential Future Therapies Additional potential future therapies include but are not limited to monoclonal antibodies, and corticosteroid- eluting implants. Benralizumab **, depemokimab,** and tezepelumab, **some of** which are already approved for other indications, are being developed for the treatment of nasal polyps, and are believed to inhibit specific pathways of inflammation present in nasal polyps. Lyra Therapeutics is developing corticosteroid- eluting implants as potential treatment for patients with chronic rhinosinusitis. In addition, Insmed is studying brensocatib as a potential treatment for chronic rhinosinusitis without nasal polyps. Limitations of Therapies The current and potential future therapies to treat patients suffering from chronic rhinosinusitis with and without nasal polyps have a number of limitations, including: ▪ Limited efficacy of INS treatments using traditional nasal sprays and nasal aerosols. Although steroids are generally pharmacologically effective, conventional INS, including nasal sprays and nasal aerosols, are unable to effectively and consistently place the steroids onto the primary site of inflammation and nasal polyp origin, high and deep in the nasal passages. These products deposit a majority of the drug in the front of the nose or on the floor of the nasal passages, reducing their effectiveness and leaving many patients without sufficient symptomatic relief. ▪ Short- term benefits of oral steroids outweighed by significant side effects. Oral steroids offer only temporary benefit and are limited by the risk of significant systemic side effects associated with both short- and long-

term use. These side effects include, among others, weight gain; increased risk of infections; loss of bone mineral density; death of bone tissue; cataract formation; glaucoma; adrenal suppression; and psychiatric complications, including mania, depression, and psychosis. ▪ Varying degrees of efficacy with other medical management. Other non- surgical treatments have varying degrees of supporting data and efficacy. In addition, high- volume steroid nasal rinses are difficult to administer, can be costly, may risk systemic side effects due to the absorption of the steroid into the body, can be associated with fluid draining from the nose after the procedure and are difficult for patients to comply with over prolonged courses of outpatient therapy. ▪ Sinus surgery and other procedures are costly and may not be a complete solution. The effectiveness of sinus surgery varies significantly and many patients experience persistent or recurrent symptoms. Reports indicate that nasal polyp regrowth following surgery occurs in as high as 60 % of cases within four years. In addition, it has been reported that up to 80 % of patients continued to have symptoms within two years of surgery. Because sinus surgery is often not curative and may not address the underlying cause of the inflammation, many patients receive short- and long- term courses of INS after surgery and approximately 20 % of patients elect surgical revisions. Postoperative scarring and persistent inflammation are common and can compromise symptom outcomes and also negatively impact the ability of the sinuses to heal. Sinus surgery is also a costly procedure, with estimated costs on average **of** $ 13, 500 per procedure **, based on data published in 2019** . While balloon sinus dilation has the ability to open sinuses in a less invasive manner, it also may not address the underlying cause of the inflammation associated with chronic rhinosinusitis and is costly. Similarly, steroid- releasing sinus implants have limited duration of anti- inflammatory effect, are costly and face reimbursement challenges. ▪ Treatment with monoclonal antibodies is costly, difficult to administer and may have negative side effects. The current FDA- approved monoclonal antibodies for the treatment of nasal polyps cost approximately $ ~~36~~ **37** , 000 to $ ~~49~~ **52** , 000 per year. Monoclonal antibodies also require subcutaneous injections or intravenous administration. We believe the systemic nature of these treatments, which target components of the immune response, may result in more adverse side effects than treatments with topically- acting steroids. Our Solution XHANCE combines the EDS with a liquid formulation of fluticasone propionate, a well- characterized, second- generation corticosteroid. XHANCE is designed to deliver medication into the high and deep regions of the nasal passages where both nasal polyps and inflamed and swollen membranes can obstruct normal sinus ventilation and drainage. In multiple studies utilizing advanced imaging, the EDS produced a differentiated pattern of drug delivery in healthy subjects with significant drug deposited in the high and deep regions of the nasal passages, areas not well accessed by conventional INS delivery mechanisms. We believe XHANCE has the potential to become part of the standard of care for the treatment of patients with chronic rhinosinusitis that are dissatisfied with the relief they obtain from conventional INS and before they progress to more costly treatment alternatives. We also believe that the current treatment practice of postoperative INS use could support XHANCE' s adoption as a maintenance therapy to improve outcomes following sinus surgery. To support FDA approval of XHANCE as a treatment for nasal polyps, we conducted five clinical trials evaluating over 1, 500 adult patients, including two randomized, double- blinded, placebo- controlled Phase 3 pivotal clinical trials in adults with nasal polyps and two supportive open- label Phase 3 clinical trials in adults with symptoms of chronic sinusitis with or without nasal polyps. In both Phase 3 pivotal clinical trials, patients treated with XHANCE experienced statistically significant reductions of both nasal congestion / obstruction symptoms and total polyp grade, which were the co- primary endpoints. Treatment benefits were also observed in all four defining symptoms of chronic rhinosinusitis, as well as in polyp elimination (reduction of polyp to grade 0), quality of life measures, need for sinus surgery based on study- defined criteria and patient global impression of change. In addition, the magnitude of improvement for patients treated by XHANCE in our Phase 3 pivotal clinical trials, as measured by the Sinonasal Outcome Test- 22, a validated clinical outcome assessment, was comparable to the reported benefits in third- party studies of endoscopic sinus surgery (ESS) and balloon sinus dilation. In our supportive open- label Phase 3 clinical trials, which evaluated approximately 900 patients with symptoms of chronic sinusitis with and without nasal polyps for a period of up to one year, XHANCE was generally well tolerated and produced results on efficacy measures similar to those observed in our Phase 3 pivotal clinical trials. In these supportive trials, we observed comparable symptom improvements in patients with and without nasal polyps and continuing incremental polyp reduction and symptom improvement through 12 months. XHANCE had an adverse event profile generally comparable to the profile reported in similarly designed trials with conventional INS. The most common adverse reactions (incidence ≥ 3 %) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis. **To support** ~~In September 2017, the~~ FDA ~~approved~~ **approval** ~~our NDA~~ **of XHANCE as a treatment** for **chronic rhinosinusitis without** ~~XHANCE for the treatment of~~ nasal polyps ~~in~~ **, we conducted two randomized, double- blinded, placebo- controlled Phase 3 pivotal clinical trials evaluating more than 550 adult** patients ~~18 years of age or older~~ **, in adults with chronic rhinosinusitis** . In ~~January 2023~~ **both trials** , **patients treated with XHANCE experienced statistically significant reductions on two co- primary endpoints of: (i) change in a composite score of nasal congestion / obstruction symptoms, nasal discharge, and facial pain and pressure from baseline to week, and (ii) change in average percent of opacified volume of** the ~~indication statement~~ **ethmoid and maxillary sinuses from baseline to week 24. In addition, pooled results from the ReOpen program were used to perform pre- planned analyses including: (i) an analysis of symptom improvement** for **patients entering the trials with at least moderate symptoms despite reporting use of a standard nasal steroid spray and (ii) an analysis of pooled data which found that the 372 mcg treatment group achieved a type 1 error controlled statistically significant reduction of 66 % in the incidence of exacerbations compared to placebo comparator. Exacerbations were defined as a worsening of at least one of the four cardinal symptoms of chronic sinusitis (nasal congestion / obstruction, rhinorrhea, facial pain / pressure, and loss of sense of smell) lasting at least 3 days accompanied by an escalation in medical care, such as doctor visits or antibiotic or steroid prescription.** XHANCE was **well tolerated across** ~~changed from " for~~ the ~~treatment of nasal polyps " to " for~~ **186- and 372- mcg dose groups and** the ~~treatment of chronic rhinosinusitis~~ **safety profile in the ReOpen program was generally consistent** with **the safety profile contained in** ~~nasal~~

~~polyps " to reflect current FDA labeling terminology and not based on new~~ XHANCE **' s previously** ~~clinical data. In March and June 2022, we announced positive top line results from our two Phase 3b clinical trials in of XHANCE for a follow- on indication for the treatment of chronic sinusitis. In February 2023, we submitted a prior approval efficacy supplement (sNDA) to support the approval of a new indication for XHANCE for the treatment of chronic sinusitis. FDA accepted the filing and set a PDUFA goal date of December 16, 2023. In December 2023, FDA notified us that it required additional time to complete its review, and that the PDUFA goal date for the sNDA would be extended to March 16, 2024. If the sNDA is~~ approved ~~,~~ ~~XHANCE has~~ **label. No serious adverse events were reported in** the **ReOpen program** ~~potential to be the first drug therapy approved by the FDA for the treatment of chronic sinusitis~~ . We believe XHANCE offers a cost- effective treatment solution to payors who are increasingly being asked to pay for multiple high- cost therapies for a variety of diseases priced at tens of thousands of dollars per year. As of January 1, ~~2024~~ **2025** , the wholesale acquisition cost for XHANCE was $ ~~626~~ **656** . ~~82~~ **34** . XHANCE is priced significantly higher than low cost generic INS and over- the- counter (OTC) INS products. We expect XHANCE to be adopted by physicians at a natural point in the care pathway for use in patients with chronic rhinosinusitis with **and** ~~or (if approved)~~ without nasal polyps after treatment failure with cheaper generic or OTC traditional INS therapies but before they progress to costly surgical interventions and monoclonal antibodies. We estimate that sinus surgery costs on average $ 13, 500 per procedure **based on data published in 2019** , and monoclonal antibodies cost approximately $ ~~36~~ **37** , 000 to $ ~~49~~ **52** , 000 per year based on the wholesale acquisition cost and recommended dosing for XOLAIR ™ (omalizumab), NUCALA ™ (mepolizumab), and DUPIXENT ™ (dupilumab) **as of January 2025** . The Exhalation Delivery System (EDS) The EDS enables the development of drug- device combination products intended for self- administration. We have developed both a liquid delivery EDS and a powder delivery EDS utilizing natural functional behaviors of the upper nasal airways intended to offer better drug deposition. The EDS is designed to overcome many limitations inherent in conventional nasal spray and nasal aerosol delivery systems, most notably, enabling higher and deeper intranasal drug delivery. Liquid Exhalation Delivery System The liquid EDS depicted below, which is the EDS used in XHANCE, consists of the primary drug container for the liquid drug formulation, an amber glass vial sealed by a crimp- fitted metering spray pump, enclosed within a proprietary liquid delivery subassembly. The nasal spray applicator, which is a component of the subassembly, is attached to the pump and extends to the top of the nosepiece of the liquid delivery subassembly. The EDS includes a flexible mouthpiece and an asymmetrically- shaped nosepiece, covered by an orange cap, as part of a mechanism that uses the patient' s exhaled breath to naturally seal closed the soft palate and to facilitate delivery of drug to the nasal passages through the sealing nosepiece. The nosepiece is designed to create a seal with the nostril and also to expand and stent the upper part of the nasal valve, which is an important anatomical structure that is the narrowest part of the entire respiratory tract and a barrier that causes most medication delivered by conventional INS to deposit in the front part of the nose. Powder Exhalation Delivery System The powder EDS depicted below, which is the EDS used in Onzetra ® Xsail ®, consists of a reusable device body incorporating a flexible mouthpiece to adjust to individual anatomic variations, and a white button piercing assembly to pierce the medication capsule. Disposable nosepieces are provided in a foil pouch to be inserted into the drug delivery device body. Each pre- filled nosepiece section contains a medication capsule containing a dry powder formulation and a clear release tab. The capsule is pierced by pressing and releasing the white button piercing assembly. The flexible mouthpiece and an asymmetrically- shaped nosepiece are part of the mechanism that uses the patient' s exhaled breath to naturally seal closed the soft palate and to facilitate delivery of drug to the nasal passages through the sealing nosepiece. The medication capsule is intended for single dose administration and is not refillable or removable from the nosepiece. Following drug administration, the disposable nosepiece, including the dose-expended medication capsule, is then removed and discarded. How the Exhalation Delivery System (EDS) works When exhaling into the EDS, the soft palate automatically elevates and creates an air- tight seal separating the nasal cavity from the throat and lungs. This natural action is the same as that which prevents air from escaping from the nose when trying to blow up a balloon or blow a trumpet. The exhaled air is then routed through the EDS which introduces medication into the air flow and then directs the air and medication through the sealing nosepiece. The positive air pressure, which is the opposite of the negative pressure produced by sniffing with ordinary nasal sprays, acts to dynamically expand the nasal valve and the narrowed nasal passages, helping to deliver the drug around obstructing anatomic barriers and fill one side of the nasal cavity. This enables high and deep deposition of medication in the nasal passages. The positive air pressure, proportional to the pressure on the other side of the soft palate, helps to open a passage between the two sides of the nasal cavity, behind the back edge of the nasal septum. The picture below illustrates this action, which allows the exhaled air pressure to escape from the opposite nostril. The drug delivery mechanism of the EDS is designed to overcome the drug deposition shortcomings of conventional nasal sprays and nasal aerosols. In conventional nasal sprays and nasal aerosols, the medication is inhaled or sniffed into the nose creating negative pressure within the nasal passages, which does not facilitate the expansion of the nasal valve or the nasal passages and may obstruct the drug from reaching deep into the nose where most nasal polyps and inflamed and swollen sinus membranes exist. The pattern of drug deposition produced by conventional nasal sprays and the EDS has been evaluated in multiple studies using a combination of advanced imaging modalities to depict the regions of the nasal passages where drug is deposited after administration in healthy human volunteers. In an open label, crossover study conducted by a third party in nine patients with allergic rhinitis, investigators examined the nasal deposition of radio- labeled materials that allow for traceability following use of Qnasl ™ (HFA- beclomethasone, nasal aerosol), Flonase ™ (fluticasone propionate, nasal spray) and Nasonex ™ (mometasone furoate monohydrate, nasal spray). In this study, gamma cameras were used to capture emitted radiation from these tracers to create two- dimensional images in a similar process to the capture of x- ray images. These gamma images were merged with magnetic resonance images (MRI) to quantify regional deposition within the nasal passages. The images below illustrate how the pattern of drug deposition in the nasal passages produced by Qnasl ™, Flonase ™ and Nasonex ™ was concentrated in the front and lower regions of the nasal passages, as opposed to the high and deep regions of the nasal passages targeted in the treatment of CRS. 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DRUG DELIVERY 28 / 8, 2015, by Leach et al, published by Mary Ann Liebert, Inc., New Rochelle, NY. We conducted six deposition studies evaluating 53 healthy subjects that produced approximately 250 images. As depicted in the representative figures below, the EDS produced a differentiated pattern of drug delivery with significantly more drug deposited in the high and deep regions of the nasal passages. The pictures above use gamma camera image information, which was then superimposed on the corresponding MRI section. These images represent deposition in healthy subjects two minutes after delivery using a traditional liquid nasal spray and a version of the liquid EDS. Deposition with traditional liquid nasal spray was greatest in the front parts of the nose, whereas deposition with the EDS was greatest in the high and deep regions of the nose. The pictures below illustrate how the liquid EDS (with exhalation) places medication higher and deeper in the nasal passages than a conventional nasal spray (without sniffing) in nasal cast models. As depicted below, although conventional nasal spray systems can reach, and therefore treat, large nasal polyps, they are not generally suitable for reaching nasal polyps or inflammation in the higher and deeper regions where obstruction of the sinus openings occurs. The liquid EDS is also designed to address user dissatisfaction with conventional nasal delivery by reducing drug drip- out from the front and back of the nose and the bad taste that often accompanies drug entering the throat. By reducing the loss of drug to non- targeted sites, such as the gastrointestinal tract by swallowing, or lungs, the EDS has the potential to improve the efficiency of drug activity and to improve tolerability by reducing off- target effects. ~~Our Pipeline XHANCE for Chronic Sinusitis In addition to XHANCE' s existing indication for the treatment of nasal polyps, in order to broaden our U. S. market opportunity, we conducted a clinical trial program in pursuit of a follow- on indication for the treatment of CS in the U. S. We announced positive top- line results from the clinical trials in March and June 2022 and submitted a supplemental new drug application (sNDA) in February 2023. FDA accepted the filing and set a PDUFA goal date of December 16, 2023. In December 2023, FDA notified us that it required additional time to complete its review, and that the PDUFA goal date for the sNDA would be extended to March 16, 2024. If the sNDA is approved, XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment of chronic sinusitis. In the future, as appropriate, we intend to broaden, through potential collaborations, our commercialization efforts to additional primary care physicians that we believe treat an additional estimated 6. 25 million U. S. patients with chronic rhinosinusitis, an estimated one- third of whom have chronic rhinosinusitis with nasal polyps. In addition, at some point in the future, we intend to consider, with a collaboration partner, directing promotional resources to an additional estimated 20 million adults who are not regularly under the care of physicians for this disease using programs such as direct- to- consumer and direct- to- patient promotion.~~ EDS Technology We opportunistically evaluate opportunities to develop product candidates using the EDS and related technologies for indications and markets outside of our ENT and allergy focus through business development and partnering activities. Although our current focus is to prioritize the successful commercialization of XHANCE for the ENT and allergy specialty segment and the pursuit of FDA approval of XHANCE for the treatment of chronic sinusitis, we may apply or out- license the EDS and related technology to other product candidates across a broad range of disease areas. For example, by placing drug high and deep in the nose, in regions where cranial nerves connect directly with the brain, we believe it may be possible to deliver medications directly into the brain and avoid the difficulties of getting drug past the blood- brain barrier. This may enable treatment of brain diseases using small or large molecules that otherwise do not readily enter the nervous system. Sales and Marketing We have established a commercial infrastructure designed to drive adoption and sales of XHANCE with healthcare professionals who treat patients with ~~nasal polyps~~ **chronic rhinosinusitis** . We believe that approximately 15, 000 physicians treat an estimated 3. 5 million chronic rhinosinusitis patients, an estimated 1. 2 million of whom have chronic rhinosinusitis with nasal polyps. Customer Model. **We have** ~~At the start of 2022 we had~~ a sales force of **75** ~~approximately 90~~ territory managers who targeted ~~over 10~~ **approximately 7** , 000 ENTs, allergists and " specialty- like " primary care physicians. ~~At~~ **In order to increase** the ~~end~~ **frequency** of ~~2022~~ **in- person promotion** we ~~had~~ reduced the ~~size~~ **number** of ~~our sales~~ **target physicians** ~~force~~ -- **for** ~~to~~ **territory manager call plans from** approximately **105 to** 75 ~~territory managers,~~ **in the fourth quarter of 2024 and** as **a result** ~~part of actions intended to reduce our operating expenses, who target~~ **targeted** approximately ~~7~~ **5** , ~~000~~ **600** ENTs, allergists and " specialty- like " primary care physicians. In addition to in- person promotion by our territory managers we target additional physicians through digital and non- personal promotion in areas where we do and do not have territory managers. Our sales team is equipped with educational materials demonstrating the benefit and safety profile of XHANCE. In the future ~~, particularly after receipt of a potential future new indication for the treatment of chronic sinusitis~~ , we may increase the number of geographic territories as well as hire additional territory managers in order to increase the number of called- on target physicians and frequency of calls. We believe that in the long term, direct to consumer (DTC) advertising could be an effective way to increase XHANCE prescription growth. XHANCE Co- Pay Savings Program. We believe our co- pay savings program provides an affordability solution for patients that physicians will support. This program provides patient co- pay assistance to eligible commercially insured patients. These patients may obtain XHANCE for as little as $ 0 out- of- pocket. Market Access. Based on currently available third- party data as of ~~December~~ **January** 31, ~~2023~~ **2025** , we believe that approximately 70 % of insured lives are currently in a plan that covers XHANCE. However, payors may change coverage levels for XHANCE, positively or negatively, at any time. Additionally, payors generally impose restrictions on access to or usage of XHANCE, such as by requiring prior authorizations or" step- edits". For example, insurers may require that a physician attest that they are treating a patient for an approved indication prior to becoming eligible for coverage for XHANCE. **As of January 31, 2025,** ~~Approximately~~ **approximately** half of the **commercial** covered lives **in plans that cover XHANCE** ~~as of December 31, 2023~~ are in a plan that requires a prior authorization and most of those prior authorizations request information regarding prior use of INS and patient diagnosis. In some cases, patients do not meet the payors' utilization management criteria, and in other cases, healthcare providers may not complete the administrative process required to demonstrate or document that the patients for whom XHANCE has been prescribed meet the payors' utilization management criteria (i. e., prior authorizations or step- edits) and, as a result, patients may not gain access to XHANCE treatment. In our contract negotiations with payors we seek to balance patient access and affordability, breadth of coverage, payor utilization management and rebates levels. Trade and

Distribution. ~~We currently sell~~ **Historically, we sold** XHANCE primarily to PPN partners. We established this channel to offer patients the option of filling prescriptions through a network of preferred pharmacies that may be able to better serve the needs of patients through services including delivery of XHANCE by mail and performing certain patient services such as patient insurance benefit verification. **In January 2024 we launched a patient support program which serves as a central intake pharmacy model (referred to as a" HUB") and provides patients with support by navigating payor restrictions and offering affordability solutions. During the second quarter we transitioned a significant proportion of the XHANCE business from our historical preferred pharmacy network to the HUB.** We also sell XHANCE to wholesale pharmaceutical distributors, who, in turn, sell XHANCE to retail **and specialty** pharmacies **(including our prior PPN partners)** , hospitals and other customers. We have contracted with a third- party logistics provider for key services related to logistics, warehousing and inventory management, and distribution. Further, our third- party logistics provider provides customer order fulfillment services and accounts receivable management. ~~In addition, in January 2024 we launched a patient support program which serves as a central intake pharmacy model (referred to as a" HUB") and provides patients with support by navigating payor restrictions and offering affordability solutions. In the future, we may expand our use of our HUB for prescriptions.~~ Customers Approximately ~~77~~ **59** % of our XHANCE net revenues during the fiscal year ended December 31, ~~2023~~ **2024** were to PPN partners. The three leading PPNs accounted for approximately ~~25~~ **36** % of our XHANCE net revenues. The largest PPN was Professional Arts Pharmacy which accounted for approximately ~~15~~ **25** % of our XHANCE revenue. Additionally, approximately ~~23~~ **41** % of our XHANCE net revenues during the fiscal year ended December 31, ~~2023~~ **2024** were to the three largest wholesale pharmaceutical distributors, Cardinal Health, McKesson Corporation, and AmerisourceBergen Drug Corporation. Manufacturing We contract with third parties for the manufacture, testing and storage of XHANCE. In our experience, contract manufacturers (CMOs) are generally cost- efficient and reliable and therefore we currently have no plans to build our own manufacturing capabilities. Because we rely on CMOs, we employ personnel with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record- keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program **. We purchase XHANCE and its components from several third- party suppliers and manufacturing partners, certain of which are available through a single source. Although we could obtain each of these components from alternative third- party suppliers, we would need to qualify and obtain FDA approval for another supplier as a source for each such component** . We have entered into the following key supply agreements for the commercial manufacture and supply of XHANCE: ▪ A supply agreement with Hovione Inter Ltd for the supply of fluticasone propionate, the active pharmaceutical ingredient included in **XHANCE** ~~the liquid suspension formulation~~ . This agreement ~~was amended and renewed in December 2023 and now~~ terminates ~~in~~ on December 31, ~~2024~~ **2026** , subject to earlier termination or extension in accordance with the terms of the agreement. ▪ A manufacture and supply agreement with Contract Pharmaceuticals Limited Canada (CPL) for the formulation and assembly of ~~the~~ finished **dose forms of XHANCE** ~~drug product during the fill / pack operation~~ . This agreement ~~was amended and renewed in February 2021 and now~~ terminates on December 31, ~~2024~~ **2026** , subject to earlier termination or extension in accordance with the terms of the agreement. • A manufacturing services agreement with Advance Mold & Manufacturing, Inc. for the manufacture of the liquid delivery sub- ~~assembly~~ **assemblies for XHANCE** , which consists of injection molded parts and other purchased components. The agreement ~~expired in October 2023 (subject to earlier termination~~ **terminates on December 31, 2025** ~~or extension in accordance with its terms)~~ but ~~was~~ automatically ~~renewed~~ **renews** for ~~a~~ successive one- year ~~term~~ **terms** through ~~October~~ **December 31,** ~~2024~~ **2026** , unless either party provides at least ninety days prior written notice to the other that it does not intend to renew the agreement. **• A manufacture and supply agreement with Hikma Pharmaceuticals USA, Inc. for the manufacture and supply of finished dose forms of XHANCE. The agreement terminates on December 31, 2026, subject to earlier termination or extension in accordance with the terms of the agreement.** We believe our third- party manufacturers have adequate capacity to manufacture sufficient quantities of XHANCE to meet anticipated commercial demands ~~and we are pursuing opportunities to decrease our reliance on sole- source suppliers and increase the third party manufacturing capacity that is available to us. We have initiated the process of qualifying alternate third party suppliers for select components of XHANCE. Alternate third party suppliers of XHANCE components are subject to qualification and approval from the FDA~~ . Competition Our industry is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We believe our scientific knowledge, technology, and development capabilities provide us with substantial competitive advantages, but we face potential competition from multiple sources, including large pharmaceutical, biotechnology, specialty pharmaceutical and, to a lesser degree, medical device companies. XHANCE competes primarily with INS, oral steroids, monoclonal antibodies and other medical management products, including locally compounded liquid budesonide in high- volume nasal rinses. XHANCE also competes with surgical procedures, balloon sinus dilation products and steroid- releasing sinus implants. Key competitive factors affecting the commercial success of XHANCE and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement. The only other branded INS to receive an indication for the treatment of nasal polyps is Nasonex ™, which was marketed by Merck & Co., Inc. before being removed from the prescription market but is available over- the- counter without a prescription for other treatment indications. Generic versions of Nasonex ™, mometasone furoate monohydrate, were first approved by the FDA for, among other indications, the treatment of nasal polyps and launched in 2016 and remain available by prescription. Also, Beconase AQ ™, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection. In addition, SINUVA ™

is a commercially available corticosteroid- eluting implant indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. In the SINUVA ™ clinical studies, patients were advised to use INS and sinus rinses for the duration of the study. Also, Lyra Therapeutics is developing corticosteroid- eluting implants as potential treatment for patients with chronic rhinosinusitis. There are no products approved for the treatment of chronic sinusitis without nasal polyps. There are two categories of INS: first-generation INS products, which include Rhinocort ™, Nasacort AQ ™ and Qnasl ™; and second- generation INS products, which include Flonase ™, Veramyst ™, Omnaris ™ and Zetonna ™. The primary difference between first- and second-generation INS products is that first- generation INS are absorbed into the blood to a greater extent than second- generation INS, with systemic bioavailability ranging from 10 % to 50 % compared to a systemic bioavailability with fluticasone propionate, a second- generation INS, of less than 2 %. Many of the most widely- prescribed INS products are available in generic form and some, such as Flonase ™ (which contains fluticasone propionate the same active pharmaceutical ingredient as XHANCE), Nasonex (which contains mometasone furoate monohydrate) and other products containing fluticasone propionate and mometasone furoate monohydrate, are available over- the- counter without a prescription at prices generally ranging from approximately $ 15- 30 per month supply. Several companies have developed or are currently developing monoclonal antibodies for the treatment of nasal polyps. These monoclonal antibodies, which inhibit specific pathways of inflammation present in nasal polyps, include benralizumab **, depemokimab** , tezepelumab, DUPIXENT ™, XOLAIR ™, and NUCALA ™. In June 2019, the FDA approved DUPIXENT ™ as an add- on (to an INS) maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis. In November 2020, the FDA approved XOLAIR ™ as an add- on maintenance treatment of nasal polyps in adult patients with inadequate response to nasal corticosteroids. In July 2021, the FDA approved NUCALA ™ as an add- on maintenance treatment of chronic rhinosinusitis with nasal polyps in adult patients with inadequate response to nasal corticosteroids. In addition these monoclonal antibodies or others may be studied as potential treatments for patients with chronic rhinosinusitis without nasal polyps. Monoclonal antibodies could represent significant competition for XHANCE. In addition, Insmed is studying brensocatib as a potential treatment for chronic rhinosinusitis without nasal polyps by targeting inhibition of Dipeptidyl peptidase- 1 (DPP1). Seasonality A seasonal effect has historically been observed in the INS prescription market in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year. Although the underlying disease that we are treating is chronic and causes symptoms year- round, we believe the variation in patient flow through the offices of relevant physician specialists, and seasonality in disease flare- ups, has an impact on the number of patients that present themselves and who are therefore available to receive a new prescription for XHANCE. Demand has historically been, and we expect will continue to be, impacted by seasonality and the seasonal variation in patient visits with their doctor resulting in reduced XHANCE prescription demand in the third quarter. Additionally, as we experienced historically, we expect that the first quarter prescription demand and **gross margin percentage** ~~average net revenue per prescription~~ for XHANCE will be adversely impacted in ~~2024~~ **2025** and future years by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January. XHANCE Clinical Development Nasal Polyps Program Our clinical trial program for nasal polyps evaluated XHANCE in the following five clinical trials comprised of over 1, 500 patients: ▪ two randomized, double- blinded, placebo- controlled Phase 3 pivotal clinical trials designed to compare the safety and efficacy of XHANCE to a placebo EDS in adults with bilateral nasal polyps, which we refer to as NAVIGATE I and NAVIGATE II or collectively, our pivotal clinical trials. Each of NAVIGATE I and NAVIGATE II had co- primary endpoints of (i) change in subjective nasal congestion / obstruction symptoms from baseline to week 4 and (ii) change in objectively measured total (bilateral) nasal polyp grade from baseline to week 16. These trials also evaluated several secondary endpoints, including the impact of XHANCE treatment on study- defined surgical eligibility criteria and changes in Sinonasal Outcome Test 22 score, which considers the core defining signs and symptoms of nasal polyps and the impact on functioning, quality of life and sleep. We also conducted a complete response analysis to evaluate the percentage of patients with a recorded nasal polyp grade of zero on at least one side of the nasal cavity. ▪ two open- label Phase 3 clinical trials which we refer to as EXHANCE- 3 and EXHANCE- 12 or collectively, as our supportive clinical trials, to evaluate the safety of XHANCE in adults with symptoms of chronic sinusitis with or without nasal polyps over an extended period of time (3 months in the case of EXHANCE- 3 and 12 months in the case of EXHANCE- 12). In these trials we also assessed a variety of objective and subjective efficacy parameters, including an assessment of each patient' s symptoms and functioning and the impact of XHANCE treatment on study- defined surgical eligibility criteria. ▪ one Phase 1, open- label, randomized, single- dose, bioavailability study to compare the bioavailability of fluticasone propionate from XHANCE to Flonase ™ and Flovent HFA ™ in healthy patients and patients with mild- to- moderate asthma. We conducted this Phase 1 trial to establish a bridge between XHANCE, which consists of our fluticasone propionate formulation combined with our EDS device, and Flonase ™ and Flovent HFA ™, the referenced listed drugs for our NDA. In our NDA, we relied in part on the FDA' s previous findings of safety for Flonase ™ and Flovent HFA ™, including non- clinical toxicology findings and finding related to hypothalamic pituitary adrenal (HPA) axis suppression, which is a known side effect of corticosteroids. To do so, we were required to establish that the systemic exposure, or the amount of drug absorbed into the body, to fluticasone propionate following use of XHANCE did not exceed the exposure produced by Flovent HFA ™. Clinical Trial Highlights Our Phase 3 clinical development program for nasal polyps included a population of patients generally reflective of our intended patient population, with approximately 90 % having previously tried INS therapy and almost one- third having previously undergone sinus surgery. Key results from this Phase 3 clinical trial program include: ▪ In our pivotal clinical trials, XHANCE produced statistically significant benefits on both of the co- primary endpoints: a reduction of nasal congestion / obstruction symptoms at week 4 and a reduction in total polyp grade at week 16. ▪ In our Phase 3 clinical trials, patients with nasal polyps generally experienced greater improvements in symptoms and reductions in polyp grade with longer duration of use. ▪ In our pivotal clinical trials,

approximately 16 % of patients treated with XHANCE had nasal polyps eliminated (reduced to polyp grade 0) in at least one nostril after 16 weeks of treatment, and approximately 27 % had nasal polyps eliminated in at least one nostril after an additional eight weeks of treatment. In our supportive trials, we observed complete response rates in at least one nostril of 48 % of patients in EXHANCE- 3 and 47. 1 % of patients in EXHANCE- 12. ▪ In our pivotal clinical trials, XHANCE produced improvement across all four defining symptoms of chronic rhinosinusitis with nasal polyps. ▪ Over 85 % of patients receiving XHANCE across our pivotal clinical trials reported improvement, and approximately two- thirds reported being" much" or" very much" improved, compared to approximately one- third of patients in the placebo EDS group. In our supportive clinical trials, approximately 70 % of patients with symptoms of chronic sinusitis, both with and without nasal polyps, reported that they were" much" or" very much" improved after treatment with XHANCE. ▪ On a Sinonasal Outcome Test- 22, the improvement with the 186- and 372- mcg doses of XHANCE was superior to the placebo EDS in both NAVIGATE I and NAVIGATE II. The magnitude of improvement associated with treatment with XHANCE was approximately 20 points. Although cross- trial comparisons have significant limitations and must be interpreted with caution, in a previous third- party study evaluating a large cohort (n = 1468) of patients who were underwent sinus surgery, the degree of change on this outcome measure was approximately 18 points. ▪ After 12 months of treatment with XHANCE in our supportive clinical trials, at least 50 % of patients had a Sinonasal Outcome Test- 22 score that was at or below 9. 3, which is the average score that has been reported for healthy individuals. ▪ XHANCE was well tolerated and had an adverse event profile generally similar to that observed in several comparably designed third party studies with traditional INS. The most common adverse reactions (incidence ≥ 3 %) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis. ~~In connection with the approval of our NDA for XHANCE, the FDA required that we complete a clinical trial of XHANCE for the treatment of nasal polyps in pediatric patients by January 2022. Although this trial is ongoing, we will need to submit a request to the FDA to extend this deadline due to enrollment rates.~~ Chronic Sinusitis Program **Our** ~~In addition to XHANCE' s existing indication for the treatment of nasal polyps, in order to broaden our U. S. market opportunity, we conducted a~~ clinical trial program ~~in pursuit of a follow- on indication~~ for ~~the treatment of~~ chronic sinusitis **evaluated** ~~in the U. S. We believe~~ XHANCE ~~has~~ **in** the ~~potential~~ **following** ~~to~~ **two clinical trials comprised** ~~be the first drug therapy approved by the FDA for the treatment~~ of **over 550 patients** ~~chronic sinusitis. We announced positive top- line results for~~ ReOpen1 ~~and ReOpen2 in March and June 2022, respectively. In September 2022, we met with the FDA to discuss our planned sNDA for XHANCE as a treatment for adults with chronic sinusitis and submitted the sNDA in February 2023.~~ Re- Open1 was a randomized double- blinded, placebo controlled Phase 3 clinical trial examining the safety and efficacy of XHANCE versus a placebo EDS in adults with chronic sinusitis with or without nasal polyps. ReOpen1 served as one of two pivotal clinical trials we submitted to the FDA with our sNDA in February 2023 for XHANCE for the treatment of adults with chronic sinusitis. This clinical trial was conducted in the United States, Canada, Sweden, Poland, Bulgaria, The Republic of Georgia and Russia. Top- line results from ReOpen1 are summarized below. Study Design The clinical trial included a single- blind EDS- placebo lead- in and an EDS- placebo control group, a multi- center, multi- national study population to increase generalizability and an assessment of the safety and efficacy of multiple doses (186 or 372 mcg twice daily) over a 24- week period. A total of 332 adult subjects were enrolled in this study. Placebo EDS (N = 110) OPN- 375 186 µg (N = 110) OPN- 375 372 µg (N = 107) Full Analysis Set110110107Completed Study96102101Subjects Discontinuing **Early1698Subjects** ~~Early1698 Subjects~~ with Nasal Polyps696967Subjects without Nasal Polyps414140 ReOpen1 had co- primary endpoints of (i) change in a composite score of nasal congestion / obstruction symptoms, nasal discharge, and facial pain and pressure from baseline to week, and (ii) change in average percent of opacified volume of the ethmoid and maxillary sinuses from baseline to week 24. The severity of nasal symptoms was recorded by patients in an electronic diary immediately before dosing in the morning (AM) and evening (PM), and was measured using 7- day average instantaneous AM diary scores. Each symptom was scored from 0- 3. The volume of the ethmoid and maxillary sinuses occupied by disease was assessed using computer- assisted assessment of CT scans to determine the percentage (0- 100 %) of the sinus cavity space summed across all ethmoid and maxillary sinuses that was opacified. CT scans were performed at screening and at Week 24. This trial also evaluated several secondary endpoints, including the proportion of patients with acute disease exacerbations and their time to exacerbation and the Sinonasal Outcome Test- 22 score, which considers the core defining signs and symptoms of chronic sinusitis and the impact on functioning, quality of life and sleep. Top- Line Efficacy Results The 186- and 372- mcg treatment groups achieved statistically significant reductions in the primary assessments of composite symptom scores at week 4 and reductions in the opacified volume of the maxillary and ethmoid sinuses on CT scans at week 24 relative to a placebo EDS. The following table summarizes the mean change in composite symptom scores (or CSS) from baseline to week 4 and the change in the percent of opacified volume (or APOV) of the ethmoid and maxillary sinuses from baseline to week 24. Difference from Placebo EDSTreatmentnBaseline Score (Standard Deviation) Mean (Standard Error) Change from BaselineMean95 % confidence intervalP- value (1) Change in CSS from Baseline to Week 4XHANCE 372 mcg1075. 48 (1. 83)- 1. 60 (0. 16)- 0. 98- 1. 43,- 0. 54 < 0. 001XHANCE 186 mcg1105. 42 (1. 81)- 1. 58 (0. 16)- 0. 97- 1. 41,- 0. 52 < 0. **001** ~~001Placebo~~ --- **Placebo** EDS1105. 77 (1. 78)- 0. 62 (0. 16)--- Change in APOV in the Ethmoid and Maxillary Sinuses from Baseline to Week 24XHANCE 372 mcg10768. 95 (18. 84)- 6. 20 (1. 41)- 4. 59- 8. 41,- 0. 780. 018XHANCE 186 mcg11068. 88 (19. 51)- 5. 58 (1. 44)- 3. 98- 7. 86,- 0. 090. 045Placebo EDS11068. 94 (20. 33)- 1. 60 (1. 42)--- The p- value, or probability value, is a measure of statistical significance reflecting the likelihood that an observed result occurred by chance. In addition to the co- primary efficacy endpoints described above, we also assessed a number of secondary endpoints in the trial, including the following: ▪ Defining Symptoms (secondary endpoint). The XHANCE 186- and 372- mcg treatment groups achieved statistically significant improvement relative to the subjects receiving placebo EDS on all four of the core defining symptoms of chronic sinusitis (nasal congestion, rhinorrhea, facial pain / pressure, and sense of smell) at week 4. ▪ Acute exacerbations (secondary endpoint). The XHANCE 186- and 372- mcg treatment groups had a reduced occurrence of acute exacerbations of sinusitis relative to the

subjects receiving placebo EDS which reached statistical significance in the high dose group. ▪ Sinonasal Outcome Test- 22 (secondary endpoint). The XHANCE 186- and 372- mcg treatment groups had statistically significant improvements in SNOT-22 scores by week 4 relative to the subjects receiving placebo EDS. Although ReOpen1 was not designed or powered to detect statistical differences between the XHANCE treatment groups and placebo EDS in patient subgroups, we also performed the following subgroup analyses: ▪ Subgroup Analysis- CSS. The subgroup of chronic sinusitis patients without nasal polyps receiving XHANCE and the subgroup of chronic sinusitis patients with concomitant nasal polyps receiving XHANCE had statistically significant reductions in CSS scores relative to the subjects receiving placebo EDS in each of these subgroups despite the lack of powering for this subgroup analysis. ▪ Subgroup Analysis- APOV. The subgroup of chronic sinusitis patients with concomitant nasal polyps receiving XHANCE achieved a statistically significant reduction in APOV relative to the subjects receiving placebo EDS in this subgroup despite the lack of powering for this subgroup analysis. The subgroup of chronic sinusitis patients without nasal polyps receiving XHANCE did not achieve a statistically significant change in APOV relative to the subjects receiving placebo EDS in this subgroup. Top- Line Safety Results XHANCE was well tolerated across the 186- and 372- mcg dose groups and the safety profile in this trial was generally consistent with the safety profile contained in XHANCE' s currently approved label. No serious adverse events were reported in ReOpen1. The table below summarizes adverse events that occurred at a rate of more than 3 % with XHANCE and more common than the placebo EDS in this trial. Summary of Adverse Events with XHANCE Reported in ≥ 3 % and More Common Than Placebo EDS in ReOpen1 Adverse Event (AE) Placebo EDS BID (N = 112) n (%) XHANCE 186 mcg BID (N = 111) n (%) XHANCE 372 mcg BID (N = 109) n (%) Epistaxis1 (0. 9) 5 (4. 5) 13 (11. 9) Nasopharyngitis3 (2. 7) 6 (5. 4) 3 (2. 8) Asthma1 (0. 9) 5 (4. 5) 4 (3. 7) Nuclear Cataract05 (4. 5) 4 (3. 7) Cortical Cataract1 (0. 9) 6 (5. 4) 2 (1. 8) ReOpen2 **ReOpen2** was a randomized double- blinded, placebo controlled Phase 3 clinical trial examining the safety and efficacy of XHANCE versus a placebo EDS in adults with chronic sinusitis without nasal polyps. ReOpen2 served as the second of two pivotal clinical trials we submitted to the FDA with our sNDA in February 2023 for XHANCE for the treatment of adults with chronic sinusitis. This clinical trial was conducted in the United States, Australia, Bulgaria, Czechia, New Zealand, Poland, Romania, Spain, The Republic of Georgia and the United Kingdom. Top- line results from ReOpen2 are summarized below. The clinical trial included a single- blind EDS- placebo lead-in and an EDS- placebo control group, a multi- center, multi- national study population to increase generalizability and an assessment of the safety and efficacy of multiple doses (186 or 372 mcg twice daily) over a 24- week period. A total of 222 adult subjects were enrolled in this study. Placebo EDS (N = 110) OPN- 375 186 µg (N = 110) OPN- 375 372 µg (N = 107) Full Analysis Set757273Completed Study697071Subjects Discontinuing Early633 ReOpen2 had co- primary endpoints of (i) change in a composite score of nasal congestion / obstruction symptoms, nasal discharge, and facial pain and pressure from baseline to week, and (ii) change in average percent of opacified volume of the ethmoid and maxillary sinuses from baseline to week 24. The severity of nasal symptoms was recorded by patients in an electronic diary immediately before dosing in the morning (AM) and evening (PM), and was measured using 7- day average instantaneous AM diary scores. Each symptom was scored from 0-3. The volume of the ethmoid and maxillary sinuses occupied by disease was assessed using computer- assisted assessment of CT scans to determine the percentage (0- 100 %) of the sinus cavity space summed across all ethmoid and maxillary sinuses that was opacified. CT scans were performed at screening and at Week 24. Difference from Placebo EDSTreatmentnBaseline Score (Standard Deviation) Mean (Standard Error) Change from BaselineMean95 % confidence intervalP- value (1) Change in CSS from Baseline to Week 4XHANCE 372 mcg735. 97 (1. 59)- 1. 74 (0. 20)- 0. 93- 1. 49,- 0. 370. 001XHANCE 186 mcg725. 87 (1. 48)- 1. 54 (0. 20)- 0. 73- 1. 29,- 0. 170. 011Placebo EDS756. 15 (1. 77)- 0. 81 (0. 20)--- Change in APOV in the Ethmoid and Maxillary Sinuses from Baseline to Week **24** ~~24XHANCE~~ -- **XHANCE** 372 mcg7361. 50 (18. 46)- 5. 14 (1. 74)- 6. 33- 11. 08,- 1. 580. 009XHANCE 186 mcg7260. 51 (19. 37)- 7. 00 (1. 73)- 8. 19- 12. 93,- 3. 45 < 0. 001Placebo EDS7564. 09 (17. 74) 1. 19 (1. 74)--- 1- The p- value, or probability value, is a measure of statistical significance reflecting the likelihood that an observed result occurred by chance. XHANCE was well tolerated across the 186- and 372- mcg dose groups and the safety profile in this trial was generally consistent with the safety profile contained in XHANCE' s currently approved label. No serious adverse events were reported in ReOpen2. The table below summarizes adverse events that occurred at a rate of more than 3 % with XHANCE and more common than the placebo EDS in this trial. and More Common Than Placebo EDS in ReOpen2 Adverse Event (AE) Placebo EDS BID (N = 75) n (%) XHANCE 186 mcg BID (N = 73) n (%) XHANCE 372 mcg BID (N = 74) n (%) COVID- 192 (2. 7) 3 (4. 1) 7 (9. 5) Epistaxis04 (5. 5) 7 (9. 5) Headache6 (8. 0) 2 (2. 7) 7 (9. 5) Depression1 (1. 3) 03 (4. 1) Pooled Results from the ReOpen Program In July 2022, we announced selected pooled results from the ReOpen program. First, to inform possible differences in response of patients previously using a standard nasal steroid spray, a pre- planned analysis of pooled data assessed symptom improvement for patients entering the trials with at least moderate symptoms despite reporting use of a standard nasal steroid spray. For this subgroup, patients receiving XHANCE improved more from baseline than patients receiving placebo comparator. Second, a pooled analysis was performed to assess change in CT scans, measured by APOV at week 24, for the subgroup of patients receiving XHANCE who had chronic sinusitis without nasal polyps. Compared to patients treated with placebo comparator, XHANCE treatment produced greater reduction in sinus opacification in this subgroup. Differences between active and placebo in 186 mcg or 372 mcg XHANCE treatment groups were similar and nominally statistically significant. Finally, an analysis of pooled data found that the 372 mcg treatment group achieved a type 1 error controlled statistically significant reduction of 66 % in the incidence of exacerbations compared to placebo comparator. Reductions in the number of exacerbations, ranging from 53 to 80 %, were found for subgroups of chronic sinusitis patients with or without nasal polyps in the 186 mcg or 372 mcg XHANCE treatment groups in additional pre- planned exploratory analyses that were not type 1 error controlled. Exacerbations were defined as a worsening of at least one of the four cardinal symptoms of chronic sinusitis (nasal congestion / obstruction, rhinorrhea, facial pain / pressure, and loss of sense of smell) lasting at least 3 days accompanied by an escalation in medical care, such as doctor visits or antibiotic or steroid prescription. In addition, we completed an analysis of mean change in APOV by Patient- Reported Global Change Score (PGIC). The PGIC is a 7- point

Likert scale on which the subject directly reports their perceived overall change in disease since initiating study medication. The following three tables summarize these results. Difference from Placebo EDSTreatmentnBaseline ScoreLS Mean Change from BaselineLS MeanNominalP- value (1) Change in Symptoms in Prior Nasal Steroid Users from Baseline to Week 4 (Pooled) XHANCE 186 or 372 mcg1725. 63- 1. 46- 0. 7 < 0. 001Placebo EDS1085. 84- 0. 77-- Change in APOV in CS Patients without Nasal Polyps from Baseline to Week 24 (Pooled) XHANCE 186 or 372 mcg22561. 33- 6. 31- 4. 760. 004XHANCE 372 mcg11261. 26- 6. 5- 4. 950. 01XHANCE 186 mcg11361. 4- 6. 12- 4. 570. 019Placebo EDS11663. 32- 1. 55-- Treatment GroupnEventsLS MeanIncidence Rate Ratio (Active / PBO) P- value (1) Frequency of Exacerbations over 24 Weeks (Full Analysis Set / All Patients) XHANCE 186 or 372 mcg362350. 0810. 3890. 001XHANCE 372 mcg180150. 0720. 3430. 002 (2) XHANCE 186 mcg182200. 0920. 4410. 012Placebo EDS185410. 208-- Frequency of Exacerbations over 24 Weeks (Patients with Nasal Polyps) XHANCE 186 or 372 mcg137120. 0520. 2760. 005XHANCE 372 mcg6840. 0380. 2030. 01XHANCE 186 mcg6980. 070. 3760. ~~055 Placebo~~ **055Placebo** EDS69170. 187-- Frequency of Exacerbations over 24 Weeks (Patients without Nasal Polyps) XHANCE 186 or 372 mcg225230. 1130. 4720. 032XHANCE 372 mcg112110. 1130. 470. 077XHANCE 186 mcg113120. 1130. 4740. 076Placebo EDS116240. 239-- 1. The p- value, or probability value, is a measure of statistical significance reflecting the likelihood that an observed result occurred by chance and compares the indicated group to the relevant placebo EDS group. Unless otherwise noted, all p- values shown in this table represent nominal p- values (meaning they are exploratory, not type 1 error controlled) and therefore have an increased possibility of being a chance finding2. This p- value for all patients receiving XHANCE 372 mcg in the ReOpen Program is a type 1 error controlled statistically significant result. All other p- values shown in this table are nominal p- values. Mean change in APOV by Patient- Reported Global Change Score at Week 24PGIC CategoryVery Much ImprovedMuch ImprovedMinimally ImprovedNo ChangeMinimally WorsenedMuch WorsenedVery Much WorsenedSubjects67641649016104Mean Change in APOV (10. 53) % (7. 26) % (2. 86) % (0. 32) % 2. 01 % 4. 82 % 5. 30 % Pooled Safety Results from the ReOpen Program XHANCE was well tolerated across the 186- and 372- mcg dose groups and the safety profile in the ReOpen program was generally consistent with the safety profile contained in XHANCE' s currently approved label. No serious adverse events were reported in the ReOpen program. The table below summarizes adverse events that occurred at a rate of more than 3 % with XHANCE and more common than the placebo EDS in this trial. Summary of Adverse Events with XHANCE Reported in ≥ 3 % and More Common Than Placebo EDS in Pooled dataAdverse Event (AE) Placebo EDS BID (N = 187) n (%) XHANCE 186 mcg BID (N = 184) n (%) XHANCE 372 mcg BID (N = 183) n (%) Epistaxis1 (0. 5) 9 (4. 9) 20 (10. 9) COVID- 198 (4. 3) 5 (2. 7) 12 (6. 7) Nasopharyngitis8 (4. 3) 9 (4. 9) 7 (3. 8) Headache7 (3. 7) 4 (2. 2) 10 (5. 5) Intellectual Property and Barriers to Entry XHANCE benefits from substantial intellectual property and barriers to entry, including the following: ▪ Strong patent protection. Our XHANCE U. S. patent portfolio consists of 14 issued device and method of use patents expiring on various dates from ~~2024~~ **2025** through 2036 which are listed in the FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, as well as three issued design patents expiring through 2030 and pending patent applications. We rely primarily on the protections afforded by these device and method of use patents which are generally based on the EDS and related technology, including the combination of this technology with fluticasone propionate. ▪ Complex drug- delivery system. We believe the unique features of our liquid EDS device, as well as its delivery of a topical- acting corticosteroid, affords us significant protection against generic competition, as well as against a potential 505 (b) (2) NDA, that seeks to reference XHANCE in order to obtain approval for a therapeutically equivalent, substitutable competitor product. XHANCE, utilizing our liquid EDS device, presents technical and human factors engineering complexities for drug- device combination products and chemistry, manufacturing and controls challenges unique to suspension and respiratory products. Any future substitutable generic entrant will need to have considerable combination product know- how to develop and validate a substitutable drug delivery device or technology to compete with XHANCE. ▪ Clinical and regulatory complexity. We conducted a clinical development program comprised of ~~over 1~~ **more than 2** , ~~500~~ **000** patients to support FDA approval of ~~our NDA for~~ XHANCE for the treatment of **chronic rhinosinusitis with and without** nasal polyps, including human factors studies and Phase 3 clinical trial assessments evaluating and validating the use of XHANCE. As with other drugs that primarily have local activity, we believe the regulatory pathway for products seeking approval as substitutable generic equivalents to XHANCE will be more complex and costly than the pharmacokinetic studies generally required for systemically- acting medications. We believe that any future substitutable generic competitors may be required to conduct, among other things, non- inferiority clinical trials demonstrating equivalent efficacy and safety outcomes to establish clinical bioequivalence to XHANCE. We believe these clinical trials, if required, would necessitate a significant amount of time and capital investment and present clinical development uncertainties. **The** ~~However, the~~ FDA has included XHANCE on ~~the~~ **its** list ~~of upcoming~~ product specific guidances for complex generic drug products that the FDA plans to issue **within the next 12- months** , which may provide clarity for generic competitors to develop generic products that compete with XHANCE. We strive to protect our proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and technologies that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, as well as know- how, trademarks, continuing technological innovation and in- licensing opportunities to develop and maintain our proprietary position. We internally developed our intellectual property related to XHANCE, Onzetra Xsail, the Exhalation Delivery System and related technologies. We have sought and intend to continue to seek appropriate patent protection for our product candidates, as well as other proprietary technologies and their uses by filing patent applications in the U. S. and other select countries. Patents As of March 1, 2024, we owned over ~~60~~ **50** U. S. patents expiring between ~~2024~~ **2025** and 2036, and pending U. S. patent applications. In addition to our U. S. intellectual property, as of March 1, 2024, we also owned over 150 foreign issued patents expiring between ~~2024~~ **2025** and 2035, and foreign patent applications ~~. As part of actions intended to reduce operating expenses, in 2023 we reduced the scope of our patent portfolio primarily in certain foreign countries where we believe~~

~~commercial potential is more limited~~ . Our XHANCE U. S. patent portfolio consists of 14 issued device and method of use patents expiring on various dates from ~~2024~~ **2025** through 2036, three issued design patents expiring between 2029 and 2030 and pending patent applications. The 14 device and method of use patents are published in the FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated NDA (ANDA), or a 505 (b) (2) NDA. If any of these potential generic competitors claim that their product will not infringe XHANCE' s listed patents, or that such patents are invalid, then they must send notice to us once the ANDA or 505 (b) (2) NDA has been accepted for filing by the FDA. We may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification, which would automatically prevent the FDA from approving the ANDA or 505 (b) (2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505 (b) (2) NDA applicant. **In September 2023, the Federal Trade Commission (FTC) issued a policy statement articulating its view that certain" improper" patent listings by pharmaceutical manufacturers in the FDA' s Orange Book represent a potential unfair trade practice and indicated that industry should be prepared for potential enforcement actions based on its analysis. The FTC followed that action in November 2023 by initiating an FDA administrative process with respect to over 100 patent listings that it contends are" improper" with a focus on certain patents covering drug- device combination products. We believe the 14 patents we have listed in the FDA' s Orange Book for XHANCE are properly listed, and no administrative process has been initiated to delist any such patents. Nevertheless, this is an evolving area of law and there could be future changes or clarifications to such laws which could adversely impact the continued listabilty of one or more of our Orange Book- listed patents for XHANCE.** The rest of our patent portfolio largely relates to patents and applications owned by us and directed to Onzetra Xsail, the powder EDS, the liquid EDS and related technologies. Trade Secrets and Other Proprietary Information We seek to protect our proprietary information, including our trade secrets and proprietary know- how, by requiring our employees, consultants and other advisors to execute confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from business partners and other third parties that receive our confidential information. Trademarks We also rely on trademarks and trade designs to develop and maintain our competitive position. OPTINOSE ®, XHANCE ®, Exhalation Delivery System ™ and EDS ® are trademarks of ours in the U. S. Licensing of the Exhalation Delivery System Currax License Agreement In 2019, we entered into a license agreement with Currax Pharmaceuticals LLC (the Currax License Agreement). Under the terms of the Currax License Agreement, we granted Currax an exclusive license to certain OptiNose patents and a non- exclusive license to certain OptiNose know- how to use, sell, offer for sale, have sold and import Onzetra ® Xsail ® (sumatriptan nasal powder) in the U. S., Canada and Mexico ~~. Under the terms of the Currax License Agreement, we received a $ 3. 7 million upfront payment in 2019, and an additional $ 0. 75 million in December 2020 upon expiration of the escrow that was established for a limited period to cover potential indemnification obligations, and an additional $ 1. 0 million milestone payment in January 2021 upon the achievement of a specified regulatory milestone~~ . We do not expect to receive any further payments from Currax under the terms of the License Agreement other than reimbursement for certain expenses. Government Regulation We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act (the FD & C Act) and the FDA' s implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record- keeping, reporting, distribution, import, export, sale, advertising and promotion of our products and product candidates. Although the discussion below focuses on regulation in the U. S., because that is currently our primary focus, we may seek approval for, and market, our products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U. S., although there can be important differences. Development and Approval Under the FD & C Act, FDA approval of an NDA is required before any new drug can be marketed in the U. S. NDAs require extensive studies and submission of a large amount of data by the applicant. Preclinical Testing. Before testing any compound in human patients in the U. S., a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product. Certain animal studies must be performed in compliance with the FDA' s Good Laboratory Practice (GLP) regulations and the U. S. Department of Agriculture' s Animal Welfare Act. IND Application. Human clinical trials in the U. S. cannot commence until an investigational new drug (IND) application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on" clinical hold" because of concerns about the safety of the product being tested, or for other reasons. Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA' s bioresearch monitoring regulations and current Good Clinical Practice (cGCP) requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well- being of study participants are

protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board (IRB) for each clinical site. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events (AEs). Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U. S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with cGCP and the FDA is able to validate the data. A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e. g., http: / / clinicaltrials. gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap, be combined, or be subdivided in some cases: ▪ Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. ▪ Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop initial data regarding the product' s effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs. ▪ Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug' s overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, multi- site, large- scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen. Phase 3 data often form the core basis on which the FDA evaluates a drug’ s safety and effectiveness when considering the product application. The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early- stage clinical trials does not assure success in later- stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval. NDA Submission and Review. The FD & C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505 (b) (1) of the FD & C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505 (b) (1) NDA contains results of the full set of preclinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate. Section 505 (b) (2) of the FD & C Act provides an alternate regulatory pathway to obtain FDA approval that permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA' s findings of safety and effectiveness for an approved product that acts as the reference drug and submit its own product- specific data — which may include data from preclinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the reference drug. We obtained FDA approval of XHANCE through the Section 505 (b) (2) regulatory approval pathway, with Flonase ™ and Flovent HFA ™ as the reference drugs. Flonase ™ and Flovent HFA ™ contain fluticasone propionate, which is also the active ingredient in XHANCE. The submission of an NDA under either Section 505 (b) (1) or Section 505 (b) (2) generally requires payment of a substantial user fee to the FDA. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product' s identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency considers such recommendations carefully when making decisions. Our product and product candidates include products that combine drug and device components in a manner that the FDA considers to meet the definition of a" combination product" under FDA regulations. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. For XHANCE, FDA' s Center for Drug Evaluation and Research (CDER) had primary jurisdiction for review of the NDA, and both the drug and device were reviewed under one marketing application. However, for a drug- device combination product CDER typically consults with the Center for Devices and Radiological Health in the NDA review process. The FDA may determine that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practice (cGMP) requirements and adequate to assure consistent production of the product within required specifications. Once the FDA accepts an NDA submission — which occurs, if at all, within 60 days after submission of the NDA — the FDA' s goal for a non- priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information, studies, or

clarification. After review of an NDA and the facilities where the product is manufactured, the FDA either issues an approval letter or a complete response letter (CRL) outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as" Phase 4" or" post- marketing" studies. Post- approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval. Post-Approval Regulation Once approved, drug products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials, changes to a product' s approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution- related restrictions, if there are new safety information developments. Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product- specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re- inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement action or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third- party manufacturers, we cannot be certain that our present or future third- party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements. We also need to comply with some of the FDA' s manufacturing and safety regulations for devices. In addition to cGMP, the FDA requires that our drug- device combination product comply with the Quality System Regulation (QSR), which sets forth the FDA' s manufacturing quality standards for medical devices. The FDA also requires that we comply with some device safety reporting requirements for our drug- device combination product. Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct- to- consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry- sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for" off- label" uses — that is, uses not approved by the FDA and not described in the product' s labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off- label uses. Broadly speaking, a manufacturer may not promote a drug for off- label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off- label use. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug. Other Requirements. NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records. Hatch- Waxman Act The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch- Waxman Act) establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products. Generic Drugs. A generic version of an approved drug is approved by means of an ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand- name drug, which is referred to as the reference listed drug (RLD). Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product' s safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective. 505 (b) (2) NDAs. As discussed above, if a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under section 505 (b) (2) of the FD & C Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product' s safety

and effectiveness. Rather, the sponsor is permitted to rely to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, and must submit its own product- specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505 (b) (2) may in turn serve as an RLD for subsequent applications from other sponsors. RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the Orange Book. The sponsor of an ANDA or 505 (b) (2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A " Paragraph I " certification is the sponsor' s statement that patent information has not been filed for the RLD. A " Paragraph II " certification is the sponsor' s statement that the RLD' s patents have expired. A" Paragraph III" certification is the sponsor' s statement that it will wait for the patent to expire before obtaining approval for its product. A" Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Regulatory Exclusivities. The Hatch- Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505 (b) (2) application. If a product is a" new chemical entity," or NCE — generally meaning that the active moiety has never before been approved in any drug — there is a period of five years from the product' s approval during which the FDA may not accept for filing any ANDA or 505 (b) (2) application for a drug with the same active moiety. An ANDA or 505 (b) (2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification. A product that is not an NCE may qualify for a three- year period of exclusivity if the NDA contains new clinical data, (other than bioavailability studies) derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505 (b) (2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505 (b) (2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. Once the FDA accepts for filing an ANDA or 505 (b) (2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD or listed drug NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant' s assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505 (b) (2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505 (b) (2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends until 7. 5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. In connection with the submission of our sNDA for XHANCE in February 2023, we provided Paragraph IV certification notices to the NDA holder and patent owner of the two unexpired Orange Book- listed patents covering Flovent HFA. As noted above, these parties have 45 days from receiving the Paragraph IV certification notices to file a patent infringement suit which would prohibit the FDA from approving our sNDA for up to 30- months. Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one- half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U. S. Patent and Trademark Office (USPTO) in consultation with the FDA, reviews and approves the application for patent term restoration. Other Exclusivities Pediatric Exclusivity. Section 505A of the FD & C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA' s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505 (b) (2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate. Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200, 000 individuals in the U. S. If a sponsor demonstrates that a drug product qualifies for orphan drug designation, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. The FDA can revoke a product' s orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. U. S. Healthcare Reform The Patient Protection and Affordable Care Act, as amended (the" Affordable Care Act"), is a sweeping measure intended to expand healthcare coverage within the U. S., primarily through the

imposition of **certain** health insurance mandates **, the provision of subsidies to eligible individuals enrolled in plans offered** on ~~employers and individuals~~ **the health insurance exchanges,** and expansion of the Medicaid program. This law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. **For further** ~~Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the" donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service Act' s 340B drug pricing program (340B Program), fraud and abuse, and enforcement. These changes impact existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives. Details~~ **detail** ~~of the changes~~ **, please refer** to ~~the Medicaid Drug Rebate program and the 340B Program are discussed under~~ the risk factor **entitled** " ~~If~~ **The Affordable Care Act and any other healthcare reform measures may increase the difficulty and cost for us to commercialize XHANCE and affect the price** we **may obtain** ~~fail to comply with our reporting and payment obligations under the Medicaid drug rebate program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects~~ " in the" Risk Factors" section of this Annual Report on Form 10- K. Some states have elected not to expand their Medicaid programs to **certain** individuals with an income of up to 133 % of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products and product candidates for which we receive regulatory approval, and our business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. Certain provisions of the Affordable Care Act have been subject to judicial challenges, as well as efforts to modify them or to alter their interpretation and implementation ~~. For example, on December 22, 2017, the U. S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act (the Tax Act), which includes a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drug plans, commonly known as the " donut hole, " by raising the required manufacturer point- of- sale discount for pharmaceutical manufacturers who participate in Medicare Part D from 50 % to 70 % off the negotiated price effective as of January 1, 2019. The IRA (defined below) replaces the Part D coverage gap discount program with a new Part D manufacturer discount program beginning in 2025. It is unclear how efforts to modify or invalidate the Affordable Care Act or its implementing regulations, or portions thereof, will affect the Affordable Care Act or our business~~ . Additional legislative changes, regulatory changes, and further judicial challenges related to the Affordable Care Act remain possible. Any such changes could decrease the number of individuals with health coverage. It is possible that the Affordable Care Act, as currently enacted or as it or its implementation may be modified in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our products or product candidates for which we receive regulatory approval or to successfully commercialize our products and product candidates. Additionally, on December 20, 2019, then- President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P. L. 116- 94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or " the CREATES Act. " The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on " commercially reasonable, market- based terms. " In 2021 ~~and ,~~ 2022 **, and 2024** we provided units of XHANCE to a generic manufacturer in compliance with the CREATES Act. Coverage and Reimbursement Significant uncertainty exists as to the coverage and reimbursement status of our products and any product candidates for which we may obtain regulatory approval. Sales of any of our products and product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third- party payors, including government healthcare programs such as Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third- party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U. S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third- party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA- approved products for a particular indication. In order to secure coverage and reimbursement for our products we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our products and product candidates may not be considered medically necessary or cost- effective by payors. Further, a payor' s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates or rebates, such as

average sales price (ASP), average manufacturer price (AMP), and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The Centers for Medicare and Medicaid Services (CMS) surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. Participation in the Medicaid Drug Rebate Program requires us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the" basic" portion of the rebate for each product is set by law as the larger of: (i) 23. 1 % of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price (Best Price), which, in general, represents the lowest price available from the manufacturer to any entity in the U. S. in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. AMP must be reported on a monthly and quarterly basis, and Best Price is reported on a quarterly basis, to CMS, the federal agency that administers the Medicaid Drug Rebate Program. In addition, the rebate also includes the" additional" portion, which adjusts the overall rebate amount upward as an" inflation penalty" when the drug' s latest quarter' s AMP exceeds the drug' s AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index- Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation- adjusted AMP from the first full quarter of sales. The rebate amount is recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for the relevant drug. The statutory Medicaid drug rebate cap for single- source and innovator multiple- source drugs has been eliminated effective January 1, 2024. The terms of our participation in the Medicaid Drug Rebate Program require us to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due, and CMS may request or require restatements for earlier periods as well. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. **CMS has issued final regulations** ~~The Affordable Care Act made significant changes~~ to **implement** the Medicaid Drug Rebate Program **. Manufacturers have obligations** ~~, and CMS issued a final regulation, which became effective on April 1, 2016,~~ to ~~implement~~ **report** the ~~changes~~ **ASP** to the ~~Medicaid~~ **Medicare** ~~Drug Rebate program~~ **Program as** ~~under the Affordable Care Act. On December 21, 2020, CMS issued~~ a ~~final regulation that (i) modified existing~~ **part of the agreement to participate in the** Medicaid Drug Rebate Program ~~regulations to permit reporting multiple Best Price figures with regard to value - based purchasing arrangements; and (ii) provided definitions for " line extension, " " new formulation, " and related terms with the practical effect of expanding the scope of drugs considered to be line extensions, with such changes taking effect in 2022. Our failure to comply with the aforementioned price reporting and rebate obligations, as well as pharmacy benefit manager " accumulator " programs, could negatively impact our financial results. In addition, statutory and regulatory changes or other agency action regarding the Medicaid Drug Rebate Program could negatively affect our financial results or expand our rebate liability~~. Manufacturers ~~have obligations to report the ASP to the Medicare Program as a part of the agreement to participate in the Medicaid Drug Rebate Program. For calendar quarters beginning January 1, 2022, manufacturers will~~ need to report the ASP for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate Program. Statutory or regulatory changes or CMS guidance could affect the ASP for products and the resulting Medicare payment rate, and could negatively affect results of operations. Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate Program also participate in the 340B Program in order for federal funds to be available for the manufacturer' s drugs under Medicaid and Medicare Part B. The 340B Program, which is administered by the Health Resource and Services Administration (HRSA) requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B" ceiling price" for the manufacturer' s covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low- income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. Any changes to the definition of AMP and the Medicaid rebate amount under federal legislation could affect our 340B ceiling price calculations and negatively impact our results of operations. HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities ~~, which became effective on January 1, 2019~~. It is ~~currently~~ unclear how HRSA will apply its enforcement authority under the regulation. HRSA also has implemented a ceiling price reporting requirement related to the 340B Program under which we are required to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes that information to covered entities. Moreover, under ~~a~~ final ~~regulation~~ **regulations** ~~effective January 13, 2021~~, HRSA ~~newly~~ **has** established an administrative dispute resolution, or ADR, process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, legislation may be introduced that, if passed, would further expand the 340B Program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting. In the U. S. Medicare program, outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both stand- alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C. Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic

committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and / or impose differential cost sharing or other utilization management techniques. The availability of coverage under Medicare Part D may increase demand for our products and any product candidates for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program could decrease the coverage and price that we receive for any approved products and could harm our business. In addition, manufacturers ~~are~~ **were** required to provide to CMS a 70 % discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design **, through December 31, 2024** ~~. Civil monetary penalties can be applied if a manufacturer fails to provide discounts in the amount of 125 % of the discount that was due~~ . The Inflation Reduction Act of 2022, or the IRA, ~~sunsets~~ **sunset** this discount program and replaces it with a new manufacturer discount program ~~beginning 2025~~ **, under which manufacturers provide a 10 % discount on a covered Part D drug where a beneficiary is in the initial phase of Part D coverage and a 20 % discount where a beneficiary is the catastrophic phase of Part D coverage** . In order to be eligible to have our products or any future products paid for with federal funds under the Medicaid and Medicare Part B programs, as applicable, and purchased by certain federal agencies and grantees, we also participate in the U. S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. Under this program, we are obligated to make our" innovator" drugs available for procurement on an FSS contract and charge a price to four federal agencies — the VA, U. S. Department of Defense (DoD) Public Health Service and U. S. Coast Guard — that is no higher than the statutory Federal Ceiling Price (FCP). The FCP is based on the non- federal average manufacturer price (Non- FAMP), which we calculate and report to the VA on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non- FAMP and FCP. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false AMP, best price, or Non- FAMP information to the government or fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate the Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. In addition, claims submitted to federally- funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the False Claims Act. The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U. S. government, state legislatures, and foreign governments have shown significant interest in implementing cost- containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. Any other legislative change could impact the market conditions for our products. We expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies and are seeing an increase in state interest in price reporting, transparency, and other policies to address drug pricing concerns. Beginning April 1, 2013, Medicare payments for all items and services, including drugs, were reduced by, on average, 2 % per fiscal year under the sequestration (i. e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Sequestration is currently set at 2 % and will increase to 2. 25 % for the first half of fiscal year 2030, to 3 % for the second half of fiscal year 2030, and to 4 % for the remainder of the sequestration period that last through the first six months of fiscal year 2031. As long as these cuts remain in effect, they could adversely impact payment for any of our products that are reimbursed under Medicare. Other legislative or regulatory cost containment legislation could have a similar effect. Further, the Affordable Care Act may reduce the profitability of drug products. It expanded manufacturers' rebate liability under the Medicaid program from fee- for- service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, and increased the minimum Medicaid rebate due for most innovator drugs. The Affordable Care Act and subsequent legislation also changed the definition of AMP. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. These regulations became effective on April 1, 2016. On August 16, 2022, President Biden signed into law the IRA, which, among other things, establishes a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty. The IRA also establishes a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the AMP of a Part D drug increases faster than the pace of inflation. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologics without generic or biosimilar competition will be capped by reference to, among other things, a specified non- federal AMP, ~~starting~~ **with the first negotiated prices taking effect** in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and / or a civil monetary penalty. The IRA further makes changes to the Medicare Part D benefit, including a limit on annual out- of- pocket costs, and a change in manufacturer liability under the program that could negatively affect the profitability of our products. Failure to pay a discount under this new program will be subject to a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs in the government health benefit programs. The IRA or other

legislative change could impact the market conditions for our products. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. For example, CMS may develop new payment and delivery models, such as bundled payment models. The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $ 2. 8 billion in fee year 2020 and subsequent fee years, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The Affordable Care Act also expanded the Public Health Service' s 340B Program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs. Additional legislative changes, regulatory changes and judicial challenges related to the Affordable Care Act remain possible, as discussed above under the heading" U. S. Healthcare Reform." In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third- party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for our products and any product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Additional information regarding these programs is discussed under the risk factor" If we fail to comply with our reporting and payment obligations under the Medicaid drug rebate program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects" in the" Risk Factors" section of this Annual Report on Form 10- K. Healthcare Fraud and Abuse Laws In addition to FDA restrictions on marketing of pharmaceutical products, our business is subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These laws include, but are not limited to, the following: • The federal Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti- Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, 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 federal civil False Claims Act. Violations of the federal Anti- Kickback Statute are punishable by imprisonment, criminal fines, damages, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing, or recommending pharmaceuticals, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if they do not fit squarely within the exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti- kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Arrangements that implicate the Anti- Kickback Statute and do not fit within an exception or safe harbor are reviewed on a case- by- case basis to determine whether, based on the facts and circumstances, they violate the statute. • The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the U. S. federal government. Actions under the False Claims Act may be brought by private individuals known as qui tam relators in the name of the government, and who may share in any monetary recovery. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the False Claims Act for, among other things, providing free product to customers with the expectation that the customers would bill federal programs for the product, and other interactions with prescribers and other customers including interactions that may have affected customers' billing or coding practices on claims submitted to the federal government. Other companies have faced enforcement actions for causing false claims to be submitted because of the company' s marketing the product for unapproved uses. Federal enforcement agencies also have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co- pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. • The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, HIPAA), prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third- party payors. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. HIPAA also imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their" business associates" – certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. HIPAA has four tiers of civil monetary penalties and grants state attorneys enforcement authority. The Department of Justice also may impose criminal penalties. Additionally, certain states have adopted comparable privacy

and security laws and regulations, some of which may be more stringent than HIPAA, and numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including, for example, Section 5 of the Federal Trade Commission Act, as amended, and the California Consumer Privacy Act (CCPA), govern the collection, use, and disclosure and protection of certain health- related and other personal information. • Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we may obtain health information from third parties that are subject to privacy and security requirements under HIPAA, and other privacy and data security and consumer protection laws, and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA, and could also potentially be subject to other civil and / or criminal penalties if we obtain, use or disclose information in a manner not permitted by other privacy and data security and consumer protection laws. • The majority of states **, as well as many of the non- US jurisdiction where we may operate,** also have statutes or regulations similar to the federal anti- kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing- related activities including the provision of gifts, meals, or other items to certain health care providers. Other states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co- pay assistance that pharmaceutical companies can offer to patients. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes. • The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Compliance with such laws and regulations requires substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity. Healthcare Privacy Laws We may be subject to laws and regulations covering data privacy and the protection of health- related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and / or adverse publicity that could negatively affect our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under HIPAA. Foreign Corrupt Practices Act In addition, the U. S. Foreign Corrupt Practices Act of 1997 prohibits corporations and their intermediaries from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity. Human Capital ~~Culture is a critical element in the management of our organization. Our colleagues are focused on driving our business with the Optinose values as the foundation for all our efforts. Our goal is that each colleague feels a deep connection to what they do, loves coming to work and is aligned to our One Mission – to improve lives. Our values of Authenticity, Fearless Conversations, Friendship, Openness, Perseverance and Possibility Thinking guide our actions and decisions.~~ As of February ~~16~~ **24** , ~~2024~~ **2025** , we had a total of ~~132~~ **127** full-time employees **and 1 part- time employee** all of whom are in the United States. ~~61~~ **63** % of our employees are in direct customer- facing roles. These colleagues, as well as others that are not customer- facing, have significant prior experience within the pharmaceutical, biotech or device industries. ~~We continue to focus on building a high performing organization through our emphasis on accountability for results as measured by our performance development process. To help ensure that employees fully understand the Company' s long- term strategy, and how their work contributes to the Company' s success, we utilize a variety of channels to facilitate open and direct communication, including: regular calls with all colleagues, ongoing update communications as needed, regular executive field visits and annual colleague engagement surveys. Our success is dependent on our ability to attract and retain highly talented colleagues. We provide our colleagues with competitive salaries and bonuses, opportunities for equity ownership, opportunities for professional development and a robust benefits package. Our compensation programs, including short- and long- term incentives, are designed to enable us to attract and retain individuals whose skills are critical to our current and long- term success. Our compensation philosophy is to ensure that our colleague~~

~~salaries fall within an appropriate range around the median of the marketplace for like positions, with differentiation based on performance and contribution, time in position, and criticality of skill set. Within our compensation programs, we aim to align the interests of our colleagues with those of our shareholders. We value diversity and are focused on maintaining an inclusive work environment that supports our culture and the needs of the communities we serve and in which we work. Currently, women represent 54 % of our colleagues.~~ None of our colleagues are represented by any collective bargaining unit. We believe that we maintain good relations with our colleagues. ~~As part of our stated goal to nurture an environment where people love to work, and in recognition of the ways in which work has changed over the past several years, we offer a hybrid work environment in our Yardley headquarters in which colleagues work in the office three days and may work remotely the other two days, if desired. This enables us to provide colleagues with flexibility as well as provides an environment in which creativity and innovation are fostered.~~ Properties Our principal office is located in Yardley, Pennsylvania, where we lease approximately ~~30, 000 square feet of office space pursuant to a lease that expires in May 2024. In June 2024, we will be moving our principal office to a new location in Yardley, Pennsylvania where we will lease approximately~~ 19, 780 square feet of office space pursuant to a lease that expires in May 2027. We also lease a facility in Ewing, New Jersey. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or to re- evaluate the location and amount of space needed for our operations. Legal Proceedings We are not a party to any material pending legal proceedings. Corporate Information We were incorporated under the laws of the State of Delaware in May 2010. Our corporate office is located at ~~1020 Stony Hill~~ **777 township Line** Road, Suite 300, Yardley, PA 19067. Our telephone number is (267) 364- 3500. We maintain an Internet website at www. optinose. com. The information contained on our website is not incorporated by reference into this **Annual Report on** Form 10- K. We make available free of charge under the " Investors — SEC Filings " section of our website all of our filings with the SEC, including our annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after we electronically file or furnish, as applicable, the information with the SEC. **Agreement and Plan of Merger On March 19, 2025, the Company entered into an Agreement and Plan of Merger (the" Merger Agreement ") with Paratek Pharmaceuticals, Inc' (" Paratek ") and Orca Merger Sub, Inc., a wholly owned subsidiary of Paratek (" Merger Sub "), pursuant to which Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly owned subsidiary of Paratek (the " Merger"). Pursuant to the Merger Agreement, upon the closing of the Merger, each share of Company common stock issued and outstanding immediately prior to the closing of the Merger Agreement (other than certain excluded shares of Company common stocl), will automatically be converted into the right to receive (i) $ 9. 00 in cash, without interest and (ii) one contractual contingent value right (CVR). Each CVR represents the right to receive a cash payment of (i) $ 1. 00 per CVR, payable upon achievement of net sales (as defined in the CVR agreement) of XHANCE in the United States in any calendar year equal to or in excess of $ 150 million during the period beginning on the date of the closing of the Merger Agreement and ending on December 31, 2028, and (ii) $ 4. 00 per CVR, payable upon achievement of net sales of XHANCE in the United States in any calendar year equal to or in excess of $ 225 million during the period beginning the date of the closing of the Merger Agreement and ending on December 31, 2029. The consummation of the Merger is subject to certain customary closing conditions, including (i) the adoption of the Merger Agreement by the holders of a majority of the outstanding shares of the Company' s common stock, (ii) if applicable, the expiration or termination of the waiting period under the Hart- Scott- Rodino Antitrust Improvements Act of 1976, as amended, and (iii) other customary closing conditions. The consummation of the Merger is not subject to any financing condition. Subject to the satisfaction of the closing conditions, the Company anticipates that the Merger will be consummated in the second or third quarter of 2025.** ITEM 1A. RISK FACTORS Investing in our common stock involves a high degree of risk. Before deciding to invest in our common stock, you should consider carefully the risks and uncertainties described below, together with general economic and business risks and all of the other information contained in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes and the section titled" Management' s Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occur, our business, financial condition, results of operations and prospects could be harmed. In that event, the price of our common stock could decline and you could lose all or part of your investment. This Annual Report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of specific factors, including the risks described below. See" Note Regarding Forward- Looking Statements." As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~73~~ **84** . ~~7~~ **5** million and ~~have~~ $ 130. 0 million of outstanding Pharmakon Senior Secured Notes under the A & R Note Purchase Agreement. Our accumulated deficit as of December 31, ~~2023~~ **2024** was $ ~~720~~ **741** . ~~4~~ **9** million. We have incurred significant net losses since inception and also expect to incur substantial losses in future periods. Our continuation as a going concern is dependent on our ability to maintain compliance with the financial covenants (including the requirement for us to achieve certain minimum trailing twelve- month consolidated XHANCE net sales and royalties thresholds, the requirement for us to maintain at least $ 30. 0 million of cash and cash equivalents at all times **(reduced to $ 20. 0 million following the date of the first quarterly payment of principal due on September 30, 2025)** and the requirement **that commencing with our financial statements for the fiscal year ending December 31, 2025** that our annual and quarterly financial statements not be subject to any qualification or statement as to" going concern"), and the other provisions under the A & R Note Purchase Agreement, and our ability to generate sufficient cash flows from operations to meet our debt service obligations and to fund our operations and / or obtain additional capital through equity or debt financings, partnerships, collaborations, or other sources. The A & R Note Purchase Agreement includes a requirement that we achieve certain minimum trailing twelve- month consolidated XHANCE net sales and royalties thresholds **through maturity** ~~commencing with the trailing twelve months ending March 31, 2024~~ . We believe it is probable that we will not ~~achieve~~ **maintain compliance with**

the trailing twelve- month minimum consolidated XHANCE net sales and royalties thresholds **for** ~~commencing with~~ the **entire one year** period ~~ending March 31~~ **after the filing of this Annual Report on Form 10- K. If we fail to achieve a minimum consolidated XHANCE net sales and royalties threshold** , **it** ~~2024, which~~ will constitute a default under the A & R Note Purchase Agreement if we are unable to obtain a modification or waiver of such minimum consolidated XHANCE net sales and royalties ~~thresholds~~ . **The A &** R Note Purchase Agreement also requires us to maintain at all times a minimum of $ 30.0 million of cash and cash equivalents ~~,which will be reduced to $ 20.0 million following the date of the first quarterly payment of principal due on September 30,2025~~ (referred to as,the" liquidity covenant").If we are unable to secure additional capital through equity or debt financings,partnerships,collaborations,or other sources,we believe that it is probable that ~~we~~ **our cash and cash equivalents balance** will **fall below** ~~not be able to maintain compliance with~~ the ~~liquidity covenant~~ **$ 30.0 million minimum threshold required** under the A & R Note Purchase Agreement **during** ~~beginning in~~ the ~~first~~ **third** quarter of ~~2026~~ **2024** ,which will also constitute a default under the A & **R Note Purchase Agreement if we are unable to obtain a waiver or modification of such liquidity covenant.** . Further, the A & R Note Purchase Agreement includes a requirement that commencing with the report and opinion on our consolidated financial statements commencing with **our financial statements for** the **fiscal** year ~~ended~~ **ending** December 31, ~~2023~~ **2025** ~~and~~ that all of our ~~subsequent~~ quarterly and annual financial statements, not be subject to any statement or qualification as to " going concern " (referred to as, the" going concern covenant"). As a general matter, financial statements are subject to a" going concern" uncertainty disclosure if it is probable that the company' s available capital is not sufficient to fund its operations and obligations for at least twelve months following the issuance of such financial statements including obligations that could become due during such twelve month period as a result of some future event (for instance, the potential that the Pharmakon Senior Secured Notes could become due if it is deemed probable that we will not maintain compliance with the covenants and other terms under the A & R Note Purchase Agreement during such twelve month period). ~~Our consolidated financial statements for the year ended December 31, 2023 and the auditor report and opinion thereon included in this Annual Report are subject to a statement as to going concern. On March 5, 2024, prior to the issuance of such audited financial statements, we received a waiver of the going concern covenant for our financial statements for the year ended December 31, 2023 and for our financial statements for the quarter ending March 31, 2024.~~ If we are unable to secure additional capital through equity or debt financings, partnerships, collaborations, or other sources, we believe it is unlikely that we will be able comply with the going concern covenant commencing with our financial statements for the ~~quarter~~ **fiscal year** ending ~~June 30~~ **December 31** , ~~2024~~ **2025** , which will constitute a default under the A & R Note Purchase Agreement if we are unable to obtain a modification or waiver of such going concern covenant. The A & R Note Purchase Agreement..... or modification of such liquidity covenant. In the event of any of the foregoing defaults, the holders of the Pharmakon Senior Secured Notes may declare an event of default under the A & R Note Purchase Agreement and may elect to accelerate the repayment of all unpaid principal, accrued interest and other amounts due (which would also require us to pay an interest make- whole premium as specified in the A & R Note Purchase Agreement if the repayment of the debt is accelerated prior to ~~November~~ **May** 21, ~~2025~~ **2026**), which may require us to delay or curtail our operations until we obtain additional capital which may not be available on a timely basis, on favorable terms, or at all, and such capital, if obtained, may not be sufficient to meet our payment obligations or enable us to continue to implement our long- term business strategy. In such an event, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. These factors raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the fair value for such assets or less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Additionally, if we seek additional financing to fund our debt service obligations and business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all. ~~We are a specialty pharmaceutical company with a limited operating history. To date, we have focused primarily on XHANCE and ONZETRA Xsail, as well as other product candidates using our proprietary EDS technology.~~ Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. To date, we have generated revenue from sales of XHANCE since its launch in 2018, as well as from licensing revenues from ONZETRA Xsail and our proprietary EDS technology. We incurred net losses of $ ~~35~~ **21** . 5 million and $ ~~74~~ **35** . ~~8~~ **5** million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~720~~ **741** . ~~4~~ **9** million. We expect to incur losses for the foreseeable future as we: ▪ continue to commercialize XHANCE and further scale up external manufacturing and distribution capabilities to commercialize XHANCE ~~or any other product candidate for which we may obtain regulatory approval~~ ; ▪ continue to focus our regulatory compliance efforts on requirements applicable to marketed drugs; ▪ continue ~~clinical development activities~~ **the mandated post- marketing adolescent studies** for XHANCE ~~, including mandated post- marketing pediatric studies~~ ; ▪ seek to discover and develop, in- license or acquire additional products, product candidates and technology; ▪ maintain, expand and protect our intellectual property portfolio; ▪ hire additional personnel to continue to support company growth; and ▪ incur additional legal, accounting and other expenses in operating as a publicly traded commercial- stage company. Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any **future** ~~of our~~ product candidates, our expenses could increase. We may never achieve or maintain profitability. Our ability to become and remain profitable will depend on our ability to generate revenue. Our ability to generate revenue depends upon our ability to successfully commercialize XHANCE and any of our other product candidates, if approved, that we may in- license or acquire in the future, as well as from our ability to successfully out- license any of our products or technology. Our ability to generate revenue from

our current or future products and product candidates will depend on a number of factors, including: ▪ our ability to successfully commercialize XHANCE for the treatment of **chronic rhinosinusitis with and without** nasal polyps ~~; ▪ our ability to obtain regulatory approval for, and successfully commercialize, XHANCE for the treatment of chronic sinusitis~~ ; ▪ our ability to complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize XHANCE outside the U. S.; ▪ the size of the markets in the territories for which we gain regulatory approval; ▪ the performance of our sales team, in marketing and promoting XHANCE; ▪ our ability to maintain and further develop a commercial organization capable of sales, marketing and distribution for XHANCE and any of our other product candidates for which we may obtain marketing approval; ▪ our ability to maintain commercially reasonable agreements with wholesalers, distributors and other third parties in our supply chain; ▪ our success in establishing a commercially viable price for our products; ▪ our success in defending against potential generic competition and other developments in our market generally; ▪ our ability to have commercial quantities of our products manufactured at acceptable cost levels; ▪ our ability to obtain coverage and adequate reimbursement from third parties, including government payors; and ▪ our ability to successfully complete development activities, including the necessary clinical trials, with respect to any of our future product candidates. XHANCE, as well as any of our future product candidates if approved for commercial sale, may not gain market acceptance or achieve commercial success. **Our** ~~Even if we obtain regulatory approval to market XHANCE for the treatment of chronic sinusitis, our~~ future revenues will depend upon our ability to achieve sufficient market acceptance and reimbursement from third- party payors. If our addressable market is not as significant as we estimate or the treatment population is narrowed by competition, physician choice, clinical practice guidelines or utilization management criteria imposed by payors, we may not generate significant revenue from sales of XHANCE. In addition, we would anticipate incurring significant costs associated with commercializing any approved product. We may not achieve profitability. If we are unable to generate enough product revenues to cover our operating expenses and service our debt, we will not become profitable and may be unable to continue operations without continued funding. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain drug approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We will likely require additional capital to fund our operations and, if we fail to obtain necessary financing, we may be unable to continue the commercialization of XHANCE ~~,~~ **and** service and repay our debt ~~and pursue FDA- approval of XHANCE for the treatment of chronic sinusitis~~ . Our operations have consumed substantial amounts of cash. To date, we have financed our operations primarily through the sale and issuance of ~~common and preferred~~ stock, debt, licensing revenues, XHANCE revenue and research grants. We expect to continue to spend substantial amounts to commercialize XHANCE ~~and pursue FDA- approval of XHANCE for the treatment of chronic sinusitis~~ . As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~73~~ **84** . ~~7~~ **5** million. We will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet our debt service obligations under our debt, and to carry out our planned development and commercial activities. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: ▪ the success of our commercialization of XHANCE for the treatment of ~~nasal polyps~~ **chronic rhinosinusitis** including, among other things, patient and physician acceptance of XHANCE and our ability to maintain adequate insurance coverage and reimbursement for XHANCE ~~; ▪ the outcome, timing and cost of the regulatory approval process of XHANCE for chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect; ▪ if XHANCE is approved by the FDA for the treatment of chronic sinusitis, the success of our commercialization of XHANCE for this new indication including, among other things, patient and physician acceptance of XHANCE for this new indication and our ability to obtain adequate insurance coverage and reimbursement for XHANCE for this new indication~~ , and the speed at which we are able to obtain these outcomes, if at all **;** ; ▪ the cost of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales; ▪ net product revenues received from sales of XHANCE; ▪ the level of co- pay assistance and other patient affordability programs offered for XHANCE; ▪ our clinical development plans for XHANCE, including our ongoing FDA- mandated post- marketing ~~pediatric study~~ **adolescent studies** ; ▪ the costs involved in preparing, filing and prosecuting patent applications, and maintaining and enforcing our intellectual property rights; ▪ the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us; ▪ the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates; and ▪ the extent to which we in- license, acquire or otherwise partner in the development of other products, product candidates or technologies. We cannot be certain that additional funding will be available when needed on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to (to the extent permissible under the A & R Note Purchase Agreement): ▪ significantly delay, scale back or discontinue the commercialization of XHANCE ~~and the development and pursuit of FDA- approval of XHANCE for the treatment of chronic sinusitis~~ ; ▪ relinquish or license on unfavorable terms our rights to our product, EDS technologies or other product candidates that we otherwise would seek to develop or commercialize ourselves; ▪ seek strategic collaborations to assist in the commercialization of XHANCE in the U. S. and other markets at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; ▪ delay, limit, reduce or terminate the drug development of ~~our current or~~ future product candidates, or seek collaborators for one or more of our ~~current or~~ future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or ▪ significantly curtail our operations, liquidate our assets or seek bankruptcy. If we are unable to meet our business objectives in the necessary timeframes or at all, our business would be jeopardized and we may not be able to continue operations. Additionally, the Note Purchase Agreement contains various covenants that limit our ability to obtain additional capital through the sale, transfer, lease or disposition of our assets, merger,

consolidation, the incurrence of additional debt and the granting of certain license rights related to our products, technology and other intellectual property rights. Furthermore, the warrants to purchase shares of our common stock issued in our November 2022 public offering (2022 Warrants) contain anti- dilution provisions which may adversely impact investor interest and participation in future equity financings or make such future equity financings more dilutive as a result of triggering the anti-dilution provisions of the 2022 Warrants or otherwise. Each holder of the Pharmakon Senior Secured Notes may elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes upon consummation of a specified change of control transaction or occurrence of certain events of default (as specified in the A & R Note Purchase Agreement), including, among other things: • our default in a payment obligation under the Pharmakon Senior Secured Notes; • our breach of the financial covenants, affirmative covenants, restrictive covenants or other terms of the A & R Note Purchase Agreement, including (i) the trailing twelve- month minimum consolidated XHANCE net sales and royalties covenant, (ii) the requirement to maintain at least $ 30. 0 million of cash and cash equivalents **(reduced to $ 20. 0 million following the date of the first quarterly payment of principal due on September 30, 2025)** and (iii) the requirement to deliver quarterly and annual financial statements that, commencing with the fiscal period ending ~~June 30~~ **December 31** , ~~2024~~ **2025** , are not subject to a" going concern" statement or qualification; • our breach of reporting obligations; • our failure to properly maintain the collateral; • any circumstance that could reasonably be expected to have a material adverse effect (as defined in the A & R Note Purchase Agreement) on us; • certain regulatory and / or commercial actions that cause an ongoing delay in commercialization of XHANCE; and • certain specified insolvency and bankruptcy- related events. Subject to any applicable cure period set forth in the Pharmakon Senior Secured Notes, all amounts outstanding with respect to the Pharmakon Senior Secured Notes (principal and accrued interest), as well as any applicable interest " make- whole " payments, would become due and payable immediately upon an event of default and shall be subject to a default interest rate of an additional 3 %. Our assets or cash flow may not be sufficient to fully repay our obligations under the Pharmakon Senior Secured Notes if the obligations thereunder are accelerated upon any events of default. Further, if we are unable to repay, refinance or restructure our obligations under the Pharmakon Senior Secured Notes, or obtain a waiver or modification to the financial covenants or any other terms under the A & R Note Purchase Agreement as may be required in the future, the holders of such Pharmakon Senior Secured Notes could proceed to protect and enforce their rights under the Pharmakon Senior Secured Notes by exercising such remedies (including foreclosure on the assets securing our obligations under the Pharmakon Senior Secured Notes and the A & R Note Purchase Agreement) as are available to the holders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Pharmakon Senior Secured Notes or in aid of the exercise of any power granted in the Pharmakon Senior Secured Notes. Any such action would materially and adversely affect the ongoing viability of our business. In the event that we maintain compliance with the trailing twelve- month minimum consolidated XHANCE net sales and royalties that we are required to meet each quarter, maintain at least $ 30. 0 million of cash and cash equivalents **(reduced to $ 20. 0 million following the date of the first quarterly payment of principal due on September 30, 2025)** and deliver quarterly and annual financial statements that, commencing with the fiscal period ending ~~June 30~~ **December 31** , ~~2024~~ **2025** , are not subject to a" going concern" statement or qualification, and maintain compliance with all other terms of the A & R Note Purchase Agreement, in each case, to avoid an acceleration of payments due under the Pharmakon Senior Secured Notes, then we will be required to repay the notes in eight equal quarterly payments of $ 16. 25 million starting on September 30, 2025. The Pharmakon Senior Secured Notes are guaranteed by us and ~~certain of~~ our **wholly- owned** ~~subsidiaries~~ **subsidiary , OptiNose US, Inc.,** and are secured by a pledge of substantially all of our and ~~their~~ **its** assets. We are required to achieve the following minimum trailing twelve- month XHANCE net sales and royalties under the A & R Note Purchase Agreement (in thousands): Trailing Twelve- Months EndingRequirement under the A & R Note Purchase Agreement ($) ~~September 30, 2022N / ADecember 31, 2022N / AMarch~~ **March** ~~31, 2023N / AJune 30, 2023N / ASeptember 30, 2023N / ADecember 31, 2023N / AMarch~~ 31, 2024 $ ~~82~~ **70** , ~~500June~~ **000June** 30, ~~202490~~ -- **2024 $ 70** , 000September 30, ~~2024102~~ **2024 $ 72** , 500December 31, ~~2024110~~ **2024 $ 75** , 000March 31, ~~2025115~~ **2025 $ 80** , 000June 30, ~~2025120~~ **2025 $ 87, 500September 30, 2025 $ 95, 000December 31, 2025 $ 102, 500March 31, 2026 $ 120, 000June 30, 2026 $ 130** , 000September 30, ~~2025125~~ **2026 $ 145** , 000December 31, ~~2025130~~ **2026 $ 150** , 000March 31, ~~2026135~~ **2027 $ 155** , 000June 30, **2027 $ 160** ~~2026140, 000September 30, 2026145, 000December 31, 2026150, 000March 31, 2027155, 000June 30, 2027160~~ , 000 Our A & R Note Purchase Agreement contains restrictions that limit our flexibility in operating our business. The A & R Note Purchase Agreement contains various covenants that limit our ability to engage in specified types of transactions without our lenders' prior consent. These covenants limit our ability to, among other things: • sell, transfer, lease or dispose of our assets; • create, incur or assume additional indebtedness; • encumber or permit liens on certain of our assets; • make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our common stock; • make specified investments (including loans and advances); • consolidate, merge, sell or otherwise dispose of all or substantially all of our assets; • enter into certain transactions with our affiliates; • grant certain license rights related to our products, technology and other intellectual property rights; and • permit our cash and cash equivalents held in certain deposit accounts to be less than $ 30. 0 million at any time **(reduced to $ 20** . **0 million following** ~~In addition, the A & R Note Purchase Agreement provides for, among other~~ -- **the date** ~~things, modifications to the affirmative and negative covenants and events~~ of ~~default, including, without limitation,~~ the ~~removal~~ **first quarterly payment** of **principal due on September 30** ~~certain exceptions to the negative covenants which previously permitted us to enter into certain transactions without the consent of the holders of the Pharmakon Senior Secured Notes~~ , **2025)** ~~including permitted acquisitions, swap contracts, convertible bonds and a revolving credit facility~~ . The covenants in our A & R Note Purchase Agreement and related security agreements may limit our ability to take certain actions that may be in our long- term best interests. In the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding under the Pharmakon Senior Secured Notes, plus penalties and interest, terminate their commitments to

purchase additional Pharmakon Senior Secured Notes and foreclose on the collateral granted to them to secure the Pharmakon Senior Secured Notes. Such repayment could have a material adverse effect on our business, operating results and financial condition. Provisions of the Pharmakon Senior Secured Notes and the 2022 Warrants provide for certain potential payments to the holders of such securities which could impede a sale of the Company. Subject to certain exceptions, we are required to make mandatory prepayments of the Pharmakon Senior Secured Notes, with the proceeds of asset sales, extraordinary receipts and prohibited debt issuances, and upon the occurrence of a change of control (as defined in the A & R Note Purchase Agreement). In addition, we may make voluntary prepayments of the Pharmakon Senior Secured Notes, in whole or in part. We will be required to pay an interest " make- whole " premium in respect of any principal prepayments (whether mandatory or voluntary) made prior to the ~~36~~ **42** - month anniversary of the effective date of the A & R Note Purchase Agreement, as follows: (i) for any prepayment date occurring up until and including the ~~18~~ **24** - month anniversary of the date of the A & R Note Purchase Agreement, the foregone interest from such prepayment date through the 18- month anniversary of such prepayment date; and (ii) for any prepayment after the ~~18~~ **24** - month anniversary of the date of the A & R Note Purchase Agreement, the foregone interest from such prepayment date through the ~~3~~ **42** - ~~year~~ **month** anniversary of the date of the A & R Note Purchase Agreement; provided, however, that in no event shall the amount of all make- whole premium payments exceed $ 24. 0 million in the aggregate. In addition, in the event of a fundamental transaction, as defined in the 2022 Warrants, in certain circumstances each holder of a 2022 Warrant will have the right to require us to repurchase its 2022 Warrant for cash at the Black Scholes Value (as defined in the 2022 Warrants). These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We do not have any committed external source of funds. Until such a time, if ever, that we can generate substantial revenue and maintain profitability, we may seek to raise additional capital through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of additional indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through collaborations, or strategic alliance, grants, marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us or at an earlier stage than would otherwise be desirable. As noted below, the 2022 Warrants contain price protection anti- dilution provisions. If the exercise price of the 2022 Warrants is reduced as a result of our future issuance **, deemed issuance,** of shares or other securities at prices below the **then- current** exercise price of the 2022 Warrants, this may result in additional warrant exercises and additional dilution to stockholders. We have a significant number of warrants outstanding that contain anti- dilution provisions that may result in the reduction of their exercise prices in the future. The 2022 Warrants contain anti- dilution provisions, which provisions require the lowering of the exercise price, as applicable, to the purchase price of future offerings. **For example, on May 10, 2024, we completed a registered direct offering which resulted in the exercise price of the 2022 Warrants being reduced from $ 38. 475 to $ 15. 00 (which was the offering price of each share sold in the registered direct offering completed on that date) pursuant to the anti- dilution price protection provisions of such 2022 Warrants.** If in the future we issue or are deemed to issue securities for less than the **then- current** exercise price of the 2022 Warrants, we may be required to reduce the exercise prices of the 2022 Warrants **again** . During the term that the 2022 Warrants are outstanding, the holders of those securities are given the opportunity to profit from a rise in the market price of our common stock. In addition, we may find it more difficult to raise additional equity capital while these warrants are outstanding. Any future adjustments to the exercise prices of the 2022 Warrants may have a negative impact on the trading price of our common stock. Additionally, raising additional capital with new investors may be difficult as a result of the adjustment feature. Our ability to use our net operating loss carry forwards and other tax attributes may be limited. As of December 31, ~~2023~~ **2024** , we had U. S. federal net operating loss (NOL) carry forwards of approximately $ **367** ~~360. 5~~ million available to offset future U. S. taxable income and U. S. federal research and development (R & D) tax credits of $ 2. 4 million. While some of our federal NOL carry forwards will carry forward indefinitely, some of our U. S. NOL and credit carry forwards will expire if not utilized with the first expiration occurring in 2030. We also had state NOL carry forwards of $ **283** ~~265. 3~~ million as of December 31, ~~2023~~ **2024** . These state NOL carry forwards can only offset income in the same state in which they were generated and thus there is a possibility that they may not be utilized. The carry forward period varies among the states, with the first expiration in 2028. ~~In addition, our UK subsidiary, had total foreign NOL carry forwards of $ 3. 6 million as of December 31, 2023. These foreign NOL carry forwards do not expire but can only be used to offset profits generated in the United Kingdom. These net operating losses may be limited in use based on the laws in the United Kingdom. In order to simplify the corporate structure, our board of directors approved the liquidation of our Norwegian subsidiary in 2023 and our UK subsidiary, which is expected to be completed in 2024.~~ Our U. S. NOL and tax credit carry forwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of other restrictions under U. S. tax law. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an " ownership change ", generally defined as a greater than 50 %

change, by value, in equity ownership during a three- year period, the corporation' s ability to offset pre- change tax attributes, such as NOLs and R & D tax credits, against post- change income or tax may be limited. We have not performed an analysis under Section 382 of the Code and cannot predict or otherwise determine whether utilization of our federal tax attribute carry forwards may be limited. As a result, if we have taxable income in the future, our ability to use existing U. S. NOL and R & D tax credit carry forwards to reduce U. S. taxable income or tax liability may be subject to limitation resulting in increased future tax liabilities. Similar rules at the state level may also limit our ability to use state NOLs. Also, there may be periods when the use of NOLs is suspended or otherwise limited at the state level, which could accelerate or permanently increase state taxes owed. Furthermore, the losses could expire before we generate sufficient income to utilize them. We may have ownership changes in the future due to additional changes in our stock ownership which could be outside of our control. If an ownership change occurs and our ability to use our historical net operating loss and tax credit carry forwards is limited, it could adversely impact our future operating results by increasing our tax obligations. Our ability to successfully commercialize XHANCE depends on many factors, including: ~~• our ability to obtain regulatory approval for XHANCE for a follow- on indication for the treatment of chronic sinusitis; ~~▪ our ability to have commercial quantities of XHANCE manufactured at a reasonable cost and with sufficient speed to meet commercial demand; ▪ the ability of our sales team to effectively market, promote and sell XHANCE; ▪ our success in educating physicians, patients and caregivers about the benefits, administration and use of XHANCE; ▪ patient and physician acceptable of XHANCE; ▪ the availability, perceived advantages, relative cost, relative safety and relative efficacy of competing products; ▪ the availability of coverage and adequate reimbursement for XHANCE; ▪ our ability to commercialize XHANCE at a profitable average net revenue per prescription; ▪ our ability to obtain and maintain contracts with wholesalers, distributors, PPN partners or HUB partner on acceptable terms; ▪ the effectiveness of our marketing campaigns; ▪ our ability to attract and retain qualified pharmaceutical industry personnel; ▪ a continued acceptable safety profile for XHANCE; ▪ our ability to obtain and maintain required state licenses to sell XHANCE; and ▪ our ability to successfully defend any challenges to our intellectual property relating to XHANCE. It is difficult for us to predict future performance. As we gain additional commercial experience, a number of factors over which we have limited control may contribute to fluctuations in our financial results. We expect that first quarter prescription demand and average net revenue per prescription for XHANCE will be adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January. Additionally, demand has historically been, and we expect will continue to be, impacted by the seasonal variation in patient visits with their doctor and market seasonality resulting in reduced XHANCE prescription demand in the third quarter. Many of these matters are beyond our control and are subject to other risks described elsewhere in this" Risk Factors" section. Accordingly, we cannot assure you that we will be able to successfully commercialize or generate enough revenue from XHANCE to achieve profitability or maintain compliance with minimum trailing twelve- month XHANCE net sales and royalties thresholds and other covenants under the A & R Note Purchase Agreement. If we cannot do so, or are significantly delayed in doing so, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline. The commercial success of XHANCE depends upon its acceptance by multiple stakeholders, including physicians, patients and third- party payors. The degree of market acceptance of XHANCE depends on a number of factors, including: ▪ demonstration of clinical safety and efficacy; ▪ relative convenience and ease of administration; ▪ pricing and cost- effectiveness; ▪ availability of alternative treatments and perceived advantages over such alternative treatments; ▪ the clinical indications for which XHANCE is approved; ▪ the prevalence and severity of any AEs; ▪ limitations or warnings contained in the FDA- approved label for XHANCE; ▪ the effectiveness of our or any future collaborators' sales and marketing strategies; ▪ consolidation among healthcare providers, which increases the impact of the loss of any relationship; ▪ our ability to obtain and maintain sufficient third- party coverage and adequate reimbursement; ▪ adequacy and accessibility of our patient assistance programs; and ▪ the willingness of patients to pay out- of- pocket in the absence of third- party coverage. If XHANCE does not achieve an adequate level of acceptance by physicians, patients and third- party payors, we may not generate sufficient revenue in order to become or remain profitable. Our ability to commercialize XHANCE successfully depends in part on the extent to which coverage and adequate reimbursement for XHANCE will be available in a timely manner and remains available from third- party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by particular third- party payors depend upon a number of factors, including each third- party payor' s determination that use of a product is: ▪ a covered benefit under its health plan; ▪ appropriate and medically necessary for the specific condition or disease; ▪ cost effective; and ▪ neither experimental nor investigational. Obtaining coverage and reimbursement approval for XHANCE from government authorities or other third- party payors is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost- effectiveness data, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, for the use of XHANCE to each government authority or other third- party payor. We may not be able to provide data sufficient to gain or maintain acceptance with respect to coverage and reimbursement from government authorities or other third- party payors. Third- party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost- effective diagnosis methods, as determined by the third- party payor, or was used for an unapproved indication. Third- party payors also may refuse to reimburse for procedures and devices deemed to be experimental. Third- party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA- approved products for a particular indication. Third- party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels

of reimbursement may also decrease in the future, and future legislation, regulation or reimbursement policies of third- party payors may adversely affect the demand for and reimbursement available for XHANCE, which in turn, could negatively impact pricing. Further, payors, including healthcare insurers, pharmacy benefit managers and group purchasing organizations, increasingly seek ways to reduce their costs. Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients. Such measures include more limited benefit plan designs, higher patient co- pay or co- insurance obligations and limitations on patients' use of commercial manufacturer co- pay assistance programs (including through co- pay accumulator adjustment or maximization programs). Payors also increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage. Payors may also control costs by imposing restrictions on access to or usage of our products, such as by requiring prior authorizations or" step- edits," and may choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. For example, some insurers have established a step- edit system that requires a patient to first use a lower price generic or other alternative product prior to becoming eligible for reimbursement for XHANCE and some insurers also require that a physician attest that XHANCE is being used to treat a patient for an indication for which XHANCE is **FDA-** approved **(chronic rhinosinusitis with or without nasal polyps)** . We estimate that approximately half of the covered lives as of December 31, ~~2023~~ **2024** are in a plan that requires a prior authorization and most of those prior authorizations request information regarding patient diagnosis **for an indication for which XHANCE is FDA- approved** and prior use of INS. In some cases, patients do not meet the payors' utilization management criteria, and in other cases, healthcare providers may not complete the burdensome administrative process required to demonstrate or document that the patients for whom XHANCE has been prescribed meet the payors' utilization management criteria (i. e., prior authorizations or step- edits) and, as a result, patients may not gain access to XHANCE treatment ~~. These requirements include physician attestation to a diagnosis for an FDA- approved indication (which currently is only nasal polyps) which can be a hurdle for some physicians in our target audience because it is not a diagnosis they make commonly~~ . Further, other patients may obtain coverage for XHANCE but abandon their prescriptions rather than pay their co- pay payment which could result in a meaningful shortfall in achieving our revenue expectations and negatively impact our business, prospects, results of operations and financial condition. Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors, including through integrated delivery systems, would increase the negotiating leverage such entities have over us and other drug manufacturers. Ultimately, further discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products. If we are unable to differentiate XHANCE from current and future products or existing methods of treatments, our ability to successfully commercialize XHANCE will be adversely affected. We are currently commercializing XHANCE for the treatment of chronic rhinosinusitis with ~~nasal polyps and are seeking FDA approval for~~ **or** ~~a follow- on indication of XHANCE for the treatment of chronic rhinosinusitis~~ without nasal polyps. Nasonex ™ is the only other branded drug therapy approved by the FDA for the treatment of nasal polyps. Nasonex was marketed by Merck until it removal from the prescription market, but remains available over- the- counter without a prescription for other indications. Generic versions of Nasonex ™, mometasone furoate monohydrate, continue to be available by prescription. In addition, Beconase AQ ™, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection, while SINUVA ™ is a commercially available corticosteroid- eluting implant indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. We are not aware of any drug product approved for the treatment of chronic rhinosinusitis without nasal polyps (or chronic sinusitis). In addition to competition from Nasonex ™ and Beconase AQ ™, we also need to differentiate XHANCE from other products and treatments identified in current clinical practice guidelines for the treatment of chronic rhinosinusitis with and without nasal polyps. Such products and treatments include the use of nasal rinses, decongestants, over- the- counter and prescription INS products, oral steroids, antibiotics, and sinus surgery and other procedures, including functional endoscopic sinus surgery, balloon sinus dilation and steroid- releasing sinus implants. In addition, several monoclonal antibodies have been approved for the treatment of nasal polyps and are in clinical development for the treatment of chronic rhinosinusitis without nasal polyps. In June 2019, the FDA approved DUPIXENT ™ (dupilumab) as an add- on maintenance treatment (to an intranasal steroid) in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis. In November 2020, the FDA approved XOLAIR ™ add- on maintenance treatment of nasal polyps in adult patients with inadequate response to nasal corticosteroids. In July 2021, the FDA approved NUCALA ™ add- on maintenance treatment of chronic rhinosinusitis with nasal polyps in adult patients with inadequate response to nasal corticosteroids **. Additional potential future therapies include but are not limited to monoclonal antibodies, and corticosteroid- eluting implants. Benralizumab, depemokimab, and tezepelumab, some of which are already approved for other indications, are being developed for the treatment of nasal polyps, and are believed to inhibit specific pathways of inflammation present in nasal polyps** . In addition these monoclonal antibodies or others may be studied as potential treatments for patients with chronic rhinosinusitis without nasal polyps. Lyra Therapeutics is developing corticosteroid- eluting implants as potential treatment for patients with chronic rhinosinusitis. In addition, Insmed is studying brensocatib as a potential treatment for chronic rhinosinusitis without nasal polyps by targeting inhibition of Dipeptidyl peptidase- 1 (DPP1). If we are unable to achieve significant differentiation for XHANCE against these other products and treatments, including on the basis of efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement, the opportunity for XHANCE to be commercialized successfully would be adversely affected. If the market opportunities for XHANCE are smaller than we believe, our revenue potential may be adversely affected, and our business may suffer. We believe there is a market opportunity for XHANCE consisting of ENT physicians, allergists and high- decile INS- prescribing primary care physicians

that we believe treat an estimated 3. 5 million U. S. patients with chronic rhinosinusitis, an estimated 1. 2 million of whom have chronic rhinosinusitis with nasal polyps. **We** ~~If we are able to obtain a follow- on indication of XHANCE for the treatment of chronic rhinosinusitis without nasal polyps, we~~ intend to broaden, through potential collaborations, our reach and target primary care physicians that we believe treat an additional estimated 6. 25 million patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. Our projections of both the number of people who suffer from chronic rhinosinusitis with and without nasal polyps, as well as the subset of people with these diseases who have the potential to benefit from the use of XHANCE, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys we commissioned, prescription data or other market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of chronic rhinosinusitis with nasal polyps and chronic rhinosinusitis without nasal polyps. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for XHANCE may be limited or may not be amenable to treatment with XHANCE, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our revenue potential and our business. Clinical practice guidelines and recommendations published by various organizations could have significant influence on the use of XHANCE. Government agencies may promulgate clinical practice guidelines directly applicable to XHANCE. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of XHANCE or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of XHANCE. A significant portion of our sales are to a limited number of PPN partners and pharmaceutical wholesalers. Changes in terms required by these PPN partners or wholesalers, disruptions in these relationships or a default could harm our results of operations and financial condition. Approximately ~~77~~ **59** % of our XHANCE net revenues during the fiscal year ended December 31, ~~2023~~ **2024** were to PPN **and HUB** partners. The three leading ~~PPNs~~ **PPN and HUB partners** accounted for approximately ~~25~~ **36** % of our XHANCE net revenues. The largest PPN was Professional Arts Pharmacy which accounted for approximately ~~15~~ **25** % of our XHANCE revenue. Additionally, approximately ~~23~~ **41** % of our XHANCE net revenues during the fiscal year ended December 31, ~~2023~~ **2024** were to the three largest wholesale pharmaceutical distributors, Cardinal Health, McKesson Corporation and AmerisourceBergen Drug Corporation. If any of these PPN partners or wholesalers ceases to purchase our product for any reason, then unless and until the remaining PPN partners or wholesalers increase their purchases of XHANCE or alternative distribution channels are established: ▪ our commercial operations could be significantly disrupted; ▪ the availability of XHANCE to patients could be disrupted; and ▪ we may not achieve sales of XHANCE that we expect, which would decrease our revenues. We do not require collateral from our wholesalers or PPN **and HUB** partners but rather maintain credit limits and, as a result, we have an exposure to credit risk in our accounts receivable. A default by a large PPN **or HUB** partner or wholesaler could harm our results of operations and financial condition. Our reliance on HUB and PPN partners for the distribution of XHANCE in the U. S. involves certain risks, including, but not limited to, risks that these HUB and PPN partners will: ▪ not provide us accurate or timely information regarding their inventories, the number of patients who are using our products or complaints about our products; ▪ not devote the necessary resources, or reduce or discontinue their efforts, to sell or support or otherwise not effectively sell or support our products, including, without limitation, the discontinuation of their refill programs for XHANCE and other patient support services; ▪ engage in unlawful or inappropriate business practices that result in legal or regulatory enforcement activity which could result in liability to our Company or damage our goodwill with patients; or ▪ be unable to satisfy financial obligations to us or others. In the event that any of the HUB and PPN partners with whom we work do not fulfill their contractual obligations to us or refuse to or fail to adequately serve patients, or the agreements are terminated without adequate notice, shipments of XHANCE, and associated revenues, would be adversely affected. We offer patient affordability programs through traditional retail pharmacies and our HUB and PPN partners to help reduce eligible patients' out- of- pocket costs for XHANCE prescriptions. The utilization of our patient affordability programs will depend on physician and patient awareness and acceptance of the programs. Additionally, certain co- pay assistance benefits are only available through our HUB and PPN partners. As a result, eligible patients' out- of- pocket cost for XHANCE, when dispensed through our HUB and PPN partners, may be lower than such costs when XHANCE is dispensed from traditional retail pharmacies. However, to the extent physicians are not willing to prescribe through our HUB and PPN partners or patients are not willing to receive XHANCE through our HUB and PPN partners, access to and utilization of XHANCE may decline. In addition, our patient affordability programs are not available to federal health care program (such as Medicare and Medicaid) beneficiaries. We have also contracted with certain PBMs and other payors to secure formulary status and reimbursement for XHANCE, which generally require us to pay administrative fees and rebates to the PBMs and other payors for qualifying prescriptions. While we have agreements with three of the largest PBMs, as well as other PBMs and payors, in order to facilitate formulary status for XHANCE, we cannot guarantee that we will be able to agree to terms with other PBMs and payors, or that such terms will be commercially reasonable to us. Additionally, our contracts with PBMs and payors are of limited duration and PBMs and payors with whom we contract may seek to renegotiate more favorable terms prior to the expiration of such contracts or in connection with renewals. Despite our agreements with PBMs, the extent of formulary status and reimbursement will ultimately depend to a large extent upon individual healthcare plan formulary decisions. If healthcare plans that contract with PBMs with which we have agreements do not adopt formulary changes recommended by the PBMs with respect to XHANCE, we may not realize the expected access and reimbursement benefits from these agreements. Consequently, the success of our PBM contracting strategy will depend not only on our ability to expand formulary adoption among healthcare plans, but also upon the relative mix of healthcare plans that have PBM- chosen formularies versus custom formularies. If we are unable to

realize the expected benefits of our contractual arrangements with the PBMs the adoption of XHANCE by physicians and patients may decline. If we are unable to increase adoption of our HUB and PPN partners for filling prescriptions of XHANCE by physicians or to secure formulary status and reimbursement through arrangements with PBMs and other payors, particularly with healthcare plans that use custom formularies, our ability to achieve net sales growth for XHANCE would be impaired. The negative publicity regarding specialty pharmacies, HUB and other patient support service providers may result in physicians being less willing to send prescriptions to our HUB or PPN partners or participate in our patient affordability programs, which would limit patient access and utilization of XHANCE. There has been negative publicity and inquiries from Congress and enforcement authorities regarding the use of specialty pharmacies, HUB and other patient support services providers and drug pricing. We contract with HUB and PPN partners (who may be considered specialty pharmacies) and other patient support services providers that provide certain services in connection with our patient affordability programs. These programs are in place to assist in ensuring that when a physician determines XHANCE offers a potential clinical benefit to their patients and they prescribe it for an eligible patient, financial assistance may be available to reduce the patient' s out- of- pocket costs. We do not own or possess any option to purchase an ownership stake in any pharmacy that distributes XHANCE or in our HUB partner or any other patient support services provider, and our relationship with each pharmacy, our HUB partner and other patient support services providers is non- exclusive and arm' s length. All of our sales are processed through pharmacies independent of us. Despite this, the negative publicity and interest from Congress and enforcement authorities regarding specialty pharmacies, HUBs or other patient support services providers may result in physicians being less willing to send prescriptions to our HUB and PPN partners or participate in our patient affordability programs and thereby limit patient access and utilization of XHANCE. We may be unable to form and maintain relationships with pharmacies that participate in our **Hub,** PPN and patient affordability programs, which could adversely affect the commercialization of XHANCE and our operating results. We may encounter difficulty in forming and maintaining relationships with pharmacies that participate in our PPN and patient affordability programs. We currently depend on a limited number of **Hub and** PPN partners to fulfill patient prescriptions. If these ~~PPN~~ partners are unable to process and fulfill the volume of patient prescriptions directed to them, our ability to maintain or increase prescriptions for XHANCE will be impaired. The commercialization of XHANCE and our operating results could be affected should any of the ~~PPN~~ partners choose not to continue to fulfill XHANCE prescriptions or by any adverse market events at any of the ~~PPN~~ partners. For example, pharmacies that dispense XHANCE could lose contracts that they currently maintain with payors or managed care organizations (MCOs), including PBMs. They may be required to abide by certain terms and conditions to maintain access to payors or MCO networks, including terms and conditions that could limit their ability to participate in patient affordability programs like ours. Failure to comply with the terms of their agreements with payors or MCOs could result in a variety of penalties, including termination of their agreement, which could negatively impact the ability of those pharmacies to dispense XHANCE and collect reimbursement from payors or MCOs for such medicines. Our patient affordability programs are subject to certain federal and state laws, the violation of which could have an adverse impact on our business and subject us to significant penalties. Our patient affordability programs may implicate certain federal and state laws related to, among other things, unlawful schemes to defraud, fraud and abuse, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. We have a comprehensive compliance program in place to address adherence with various laws and regulations relating to the selling, marketing and manufacturing of XHANCE. Despite our compliance efforts, to the extent the patient affordability programs are found to be inconsistent with applicable laws or the pharmacies that participate in our patient affordability programs do not comply with applicable laws or our business rules, we may be required to restructure or discontinue such programs, terminate our relationship with certain pharmacies, or be subject to other significant penalties. If the cost of maintaining our patient affordability programs increases relative to our sales revenue, we could be forced to reduce or eliminate our financial assistance programs, which could have an adverse effect on our financial results. If the cost of maintaining our patient affordability programs increases relative to our sales revenues, we could be forced to reduce the amount of co- pay support and other patient financial assistance that we offer or otherwise scale back or eliminate such programs, which could in turn have a negative impact on physicians' willingness to prescribe and patients' willingness to fill prescriptions of XHANCE. While we believe that our arrangements with PBMs and other payors will result in broader inclusion of XHANCE on healthcare plan formularies, and lower our cost of providing patient affordability programs, these arrangements generally require us to pay administrative and rebate payments to the PBMs and / or other payors and their effectiveness will ultimately depend to a large extent upon individual healthcare plan formulary decisions that are beyond the control of the PBMs. If our arrangements with PBMs and other payors do not result in increased prescriptions and reductions in our costs to provide our patient affordability programs that are sufficient to offset the administrative fees and rebate payments to the PBMs and / or other payors, our financial results may continue to be harmed. XHANCE may become associated with undesirable adverse reactions or have other properties that could result in significant negative consequences following regulatory approval. If we or others identify adverse events associated with XHANCE, a number of potentially significant negative consequences could result, including: ▪ we may be forced to suspend marketing of XHANCE; ▪ the FDA may withdraw its approval of XHANCE or impose restrictions on its distribution; ▪ the FDA may require additional warnings or contradictions in the label that could diminish the usage or otherwise limit the commercial success of XHANCE; ▪ we may be required to conduct additional post- marketing studies; ▪ we could be sued and held liable for harm caused to patients; and ▪ our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of XHANCE. If the FDA or other applicable regulatory authorities approve generic or similar products that compete with XHANCE, or if the FDA or other applicable regulatory authorities change or create new pathways that may expedite approval of such products, it could decrease our expected sales of XHANCE. Once an NDA, including a Section 505 (b) (2) application, is approved, the product covered thereby becomes a" listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA or 505 (b) (2) NDA. The FD & C Act, FDA 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 for generic substitutes. Manufacturers may be able to bring a generic product to market in a much more cost- efficient pathway than we currently anticipate. If the costs involved in bringing such a product to market are significantly less than our costs with respect to the development of XHANCE, companies that produce generic equivalents to XHANCE may be able to offer their products at lower prices. Further, if the timeline for bringing such a product to market is expedited, companies that produce generic equivalents to XHANCE may compete with XHANCE faster than we currently anticipate. For example, the FDA has communicated a priority to build on initiatives to accelerate generic entry of complex generics, which include locally acting nasal drug products and ~~the FDA has included~~ XHANCE **is** on the ~~updated~~ list of product specific guidances for complex generic drug products that the FDA plans to issue **within the next 12- months** , which may provide clarity for competitors to develop generic products that compete with XHANCE. If the FDA accepts alternatives to comparative clinical endpoint bioequivalence studies for generic versions of XHANCE like it has adopted for certain conventional INS, we may face generic competition faster than we currently anticipate and a significant percentage of any future sales of XHANCE could be lost to such generic products. For example, the FDA has published a ~~draft~~ product- specific guidance for 0. 05mg / spray fluticasone propionate nasal spray that states that a comparative clinical endpoint bioequivalence study is recommended for a fluticasone propionate nasal spray product because of an inability to adequately characterize drug particle size distribution (PSD) in aerosols and sprays using commonly used analytical methods. However, the ~~draft~~ guidance also provides that if a product' s PSD can be accurately measured using a validated analytical method such as morphology- directed Raman spectroscopy or any other advanced methodology, the product' s sponsor could submit comparative PSD data as part of their drug characterization within their ANDA application as a potential alternative to a bioequivalence study. Moreover, in addition to generic competition, we could face competition from other companies seeking approval of products that are similar to ours using the Section 505 (b) (2) pathway. Such applicants may be able to rely on XHANCE or other approved drug products or published literature to develop drug products that are similar to ours. Furthermore, in 2021 ~~and~~ **,** 2022 **and 2024** we provided units of XHANCE to a generic manufacturer in compliance with the CREATES Act. The introduction of a drug product similar to our products or product candidates could expose us to increased competition, leading to a decrease in sales of XHANCE. Competition that we may face from generic or similar versions of XHANCE could materially and adversely impact our future revenue, profitability, and cash flows. Even though we have obtained regulatory approval in the U. S. for XHANCE for the treatment of chronic rhinosinusitis with **or without** nasal polyps in adults, the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of XHANCE, or impose ongoing requirements for potentially costly post- approval studies or post- marketing surveillance. For example, as part of its approval of XHANCE for the treatment of nasal polyps in adults, the FDA **required** ~~is requiring~~ that we conduct a randomized, double- blind, placebo controlled clinical trial in adolescents 12 to 17 years of age with nasal polyps to assess the safety, efficacy, and pharmacokinetics of XHANCE in this population. We have contracted with various clinical trial sites and continue patient enrollment in this trial. The **original** post- marketing requirement at **the time of the approval of** XHANCE ~~approval~~ was to complete the trial by January 2022 and to submit a final report with respect to the trial by July 2022, however, due to enrollment rates, **these deadlines have been extended to March 2026, and September 2026, respectively. Additionally, as part of the FDA' s approval of XHANCE for the treatment of chronic rhinosinusitis without nasal polyps,** we have **a post- marketing requirement to complete a study of XHANCE in adolescent patients 12 to 17 years of age with chronic rhinosinusitis without nasal polyps by March 2028, and** ~~submitted~~ --- **submit** a ~~request~~ **final report** to the FDA ~~to extend these deadlines. FDA granted an extension of these milestone dates, and acknowledged revised milestone dates for study completion~~ by October ~~2022~~ **2028** ~~and final report submission by April 2023. Subsequent to further discussion with FDA on the extrapolation of adult data using a Bayesian borrowing approach to evaluate efficacy in the adolescent population, FDA reissued the post- marketing requirement with revised milestones for the study completion by March 2026 and final report submission by September 2026~~ . We are also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record- keeping and reporting of safety and other post- marketing information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the U. S. grant similar powers to the competent authorities and impose similar obligations on companies. In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to commitments made in the NDA. Since XHANCE is a combination product, we also need to comply with some of the FDA' s manufacturing regulations for devices. In addition to cGMP, the FDA requires that our drug- device combination product comply with the Quality System Regulation (QSR), which sets forth the FDA' s manufacturing quality standards for medical devices, and other applicable government regulations and corresponding foreign standards. If we, or a regulatory authority, discover previously unknown problems with XHANCE, such as AEs, of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to XHANCE or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by foreign regulatory authorities. If we fail to comply with applicable regulatory requirements following approval of XHANCE, a regulatory authority may: ▪ issue a warning letter asserting that we or our manufacturing partners are in violation of the law; ▪ seek an injunction or impose civil or criminal penalties or monetary fines; ▪ suspend, modify or withdraw regulatory approval; ▪ suspend any ongoing clinical trials; ▪ refuse to approve a pending NDA or a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by

us; ▪ seize our product or product candidate; and / or ▪ refuse to allow us to enter into supply contracts, including government contracts. Our current and future operations with respect to the commercialization of XHANCE, as well as potential future development programs, are subject to various U. S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third- party payors, healthcare professionals, pharmacies and others who may prescribe, recommend, purchase or provide XHANCE, and other parties through which we market, sell and distribute XHANCE. Finally, our current and future operations are subject to additional healthcare- related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws are described in greater detail in the previous section under" Business — Government Regulation — Healthcare Fraud and Abuse Laws," and include, but are not limited to: ▪ the federal Anti- Kickback Statute, prohibits persons or entities from, among other things, knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. ▪ the federal civil False Claims Act (which can be enforced through" qui tam," or whistleblower actions, by private citizens on behalf of the federal government) prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U. S. federal government. ▪ the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. • numerous federal and state laws and regulations that address privacy and data security, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act (FTC Act)), govern the collection, use, disclosure and protection of health- related and other personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating relevant compliance efforts. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space. ▪ a majority of states whom have adopted laws and regulations analogous to federal laws, including state anti- kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers. Other states have adopted laws that, among other things, require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities. In addition, some states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co- pay assistance that pharmaceutical companies can offer to patients. • the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our 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 do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement or other settlement agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating

our business. The occurrence of any event or penalty described above may inhibit our ability to commercialize and further develop XHANCE and generate revenues which would have a material adverse effect on our business, financial condition and results of operations. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We participate in the Medicaid Drug Rebate Program, and other governmental pricing programs, and therefore we are obligated to pay certain specified rebates and report pricing information with respect to XHANCE. Pricing and rebate calculations vary across product and programs, are complex and are often subject to interpretation by us, governmental and regulatory agencies and the courts. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current AMP and Best Price for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety- net providers, under the Public Health Service' s 340B Program and under other similar government pricing programs. These programs are described in greater detail in the previous section under" Business — Government Regulation — Coverage and Reimbursement." Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results. The issuance of federal regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time- consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of federal regulation. We also are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted false AMP or Best Price information to the government, we may be liable for significant civil monetary penalties. Our failure to submit monthly / quarterly AMP and Best Price data on a timely basis also could result in a significant civil monetary penalty per day for each day the information is late beyond the due date. Further, if we are found to have knowingly misclassified a drug (e. g., by knowingly classifying it as a generic drug for Medicaid Drug Rebate Program purposes, which are subject to lower rebates, instead of a single- source or innovator multiple- source drug), we could be subject to civil monetary penalties no greater than two times the difference between the rebates we should have paid and the rebates we actually paid, which penalties are in addition to the penalties discussed previously. Such failures also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid Drug Rebate Program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for XHANCE. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the regulation. HRSA also has implemented a ceiling price reporting requirement related to the 340B Program under which we are required to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes that information to covered entities. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution, or ADR, process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, changes to legislation, regulations, or guidance could modify 340B Program compliance or expand discount liability. Civil monetary penalties can also be applied if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. A covered entity or association representing covered entities can also bring claims against us through HRSA' s 340B ADR process. HRSA could terminate our 340B program Pharmaceutical Pricing Agreement for good cause, which could cause our Medicaid National Drug Rebate Agreement to be terminated, rendering federal funds for our covered outpatient drugs unavailable under Medicaid and Medicare Part B. Finally, we note again that civil monetary penalties could apply if a manufacturer fails to provide discounts under the Medicare Part D coverage gap discount program in the amount of 125 % of the discount that was due. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty. Federal law requires that a company must participate in the U. S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program to be eligible to have its products paid for with federal funds. As part of this program, we are obligated to make XHANCE available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price (FCP) to four federal agencies (VA, U. S. Department of Defense (DOD) Public Health Service, and U. S. Coast Guard). The FCP is based on the Non- Federal Average Manufacturer Price (Non- FAMP), which we calculate and report to the VA on a quarterly and annual basis. If we overcharge the government in connection with our FSS contract or Tricare Retail Pharmacy Agreement, we are required to refund the difference to the government. Failure to make necessary

disclosures and / or to identify contract overcharges can result in allegations against us under the U. S. civil False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time- consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Our promotional materials, statements and training methods must comply with applicable laws and regulations, including FDA' s prohibition of the promotion of unapproved, or off- label, use. Physicians may use our products off- label, as the FDA does not restrict or regulate a physician' s independent choice of treatment within the practice of medicine. As healthcare professionals frequently prescribe corticosteroids for the treatment of chronic nasal inflammatory diseases, such as chronic rhinosinusitis, doctors often prescribe XHANCE for the treatment of chronic rhinosinusitis and other chronic nasal inflammatory diseases, even though the FDA has granted approval of XHANCE only for the treatment of chronic rhinosinusitis with **or without** nasal polyps and we promote the use of XHANCE only for the treatment of chronic rhinosinusitis with **or without** nasal polyps. If the FDA determines that our promotional materials, statements or activities constitute promotion of an off- label use, we could be required to modify our promotional materials, statements or training methods or subject us to regulatory or enforcement actions, such as the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, disgorgement of money, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as the U. S. civil False Claims Act, civil whistleblower or" qui tam" actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials or activities to constitute promotion of an off- label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and market adoption of XHANCE could be impaired. Even though we have obtained FDA approval for XHANCE for the treatment of chronic rhinosinusitis with **or without** nasal polyps in the U. S., we may never obtain approval for or successfully commercialize XHANCE outside of the U. S., which would limit our ability to realize its full market potential. In order to market XHANCE outside of the U. S., we must obtain marketing authorizations and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by foreign regulatory authorities, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non- clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of XHANCE in those countries. While our management team has experience in obtaining foreign regulatory approvals at other companies, we do not have any product candidates approved for sale in any foreign jurisdiction, and we, as a company, do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market for XHANCE will be reduced and we would not be able to realize the full market potential of XHANCE. Furthermore, in addition to the costs to commercialize XHANCE in international markets, the pricing of XHANCE outside of the U. S. at levels acceptable to patients, prescribing physicians or a foreign government payor may be a challenge. If we are unable to achieve, or do not believe we will be able to achieve, acceptable pricing, we may not be able to profitably commercialize XHANCE in international markets. The Affordable Care Act and any other healthcare reform measures may increase the difficulty and cost for us to commercialize XHANCE and affect the prices we may obtain. The U. S. and many foreign jurisdictions have proposed and enacted legislative and regulatory changes affecting the healthcare system that could restrict or regulate post- approval activities and affect our ability to profitably sell XHANCE. The U. S. government, state legislatures and foreign governments also have shown significant interest in implementing cost- containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. These intended reforms are described in greater detail in the previous section under" Business — Government Regulation — U. S. Healthcare Reform." Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of XHANCE are the following: ▪ an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents; ▪ an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; ▪ expansion of healthcare fraud and abuse laws, including the U. S. civil False Claims Act and the Anti- Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; ▪ a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % (as of January 1, 2019) point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer' s outpatient drugs to be covered under Medicare Part D (the IRA sunsets the existing coverage gap program and replaces it with a new manufacturer discount program beginning in 2025); ▪ extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; ▪ price reporting requirements for drugs that are inhaled, infused, instilled, implanted, or injected; ▪ expansion of eligibility criteria for Medicaid programs; ▪ expansion of the entity types eligible for discounts under the Public Health Service Act' s 340B drug pricing program; ▪ a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and ▪ a Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Certain provisions of the Affordable Care Act have been subject to judicial challenges, as well as efforts to modify them or alter their interpretation and implementation. For example, on December 22,

2017, the U. S. government signed into law the Tax Act, which includes a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " It is unclear how efforts to modify or invalidate the Affordable Care Act or its implementing regulations, or portions thereof, will affect the Affordable Care Act or our business. Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the " donut hole, " by raising the required manufacturer point- of- sale discount from 50 % to 70 % off the negotiated price effective as of January 1, 2019. The coverage gap program will be sunset and replaced by a new manufacturer discount beginning in 2025. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of XHANCE or to successfully commercialize it. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have been adopted and 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 XHANCE and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, 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 from being able to generate revenues, attain profitability or successfully commercialize XHANCE ~~. If we or a partner were to seek regulatory approval to commercialize XHANCE in Europe, we would have to comply with a regulatory framework that is expected to change. In April 2023, the European Commission published a proposal to reform the current pharmaceutical framework, intending, among other things, to reduce regulatory data exclusivity allowing earlier generic competition. The legislative process for this reform is expected to take several years. It is currently uncertain if the proposal will be adopted in its current form and it is uncertain if and when the revised legislation would enter into force~~ . Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of XHANCE and any other product candidates that we may develop. We currently face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and from our commercialization of XHANCE, and this risk will increase as we further commercialize XHANCE and other product candidates that we may develop. We may face product liability claims, regardless of FDA approval for commercial manufacturing and sale as product liability claims may be brought against us by patients who have used XHANCE in any of our clinical trials, future patients, healthcare providers or others using, administering or selling XHANCE and any of our product candidates, if and when approved. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ▪ decreased demand for XHANCE; ▪ injury to our reputation and significant negative media attention; ▪ termination of clinical trial sites or entire trial programs that we conduct now or in the future relating to XHANCE or our other product candidates; ▪ withdrawal of clinical trial participants from any current or future clinical trial relating to XHANCE or our other product candidates; ▪ significant costs to defend the related litigation; ▪ substantial monetary awards to patients; ▪ loss of revenue; ▪ diversion of management and scientific resources from our business operations; and ▪ an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage. We currently carry product liability insurance with coverage up to $ 10. 0 million in the aggregate, with a per incident limit of $ 10. 0 million, which may not be adequate to cover all liabilities that we may incur. Further, 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. Our inability to maintain sufficient product liability insurance at an acceptable cost could adversely affect our XHANCE product revenues, result in additional liabilities, inhibit the development of XHANCE for additional indications or inhibit the development of our other product candidates. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our financial condition, results of operations and business. Additionally, any agreements we may enter into in the future with collaborators in connection with the development or commercialization of XHANCE, our EDS technology or any of our other product candidates may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, several of our agreements require us to indemnify third parties and these indemnifications obligations may exceed the coverage under our product liability insurance policy. We are subject to intense competition and, if we are unable to compete effectively, our product candidates, if approved, may not reach their commercial potential. The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We face competition with respect to XHANCE from prescription and over- the- counter INS, monoclonal antibodies, oral steroids and other medical management products, and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from many different sources, including large pharmaceutical, biotechnology, specialty pharmaceutical and, to a lesser degree, medical device companies. The key competitive factors that we expect to impact the commercial success of XHANCE and any other product candidates we may develop are likely to be their efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement. Nasonex ™ (mometasone furoate monohydrate) is the only other branded INS drug therapy approved by the FDA for the treatment of nasal polyps. Nasonex was marketed by Merck before being removed from the prescription market, but is available over- the- counter without a prescription for other indications. Generic versions of Nasonex ™, mometasone furoate monohydrate, remain available as prescription drugs. In addition, Beconase AQ ™, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection, SINUVA ™ is a commercially available corticosteroid- eluting implant

indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery that can be placed in the ethmoid sinus under endoscopic visualization for up to 90 days. To date, ~~four~~ **six** monoclonal antibodies have been studied in nasal polyps: **tezepelumab,** omalizumab, benralizumab **, depemokimab** , mepolizumab and dupilumab. DUPIXENT ™ (dupilumab), which is a monoclonal antibody marketed by Sanofi and Regeneron, was approved by the FDA in 2019 as an add- on maintenance treatment (to an intranasal steroid) in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis; XOLAIR ™ (omalizumab), which is a monoclonal antibody marketed by Genentech USA, Inc. and Novartis Pharmaceuticals Corporation, was approved by the FDA in 2020 as an add- on maintenance treatment of nasal polyps in adult patients with inadequate response to nasal corticosteroids; and NUCALA ™ (mepolizumab), which is a monoclonal antibody marketed by GlaxoSmithKline, was approved by the FDA in 2021 as an add- on maintenance treatment of chronic rhinosinusitis with nasal polyps in adult patients with inadequate response to nasal corticosteroids. Although we are not aware of any drug therapy approved by the FDA or foreign regulatory agencies for the treatment of chronic rhinosinusitis (or chronic sinusitis) without nasal polyps, the above referenced monoclonal antibodies or others may be studied as potential treatments for patients with chronic rhinosinusitis without nasal polyps. In addition, Lyra Therapeutics is developing corticosteroid- eluting implants as potential treatment for patients with chronic rhinosinusitis. In addition, Insmed is studying brensocatib as a potential treatment for chronic rhinosinusitis without nasal polyps by targeting inhibition of Dipeptidyl peptidase- 1 (DPP1). Even though they have not been approved for the treatment of such indications, published clinical practice guidelines do recommend the use of INS products for the treatment of chronic rhinosinusitis with and without nasal polyps in an effort to maximize medical therapy prior to surgical intervention. Currently approved branded INS products include Rhinocort ™, marketed by AstraZeneca, Nasacort AQ ™, marketed by Sanofi- Aventis, Beconase AQ ™, Flonase ™ (which contains the same active pharmaceutical ingredient as XHANCE), and Veramyst ™, each marketed by GlaxoSmithKline, Qnasl ™, marketed by Teva Pharmaceuticals, and Omnaris ™ and Zetonna ™, each marketed by Sunovion Pharmaceuticals. In lieu of prescription INS nasal sprays, physicians may recommend, and patients may elect to use, over- the- counter INS nasal sprays including over- the- counter products containing fluticasone propionate and mometasone furoate monohydrate. Most of these INS and monoclonal antibody companies, as well as other potential competitors, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval of drugs and achieving widespread market acceptance. Our competitors' drugs, or drugs they may develop in the future, may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render XHANCE or any of our other product candidates we may develop obsolete or non- competitive before we can recover the expenses of developing and commercializing XHANCE or any of our other product candidates. Our competitors may also obtain FDA or other regulatory approval of products more rapidly than expected or may obtain better or preferred market access by offering large rebates to payors or by other means. We may not have accurately or completely predicted the development of new and improved or low-cost surgical interventions, alternative medical therapies or other market- disrupting events. If we are unable to manufacture, distribute, stimulate demand reaching the predicted market share, overcome barriers to access or otherwise effectively commercialize the product, all of which factors may be influenced by current or future competition, then our opportunity to generate revenue from the sale of XHANCE or any of our other product candidates, if approved, will be compromised. ~~We have conducted a clinical program to support a follow- on indication of XHANCE for the treatment of chronic sinusitis. Although the term chronic rhinosinusitis is often used in medical literature and medical practice, the FDA did not historically recognize chronic rhinosinusitis as an indication for drug development purposes. Instead, the FDA recognized" chronic sinusitis" and" nasal polyps" as indications for drug development purposes rather than the terminology" chronic rhinosinusitis with or without nasal polyps." The FDA has approved drug products for the treatment of chronic rhinosinusitis with nasal polyps and issued a guidance document in November 2021 for clinical trial programs for nasal polyps in which it supports use of the terminology" chronic rhinosinusitis with nasal polyps" instead of" nasal polyps" and" chronic rhinosinusitis without nasal polyps" instead of" chronic sinusitis". In addition, in January 2023, at the request of the FDA, the indication statement for XHANCE was changed from" the treatment of nasal polyps" to" the treatment of chronic rhinosinusitis with nasal polyps" to conform to the FDA' s current labeling terminology and not as a result of additional clinical data. In February 2023, we submitted a prior approval efficacy supplement under our currently approved 505 (b) (2) NDA for a follow- on indication for XHANCE for the treatment of chronic rhinosinusitis. However, as a result of the FDA' s evolving view on terminology for nasal polyps, the additional indication we are seeking under the sNDA may, if approved, use the language" treatment of chronic sinusitis," the" treatment of chronic rhinosinusitis" or the" treatment of chronic rhinosinusitis without nasal polyps" or other similar terminology. It is our belief that these variations in terminology are synonymous from a promotional perspective. Furthermore, because there is no FDA- approved product for the treatment of chronic rhinosinusitis (or chronic sinusitis), we believe there is substantial risk and uncertainty in planning and conducting adequate clinical trials to meet FDA requirements to support approval for this indication. Generally, the FDA requires, among other things, that safety and efficacy be established in two adequate and well- controlled studies in the target indication. We designed and conducted the ReOpen program to include chronic sinusitis patients that had objectively verified sinus disease as measured by CT scan. In ReOpen1, we enrolled 205 subjects with chronic sinusitis with nasal polyps and 122 subjects with chronic sinusitis without nasal polyps. In ReOpen2, we only enrolled subjects with chronic sinusitis without nasal polyps. In the ReOpen1 total patient population, we demonstrated a statistically significant benefit for both primary endpoints, composite symptom relief and change in inflammation inside the sinus cavities, as measured by the change in average of percentages of volume occupied by disease (APOV). In addition, although ReOpen1 was not powered to demonstrate statistical significance in either endpoint for the subgroup of patients with chronic sinusitis without nasal polyps,~~

~~we demonstrated statistical significance for the composite symptom relief endpoint within this subgroup, but not APOV. In ReOpen2, in which only patients with chronic sinusitis without nasal polyps were enrolled, we demonstrated statistically significant benefit in both the composite symptom relief and APOV endpoints. If the FDA does not find the results of the ReOpen studies to be adequate to sufficiently demonstrate safety and efficacy of XHANCE for the treatment of chronic rhinosinusitis, we may not be successful in obtaining FDA approval for the follow- on indication without having to conduct additional trials. If we do not obtain a follow- on indication for the treatment of chronic rhinosinusitis, our promotion of XHANCE will be limited to chronic rhinosinusitis with nasal polyps, which would limit our potential sales of XHANCE, in which case our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to maintain compliance with the financial and liquidity covenants of the A & R Note Purchase Agreement or continue as a going concern.~~ The clinical and regulatory approval processes of the FDA are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business may be substantially harmed. The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the FDA. ~~For example, the FDA initially set a PDUFA goal date of December 16, 2023 for our sNDA for XHANCE for the treatment of chronic rhinosinusitis. However, in December 2023, the FDA notified us that it required additional time to complete its review, and that the PDUFA goal date would be extended to March 16, 2024.~~ In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development. ~~Our~~ **Future** product candidates could fail to receive regulatory approval for many reasons, including the following: ▪ the FDA may not accept our NDA filing or prior approval efficacy supplement; ▪ the FDA may disagree with the design, scope or implementation of our clinical trials; ▪ we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication; ▪ we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ▪ the FDA may disagree with our interpretation of data from preclinical studies or clinical trials; ▪ the data collected from clinical trials of our product candidates may not be sufficient to support the approval of an NDA or prior approval efficacy supplement; ▪ the FDA may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and ▪ the approval policies or regulations of the FDA may change in a manner rendering our clinical data insufficient for approval. The failure to obtain regulatory approval for a particular product candidate, could substantially harm our business. Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development. Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, investigators failure to comply with applicable laws, or other factors. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our ~~clinical~~ **FDA- mandated post- marketing** trials ~~for the follow- on indication~~ of XHANCE for the treatment of chronic rhinosinusitis ~~or our other product candidates~~ **with and without nasal polyps in adolescents** may not be successful or may be more expensive or time- consuming than we currently expect. If **these** clinical trials ~~for this~~ or any ~~other~~ **future** product candidate fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA may not approve **use** ~~the follow- on indication~~ of XHANCE **for the treatment of chronic rhinosinusitis with or without nasal polyps in adolescents 12 to 17 years of age,** or any ~~other~~ **future** product candidate and we would not be able to commercialize it **for such indications** , which could substantially harm our business ~~. Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales, or our ability to maintain regulatory approval~~ . Our ongoing and future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, timely enroll patients, or be completed on schedule, if at all. We have experienced and may experience further delays in ~~clinical trials of our product candidates or for~~ our FDA- mandated post- marketing ~~pediatric study~~ **adolescent trial of XHANCE** for ~~XHANCE~~ **the treatment of chronic rhinosinusitis with nasal polyps** . Our clinical trials can be delayed or terminated for a variety of reasons, including, but not limited to: ▪ inability to obtain additional capital necessary to initiate or continue a clinical trial; ▪ delays in obtaining regulatory approval to commence a clinical trial; ▪ delays in reaching agreement with the FDA or foreign regulatory authorities on final trial design or the scope of the development program; ▪ imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities; ▪ delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites; ▪ delays in obtaining required IRB approval; ▪ inability to attract clinical investigators for trials; ▪ delays in recruiting suitable patients to participate in a clinical trial; ▪ delays as a result of interim analyses, if any, of clinical trials that indicate futility of the trial or necessitate an increase in the number of patients enrolled in trial; ▪ patients' delays or failure to complete participation in a clinical trial or return for post- treatment follow- up; ▪ adverse side effects; ▪ clinical sites dropping out of a clinical trial; ▪ time required to add new clinical sites; ▪ delays by our CMOs to produce and deliver a sufficient supply of clinical trial materials; or ▪ governmental or regulatory delays, or changes in approval policies or regulations. If clinical trials for our **FDA- mandated post- marketing adolescent studies for XHANCE or future** product candidates ~~or for our FDA- mandated post- marketing pediatric study for XHANCE~~ are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed or negatively impacted and our ability to commercialize our product or product candidates could be materially harmed. If we encounter difficulties in maintaining commercial manufacturing and supply agreements with our third- party manufacturers and suppliers of XHANCE, our ability to commercialize XHANCE would be impaired. We do not own any manufacturing facilities.

We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources to manufacture and test, on a commercial scale, the technical performance of XHANCE and our other product candidates. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and CMOs and suppliers who assist in the production, assembly, test, supply, storage and distribution of XHANCE and its components for commercial and clinical supplies, and we control only some of the aspects of their activities. We may not be able to maintain terms that are favorable to us. We may not be able to enter into commercial manufacturing and supply agreements with any necessary third parties, should such additional agreements become necessary. If we are unable to enter into such agreements or maintain existing agreements, each on commercially reasonable terms, our ability to commercialize XHANCE would be impaired, and our business, financial condition and results of operations would be materially adversely affected. We have initiated the process of qualifying alternate third- party suppliers for select components of XHANCE. Alternate third party suppliers of XHANCE components are subject to qualification and approval from the FDA which can be a lengthy and expensive process. If we encounter issues with our contract manufacturers or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply XHANCE. We currently depend on contract manufacturers and suppliers for XHANCE and its components. Although we could obtain each of these components from other third- party suppliers, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for each such component, which could be costly and cause significant delays. For example, we estimate that it would take at least one year to identify and qualify an alternate contract manufacturer for XHANCE. Additionally, our commercial manufacturing and supply agreements generally include limitations on our ability to utilize alternative manufacturers or suppliers for these components above certain specified thresholds during the terms of the agreements, or may include purchase minimums, which impairs our ability to fully implement any future manufacturing strategies to prevent supply shortages or quality issues. In addition, some of our suppliers, including our active pharmaceutical ingredient (API) supplier and our contract manufacturers, conduct their manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing and supply issues. For example, if regulatory, manufacturing or other problems require one of these manufacturers or suppliers to discontinue production at their respective facility, or if the equipment used for the production of XHANCE in these facilities is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer or supplier to provide components or API needed for XHANCE, or to manufacture XHANCE may be significantly impaired. In the event that these parties suffer a temporary or protracted loss of its facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer or supplier, as applicable, as an alternate manufacturer or source for the respective component before any components manufactured by such manufacturer or by such supplier could be sold or used. Any production shortfall that impairs the supply of XHANCE or any of its components could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for XHANCE, which could adversely affect our product sales and operating results materially. For example, the sole supplier of the pump incorporated into XHANCE is discontinuing the manufacture of the pump. As a result, we are currently in the process of evaluating and testing replacement pumps. Although we have purchased excess pumps, any delay in identifying and obtaining FDA- approval of a replacement pump would have a material adverse impact in our ability to supply XHANCE. We have also initiated the process of qualifying alternate third- party suppliers for select components of XHANCE. Alternate third party suppliers of XHANCE components are subject to qualification and approval from the FDA. If third- party manufacturers, wholesalers, distributors, HUB and PPN partners fail to devote sufficient time and resources to XHANCE or their performance is substandard, our product supply may be negatively impacted. Our reliance on a limited number of manufacturers, wholesalers, distributors, HUB and PPN partners exposes us to the following risks, any of which could limit commercial supply of our products, result in higher costs, or result in a loss of potential product revenues: ▪ our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations; ▪ our wholesalers, distributors, HUB and PPN partners could become unable to sell, deliver, or provide patient support services for XHANCE for regulatory, compliance and other reasons; ▪ our CMOs, wholesalers, distributors and PPN partners could default on their agreements with us to meet our requirements for commercial supply and distribution of XHANCE; ▪ our CMOs, wholesalers, distributors, HUB and PPN partners may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute our products and we may incur additional cost; and ▪ if our CMOs, wholesalers, distributors, HUB and PPN partners were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay or cease sales and ongoing development of XHANCE, or find alternatives that may be more expensive than originally anticipated. Our reliance on third parties reduces our control over our product candidate development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third- party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates or supply our commercial volume of XHANCE. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution. We have initiated the process of qualifying an alternate third- party

supplier for select components of XHANCE. Alternate third party suppliers of XHANCE components are subject to qualification and approval from the FDA. Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization. Issues may arise involving product manufacturing of XHANCE or any of our products that may be under development, including but not limited to delays in receiving finished product or product components or raw materials, analytical testing issues, product- packaging problems and equipment malfunctions. These issues may require refinement or resolution in order to continue and not delay the commercialization of XHANCE or development of any of our products under development. In addition, quality issues may arise during commercial manufacturing processes or the scale- up of any of our products that may be under development. Any issues in our product or delivery devices could result in increased scrutiny by regulatory authorities, delays in our regulatory approval process, increases in our operating expenses, shortages in our products available for sales or clinical trial use, decreases in sales to customers, or failure to obtain or maintain approval for our products. We have initiated the process of qualifying alternate third- party suppliers for select components of XHANCE. Alternate third party suppliers of XHANCE components are subject to qualification and approval from the FDA. We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to obtain regulatory approval for or commercialize our product candidates. We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our prospective preclinical and clinical programs. We rely on these parties for execution of our clinical trials, and we control only some of the aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with federal regulations and cGCP, which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, advisors and monitors. cGCPs are enforced by the FDA and foreign regulatory authorities in the form of International Conference on Harmonization (ICH) guidelines for all of our product candidates in clinical development. Regulatory authorities enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP requirements. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat preclinical studies and clinical trials, which would increase our operating expenses and delay the regulatory approval process. Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons or if we receive additional FDA notices that do require corrective action, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed. Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third- party service providers can be difficult, time- consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third- party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third- party providers. To the extent we are unable to identify and successfully manage the performance of third- party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. It is important to our business that we continue to build a more complete product offering within the ENT and allergy markets. Developing additional product candidates is expensive and time- consuming and could divert management' s attention away from the commercialization of XHANCE. Even if we are successful in developing additional product candidates, the success of any new product candidates or enhancement to any existing product candidates will depend on several factors, including our ability to: ▪ properly identify and anticipate ENT and allergy physician and patient needs; ▪ develop, obtain necessary regulatory clearances or approvals, and introduce new product candidates or product enhancements in a timely manner; ▪ demonstrate, if required, the safety and efficacy of new product candidates with data from preclinical studies and clinical trials; ▪ avoid infringing upon the intellectual property rights of third parties; ▪ comply with all regulations relating to the

marketing of new product candidates, including any new or modified EDS technologies; and ▪ provide adequate training to potential users of our product candidates. If we are unsuccessful in developing, acquiring or licensing additional product candidates in other areas of the ENT and allergy markets, our ability to gain and maintain profitability may be impaired. ~~We are subject to risks inherent in foreign operations. We historically operated portions of our business through our foreign subsidiaries, including through our Norwegian subsidiary, OptiNose AS, which, until 2022, owned a substantial portion of our intellectual property and conducted certain development activities. We also operated a United Kingdom subsidiary, OptiNose UK Ltd. Optinose AS was dissolved in October 2023. We are in the process of dissolving OptiNose UK, Ltd. The operations we conduct in other countries, including clinical trials, and the operations conducted by third party suppliers and vendors with whom we do business, are subject to foreign laws. We are subject to a number of risks associated with our international business operations and activities that may increase liability, costs, and require significant management attention. These risks include: ▪ compliance with the laws of the U. S., the United Kingdom, Norway, and other countries that apply to our international operations, including import and export legislation; ▪ compliance with foreign data protection laws and regulations in the United Kingdom, Norway and other countries that apply to our international operations; ▪ the complexities and expenses of administering a business abroad; ▪ complications in compliance with, and unexpected changes in, tariffs, trade barriers, price and exchange controls and other foreign regulatory requirements, including potential trade conflicts, changes to trade agreements / treaties, and the implementation of trade restrictions; ▪ instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts, social upheaval or political uncertainty; ▪ production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; ▪ uncertainties of laws and enforcement relating to the protection of intellectual property or secured technology; ▪ litigation in foreign court systems; ▪ language barriers; ▪ changes in tax laws and regulations in the jurisdictions in which we operate; ▪ compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad; ▪ difficulties staffing and managing foreign operations; and ▪ workforce uncertainty in countries where labor unrest is more common than in the U. S. There can be no assurance that the policies and procedures we implement to address or mitigate these risks will be successful, that our personnel will comply with them or that we will not experience these risks in the future or that they will not have a material adverse effect on our business, results of operations and financial condition.~~ Our corporate structure and foreign operations may have adverse tax consequences and expose us to additional tax liabilities. In addition, tax returns we file are subject to examination by U. S. federal, state and foreign tax authorities. Prior to 2023, we had operations in Norway and the UK and a substantial portion of our intellectual property, including certain rights to XHANCE, were owned by OptiNose AS, our Norwegian subsidiary, until 2022. We file tax returns in various jurisdictions **(including Norway and UK prior to the dissolution of our subsidiaries in those jurisdictions)** and those returns are subject to examination by the tax authorities. During an examination, a tax authority could challenge positions taken on a return. Such a challenge could result in the loss of tax attributes or ~~in the payment of~~ **subject us to additional** tax **liabilities based on income earned by our foreign subsidiaries, including a portion of the sales of XHANCE in the U. S. or the sale of its intellectual property rights to XHANCE to OptiNose, Inc.,** which could have an unfavorable impact on our financial condition. Prior to 2023, we operated pursuant to written intercompany license, service and related agreements that establish prices for intellectual property and for services provided such as production, marketing, management, and technology development activities that are performed by one group company for another group company. The amounts paid under these intercompany agreements are commonly considered for tax purposes as transfer prices. If the affiliated companies are located in different countries, the tax laws and regulations of each country generally require that transfer prices be at arm' s length as if between unrelated companies. Our transfer pricing arrangements consider requirements of the jurisdictions in which we operate but are not binding on the tax authorities. If any tax authority is successful in challenging our transfer prices, there could be an increase in taxable income in that jurisdiction which could increase our tax liabilities. Further, if the tax authority in the other country does not agree with the adjustment, both countries could tax the same income, resulting in double taxation. ~~Any income earned by~~ **Changes in U. S. and international trade policies may adversely impact** our **business and operating results. From time to time, proposals are made to significantly change existing trade agreements and relationships between the U. S. and other countries. In recent years, the U. S. government has implemented substantial changes to U. S. trade policies, including import restrictions, increased import tariffs and changes in U. S. participation in multilateral trade agreements. Because some of our manufacturers and suppliers are located in Canada, Portugal, Europe and other** foreign ~~subsidiaries~~ **countries** , ~~including a portion of~~ **we are exposed to** the ~~sales~~ **possibility** of ~~XHANCE~~ **product supply disruption and increased costs** in the **event of changes in the policies, laws, rules and regulations of the United States or foreign governments, as well as political unrest or unstable economic conditions in foreign countries. The** U. S. **government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate , or potentially terminate, certain existing bilateral or multi- lateral trade agreements. For example, on February 1, 2025, President Donald Trump signed executive orders imposing a 25 % tariff on certain imports from Mexico and Canada, and a 10 % tariff on certain imports from China, which were to take effect on February 4, 2025. A 30- day pause was granted to Canada and Mexico, and the tariffs took effect on March 4, 2025. In March 2025, the administration announced plans to impose an additional 10 % tariff on certain imports from China. These newly proposed and imposed tariffs have resulted in threatened and actual retaliatory tariffs against U. S. goods. Our components** may **in the future** be subject to **these tariffs, which could increase our manufacturing costs and could make our products less competitive than those of our competitors whose inputs are not subject to these tariffs. We may otherwise experience supply disruptions or delays, and our suppliers may not continue to provide us with supply in our required quantities, to our required specifications and quality levels or at attractive prices. In** ~~additional~~ **addition** ~~tax liabilities. If~~ **, certain ex- US CMOs may become subject to trade restrictions, sanctions, other regulatory requirements,** ~~our~~ **or** ~~foreign~~ **proposed legislation by the U. S. government, which could restrict or even prohibit our ability to work**

with such entities, thereby potentially disrupting the supply of material to us. Such disruption could have adverse effects on the commercialization of XHANCE and our business operations ~~generate cash that we want to repatriate to the U. S. or if cash generated by our U. S. operations is not sufficient to fund our U. S. operations, we may face additional tax liabilities in returning or otherwise providing such cash to support our U. S. operations or other strategic opportunities in the U. S~~. If we are ~~forced~~ **unable** to ~~repatriate~~ **protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology, XHANCE or** any ~~foreign- held cash~~ **of our future product candidates** , ~~we~~ **our competitors** could **develop** ~~incur a significant tax charge,~~ and **commercialize technology similar to** ~~our~~ **ours** ~~business~~ , **and** ~~operating results or our financial condition~~ **competitive position** could be **harmed** ~~adversely impacted. If foreign subsidiary income is subject to the Subpart F, investment in US property or global intangible low- taxed income provisions, or similar provisions of the U. S. Internal Revenue Code, collectively referred to in this paragraph as Subpart F, the income may be subject to U. S. corporate income tax even if there is no cash distribution of those earnings to the U. S. For example, Subpart F income includes certain" passive" income, certain income from intercompany transactions, foreign subsidiary income over a legislative threshold or income of a foreign subsidiary which makes an" investment in U. S. property", such as holding the stock in a U. S. corporation. Any foreign subsidiary income subject to the Subpart F provisions would be included in determining U. S. taxable income and potentially subject to federal corporate income tax at rates up to 21 %~ . Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U. S. and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. Our strategy is to seek patent protection for XHANCE ~~,~~ **and any of** our other product candidates and, where applicable, their compositions, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business. The patent prosecution process is expensive and time- consuming, and we and any future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of **XHANCE** ~~our~~ **or future** product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. 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 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 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, which may have an adverse impact on our business, financial condition, and operating results. The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U. S. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be impaired. As of March 1, ~~2024~~ **2025** , we owned over ~~60~~ **50** U. S. issued patents and pending U. S. patent applications. Our issued U. S. patents expire between ~~2024~~ **2025** and 2036. We do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology and drugs, in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Our XHANCE U. S. patent portfolio consists of 14 issued device and method of use patents expiring on various dates from ~~2024~~ **2025** through 2036, three issued design patents expiring between 2029 and 2030 and pending patent applications. The 14 device and method of use patents are published in the FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated NDA (ANDA), or a 505 (b) (2) NDA. If any of these potential generic competitors claim that their product will not infringe XHANCE' s listed patents, or that such patents are invalid, then they must send notice to us once the ANDA or 505 (b) (2) NDA has been accepted for filing by the FDA. We may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification, which would automatically prevent the FDA from approving the ANDA or 505 (b) (2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505 (b) (2) NDA applicant. In September 2023, the Federal Trade Commission (FTC) issued a policy statement articulating its view that certain" improper" patent listings by pharmaceutical manufacturers in the FDA' s Orange Book represent a potential unfair trade practice and indicated that industry should be prepared for potential enforcement actions based on its analysis. The FTC followed that

action in November 2023 by initiating an FDA administrative process with respect to over 100 patent listings that it contends are" improper" with a focus on certain patents covering drug- device combination products. It remains to be seen whether the FTC, the FDA, other governmental agencies, pharmaceutical manufacturers, or other stakeholders continue to prioritize the policy of" improper" patent listings. Accordingly, there could be future changes or clarifications to federal laws, regulations or guidelines related to Hatch- Waxman requirements or procedures that could have a material adverse impact on pharmaceutical manufacturers and in particular the listablilty of certain patents covering drug- device combination products like XHANCE. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non- infringing manner is increased. ~~Five~~ **Several** device and method of use patents previously listed in the FDA' s Orange Book for XHANCE have expired. These patents covered certain aspects of our exhalation deliver system technology utilized by XHANCE. The laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover **XHANCE** ~~our~~ **or our future** product candidates, third parties may initiate oppositions, interferences, re- examinations, post- grant reviews, inter partes reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. For example, the issuance of ~~three~~ **two** of our patents in Europe are subject to opposition proceedings- these patent applications cover certain aspects of our flexible mouthpiece ~~, nosepiece~~ and liquid EDS. Furthermore, even if our patents are not challenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for **XHANCE** ~~our~~ **or our future** product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties. Furthermore, 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 U. S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, 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 drugs, or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours. Competitors or other third parties may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In a patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non- enablement. 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. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a federal court against a U. S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our EDS technology. Such a loss of patent protection could compromise our ability to pursue our business strategy. Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone, with our licensees, or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U. S. 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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings 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 drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize ~~current~~ **XHANCE** or future product candidates. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on XHANCE, **future** ~~our other~~ product candidates and our EDS technology throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. may be less extensive than those in the U. S. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the U. S. For example, novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions into or within the U. S. or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U. S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Furthermore, the prevalence of counterfeit medicines, which is one that has been deliberately and fraudulently mislabeled as to its identity and source, is a significant and growing industry- wide issue that could impact our revenue and our reputation for which we may have limited or no recourse. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the U. S. in several stages over the lifetime of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Our commercial success depends upon our ability to develop, manufacture, market and sell XHANCE and **future** ~~our other~~ product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. While ~~our~~ **a** product ~~candidates~~ **candidate** ~~are~~ **is** in preclinical studies and clinical trials, we believe that the use of ~~our~~ **the** product ~~candidates~~ **candidate** in ~~these~~ **such** preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U. S. C. Section 271 (e) in the U. S., which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As XHANCE and Onzetra Xsail are commercialized, the possibility of a patent infringement claim against us increases. If we use the Section 505 (b) (2) regulatory pathway for any of our **future** product candidates it will require us to provide a Paragraph IV certification to the NDA and patent holders of the RLD pursuant to the Hatch- Waxman Act if the RLD is covered by Orange Book- listed patents. If the NDA or patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is prevented from approving our Section 505 (b) (2) NDA until the earliest of 30 months, expiration of the patents, settlement of the lawsuit or a court decision in the infringement case that is favorable to us. ~~In connection with our submission of the sNDA for a follow- on indication for XHANCE for chronic rhinosinusitis in February 2023, we provided Paragraph IV certifications to the FDA and notice of such certifications to the NDA and patent holders for the two Orange Book- listed patents for Flovent HFA (one of the RLDs for XHANCE' s original NDA). To our knowledge, these NDA and patent holders did not file a patent infringement action against us within the applicable time period under the Hatch- Waxman Act or otherwise.~~ Accordingly, we may invest significant time and expense in the development of ~~our~~ **future** product candidates only to be subject to significant delay and expensive and time- consuming patent litigation before ~~our~~ **such** product candidates may be commercialized. There can be no assurance that **XHANCE** ~~our~~ **or future** product candidates do not infringe other parties' patents or other proprietary rights and competitors or other parties may assert that we infringe their proprietary rights in any event. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to **XHANCE** ~~our~~ **or future** product candidates, including interference or derivation proceedings before the USPTO. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields **relating to XHANCE and future product** ~~in which we are developing our drug~~ candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue commercializing **XHANCE** ~~our~~ **or future** product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non- exclusive, which could give our competitors access to the same technology or

intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing **XHANCE** ~~our~~ **or furue** product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management' s attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Our competitors may seek to market generic versions of XHANCE or any other product for which we obtain approval by submitting ANDAs to the FDA or new products that use our approved products as the RLD, in each case where our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with XHANCE and any future product candidates we may develop. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non- infringing manner is increased. ~~Five~~ **Several** device and method of use patents previously listed in the FDA' s Orange Book for XHANCE have expired. These patents covered certain aspects of our exhalation ~~deliver~~ **delivery** system technology utilized by XHANCE **. Changes in either U. S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products** . As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and it therefore is costly, time- consuming and inherently uncertain. In addition, on September 16, 2011, the Leahy-Smith America Invents Act (the AIA) was signed into law. The AIA includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. An important change introduced by the AIA is that, as of March 16, 2013, the U. S. transitioned to a" first- to- file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in U. S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Depending on decisions by the U. S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and / or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and / or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business. In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our

own. The assignment of intellectual property rights may not be self- executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Intellectual property rights do not prevent all potential threats to competitive advantages we may have. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative: ▪ Others may be able to make drug and device components that are the same as or similar to XHANCE and ~~our other~~ **any future** product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; ▪ We or any of our licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; ▪ We or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions; ▪ Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ▪ The prosecution of our pending patent applications may not result in granted patents; ▪ Granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors; ▪ With respect to granted patents that we own or have licensed, especially patents that we either acquire or in- license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable; ▪ Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product; ▪ Our competitors might conduct research and development activities in the U. S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates; ▪ We may not develop additional proprietary technologies that are patentable; ▪ The patents of others may have an adverse effect on our business; and ▪ We may choose not to file a patent application for certain technologies, trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects. 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 protection for certain aspects of our product candidates and delivery technologies, we also consider trade secrets, including confidential and unpatented know- how, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know- how, in part, by customarily entering into non- disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific and commercial collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, our trade secrets may otherwise become known, including through a potential cybersecurity breach, or may be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts in the U. S. and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them 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. If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. OPTINOSE ®, XHANCE ®, EDS ® and Exhalation Delivery System ™ are trademarks of ours in the U. S. Our trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively. The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this" Risk Factors" section and elsewhere in this Annual Report on Form 10- K, these factors include: ▪ our ability to successfully commercialize XHANCE; ▪ ~~any delay in our regulatory approval or filings for XHANCE for a follow- on indication for the treatment of chronic sinusitis or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a" refusal to file" letter, a request for additional information, or a CRL;~~ ▪ the success of competitive products, technologies or services; ▪ adverse regulatory actions with respect to **XHANCE** ~~our~~ **or any future** ~~product candidates, including the failure to receive regulatory approval, or our competitors' products or~~ product candidates; ▪ discovery of previously unknown problems with XHANCE, such as AEs of unanticipated severity or frequency, ▪ issues involving manufacturing of XHANCE or any **future** ~~of our~~ products that may be under development; ▪ actual or anticipated changes in our growth rate relative to our competitors; ▪ announcements by us or our competitors of significant acquisitions or divestitures, strategic collaborations, joint ventures, collaborations or capital commitments; ▪ the commencement, enrollment or results of planned clinical trials of our product candidates or any future clinical trials we may conduct, or any changes generally in the development status of our product candidates or those of our competitors; ▪ regulatory or legal developments in the U. S. and other countries; ▪ the outcome of any investigations or regulatory scrutiny of our operations or litigation that may be brought against us; ▪ developments or disputes concerning patent applications, issued patents or other proprietary rights; ▪ the

level of expenses related to **XHANCE or** any **future** ~~of our~~ product candidates or clinical development programs; ▪ actual or anticipated variations in our quarterly operating results; ▪ our ability to develop, acquire or license additional product candidates in other areas of the ENT and allergy markets; ▪ failure to meet the estimates and projections of the investment community or financial guidance that we may otherwise provide to the public; ▪ actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; ▪ actual or anticipated changes in estimates as to development timelines that we may provide to the public; ▪ variations in our financial results or those of companies that are perceived to be similar to us; ▪ fluctuations in the valuation of companies perceived by investors to be comparable to us; ▪ share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; ▪ announcement or expectation of additional financing efforts; ▪ sales of our common stock by us, our insiders or our other stockholders; ▪ significant lawsuits, including patent or stockholder litigation; ▪ changes in the structure of healthcare payment systems; ▪ market conditions in the pharmaceutical and biotechnology sectors; ▪ general political, economic, industry and market conditions; ▪ investors' general perception of our company and our business; ▪ publication of research reports about us, our competitors or our industry, or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts; and ▪ other events or factors, many of which are beyond our control. In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks stated above could have a material adverse effect on the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that the holders of a large number of shares intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. Future issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We will likely require additional capital in the future to execute our business plan. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options, restricted stock units, warrants and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors and may cause our stock price to fall. Such sales may also result in new investors receiving rights, preferences and privileges senior to those of holders of our common stock. Our principal stockholders and management own a substantial percentage of our stock and are able to exert significant control over matters subject to stockholder approval, which could prevent other investors from influencing significant corporate decisions. Our executive officers, directors, beneficial owners of 5 % or more of our capital stock and their respective affiliates, in the aggregate, beneficially own approximately **47** ~~54. 1~~ % of our outstanding common stock as of December 31, ~~2023~~ **2024** . Including entities associated with Fidelity ~~and~~ **,** MVM **and Nantahala Capital Management** , our largest stockholders, each hold approximately **12** ~~15. 0~~ % **, 10 %,** and ~~13~~ **10** % respectively, of our common stock as of December 31, ~~2023~~ **2024** . These stockholders can significantly influence the outcome of matters requiring stockholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of these and other large stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock. For example, these stockholders may be more interested in selling our company than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. Such concentration of ownership control may also: ▪ delay, defer or prevent a change in control; ▪ entrench our management and / or the board of directors; or ▪ impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. We may also take actions that our other stockholders do not view as beneficial, which may adversely affect our results of operations and financial condition and cause the value of your investment to decline. Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our fourth amended and restated certificate of incorporation, as amended, and our amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that: ▪ permit our board of directors to issue up to five million shares of preferred stock, with any rights, preferences and privileges as it may designate, which issuance could result in the loss of voting control by other stockholders; ▪ provide that our board of directors will be classified into three classes with staggered, three- year terms and that, directors may only be removed for cause by the affirmative vote of the holders of at least a majority of the voting power of outstanding shares of our capital stock; ▪ provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum; ▪ require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; ▪ provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder' s notice; ▪ require that the amendment of certain provisions of our certificate of incorporation relating to anti-takeover measures may only be approved by a vote of 66- 2 / 3 % of our outstanding common stock; ▪ require that the

amendment of our bylaws be approved by the affirmative vote of a majority of directors then in office or 662 / 3 % of our outstanding common stock entitled to vote thereon; ▪ do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and ▪ provide that special meetings of our stockholders may be called only by the chairman or vice chairman of our board of directors, our chief executive officer, or a majority of our board of directors. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. We are also governed by the provisions of Section 203 of the Delaware General Corporation Law. These provisions may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other things, prior to the time the stockholder has become an interested stockholder, the board of directors has approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder. These provisions of our fourth amended and restated certificate of incorporation, as amended, our amended and restated bylaws and Delaware law could have the effect of discouraging potential acquisition proposals and delaying or preventing a change in control. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests or provide an opportunity for our stockholders to receive a premium for their shares of our common stock. These provisions could also affect the price that some investors are willing to pay for our common stock. Our certificate of incorporation also provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our fourth amended and restated certificate of incorporation, as amended, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our fourth amended and restated certificate of incorporation, as amended, also provides that the U. S. District Court for the District of Delaware and any appellate courts thereof will be the exclusive forum for resolving any such complaint for which subject matter jurisdiction of such claim is vested exclusively in the federal courts of the U. S. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions **. The Merger Agreement contains a number of conditions that must be satisfied or waived prior to the completion of the Merger. We cannot assure you that all of the conditions to the Merger will be so satisfied or waived. If the conditions to the Merger are not satisfied or waived, we may be unable to complete the Merger. If the Merger is not completed, our ongoing business may be adversely affected as follows: • we may experience negative reactions from the financial markets, including negative effects on the market price of our common stock; • some of management' s attention will have been directed to the Merger instead of being directed to our own operations and the pursuit of other opportunities that could have been beneficial to us; • the manner in which customers, suppliers and other third parties perceive us may be negatively impacted, which in turn could affect our ability to operate our business; • we may experience negative reactions from employees; and • we may be required, in certain circumstances, to pay a termination fee of $ 4, 500, 000, as provided in the Merger Agreement. Additionally, in approving the Merger Agreement, our board of directors considered a number of factors and potential benefits, including the fact that the upfront Merger consideration to be received by holders of our common stock represented a 55. 2 % premium to the closing price of our common stock on March 18, 2025. If the Merger is not completed, neither the Company nor the holders of our common stock will realize this benefit of the Merger. Moreover, we would have incurred substantial transaction- related fees and costs and the loss of management time and resources. We have incurred and expect to continue to incur significant expenses in connection with the proposed Merger, including legal and investment banking fees. We expect these costs to have an adverse effect on our operating results. If the Merger is not consummated, we may under certain circumstances, be required to pay to Paratek a termination fee of $ 4, 500, 000. Our financial position and results of operations would be adversely affected if we were required to pay the termination fee to Paratek. The Merger Agreement requires us to act in the ordinary course of business and restricts us, unless we first obtain Paratek' s consent, from taking certain specified actions until the proposed Merger occurs or the Merger Agreement terminates. These restrictions may prevent us from pursuing otherwise attractive business opportunities and making other changes to our business before completion of the Merger or, if the Merger is not completed, termination of the Merger Agreement. Uncertainty about the effect of the Merger on our employees, customers and suppliers may have an adverse effect on our business. These uncertainties may impair our ability to attract, retain and motivate key personnel until the Merger is completed. Employee retention may be particularly challenging during the pendency of the Merger. If key employees depart and as we face additional uncertainties relating to the Merger, our business relationships may be subject to disruption as suppliers and other third parties attempt to negotiate changes in existing business relationships or consider entering into business relationships with parties other than the Company. If key employees depart or if our existing business relationships suffer, our results of operations may be adversely affected. The adverse effects of such disruptions could be further exacerbated by any delay in the completion of the Merger. The**

Merger Agreement contains provisions that make it more difficult for us to sell our business to a company other than Paratek. These provisions include a general prohibition on us soliciting any acquisition proposal or offer for a competing transaction. If we or Paratek terminate the Merger Agreement and we agree to be or are subsequently acquired by another company, we may in some circumstances be required to pay to Paratek a termination fee of $ 4, 500, 000. Further, our board of directors has agreed in the Merger Agreement, subject to limited exceptions, that it will not withdraw or modify in a manner adverse to Paratek its recommendation that our stockholders approve the Merger. If Paratek terminates the Agreement as a result of the Board' s withdrawal or modification of its recommendation in a manner adverse to Paratek, we may be required to pay Paratek a termination fee of $ 4, 500, 000. These provisions might discourage a third party that has an interest in acquiring all or a significant part of the Company from considering or proposing an acquisition, even if the party were prepared to pay consideration with a higher per share cash or market value than the cash value proposed to be received in the Merger, or might result in a potential competing acquirer proposing to pay a lower price than it might otherwise have proposed to pay because of the added expense of the termination fee that may become payable in certain circumstances . General Risk Factors We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, which could negatively impact our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense. As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial- stage products or product candidates, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost- effective basis, or at all, and we may not realize the anticipated benefits of any such transaction. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to complete technology transfers and integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities as part of the transaction. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic collaborators or identify other investment opportunities, and we may experience losses related to any such investments. To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. Our sales force and other employees, HUB, PPN partners, CMOs, CROs, principal investigators, co- promotion partners, collaborators, independent contractors, consultants and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our sales force and other employees, HUB, PPN partners, CMOs, CROs, principal investigators, collaborators, independent contractors, consultants and other vendors may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and / or negligent conduct or unauthorized activity that violates: ▪ FDA promotion or other regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; ▪ manufacturing standards; ▪ federal and state healthcare fraud and abuse laws and regulations; or ▪ laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm. We have a Code of Business Conduct and Ethics to govern and deter such behaviors, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws 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 civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations. If we fail to comply with data and privacy protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and / or adverse publicity, any of which could negatively affect our operating results and business. Our business is subject to complex and evolving U. S., state and international data and privacy protection laws. In the U. S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health- related and other personal information. Compliance with these laws is difficult, constantly evolving, and time consuming. These laws may differ from each other in significant ways, thus complicating compliance efforts. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. Failure to comply with

data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and / or criminal penalties), private litigation and / or adverse publicity. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space. We may also obtain health information from third parties (e. g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA, and other privacy and data security and consumer protection laws. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA, and could also potentially be subject to other civil and / or criminal penalties if we obtain, use or disclose information in a manner not permitted by other privacy and data security and consumer protection laws. The Federal Trade Commission (the " FTC ") also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5 (a) of the FTC Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. Additionally, EU Member States, the UK and other jurisdictions where we may in the future operate, have adopted data protection laws and regulation which impose significant compliance obligations. For example, the EU General Data Protection Regulation including as implemented in the UK (collectively, " GDPR "), applies to our activities conducted from an establishment in the EU / UK or related to products and services that we may offer to EU / UK users that involve the collection, use, storage, transfer, and other processing of personal data, including personal health data. The GDPR creates a broad range of compliance obligations and restrictions on the ability to collect, analyze and transfer personal data, which could cause us to change our business practices, and has significantly increased financial penalties for noncompliance (including possible fines of up to 4 % of global annual turnover for the preceding financial year or € 20 million (whichever is higher) for the most serious infringements). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In particular, these obligations and restrictions relate to the processing and protecting of personal data, including obligations to having a lawful basis for processing personal data (which may result in some instances in obtaining the consent of the individuals to whom the personal data relates), provide detailed information about the processing activities to the individuals, dealing with restrictions on sharing of personal data with third parties and the transferring of personal data out of the EU / UK, having contractual arrangements in place where required (such as with clinical trial sites and vendors), having appropriate technical and organizational security and confidentiality measures in place to protect the personal data we collect and process, reporting in certain instances personal data breaches to data protection authorities and / or affected individuals, appointing data protection officers, conducting data protection impact assessments, responding to privacy rights requests, and having appropriates policies and procedures in place to be able to demonstrate compliance with the obligations following the GDPR. With regard to transfer of personal data, the GDPR restricts the ability of companies to transfer personal data from the European Economic Area to the United States and other countries, which may adversely affect our ability to transfer personal data or otherwise may cause us to incur significant costs for implementing lawful transfer mechanisms, conducting data transfer impact assessments, and implementing additional measures where necessary to ensure that personal data transferred are adequately protected in a manner essentially equivalent to the EU / UK. The GDPR provides different transfer mechanisms we can use to lawfully transfer personal data from the EU / UK to countries outside the EU / UK. An example is relying on adequacy decisions of the European Commission, such as the EU- U. S. Data Privacy Framework which was adopted by the European Commission in July 2023. Another example of a lawful transfer mechanism is using the EU Standard Contractual Clauses as approved by the European Commission in June 2021, which are the most common used transfer mechanism used to transfer personal data out of the EU / UK. In order to use the EU Standard Contractual Clauses mechanism, the exporter and the importer must ensure that the importer may guarantee a level of personal data protection in the importing country' s level of protection must be adequate that is essentially equivalent to that of the EEA. Compliance with EU / UK data transfer obligations involves conducting transfer impact assessments, which includes documenting detailed analyses of data access and protection laws in the countries in which data importers are located, which can be costly and time- consuming. Data importers must also expend resources in analyzing their ability to comply with transfer obligations, including implementing new safeguards and controls to further protect personal data. Data protection authorities from the different EU member states, as well as in the United Kingdom and Switzerland, have promulgated national privacy laws that impose additional requirements, which add to the complexity of processing and transferring EU personal data, with the United Kingdom and Switzerland following the EU with the publication of new Model Clauses to be incorporated in all applicable contracts within a specified timeframe in order to legitimize data transfers from those jurisdictions. Our ability to continue to transfer personal data outside of the EU, United Kingdom, or Switzerland may become significantly more costly and may subject us to increased scrutiny and liability under the GDPR or similar local laws, and we may experience operating disruptions if we are unable to conduct these transfers in the future. The California Consumer Privacy Act, or CCPA, establishes certain requirements for data use and sharing transparency

and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act (“ CPRA ”) ballot initiative, which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency. The amendments introduced by the CPRA went into effect on January 1, 2023, and new implementing regulations continue to be introduced by the California Privacy Protection Agency. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. We implemented processes to manage compliance with the CCPA and continue to assess the impact of the CPRA, and other state legislation, on our business as additional information and guidance becomes available. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. Similarly, there are a number of legislative proposals in the European Union, the United States, at both the federal and state level, and in other jurisdictions that could impose new obligations or limitations in areas affecting our business. For example, other states, including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislations on our business as additional information and guidance becomes available. In addition, some countries are considering or have passed legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of delivering our services and research activities. These laws and regulations, as well as any associated claims, inquiries, or investigations or any other government actions may lead to unfavorable outcomes including increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, and remedies that harm our business, including fines or demands or orders that we modify or cease existing business practices. Certain of these laws and regulations are described in greater detail in the previous section under" Business — Government Regulation — Healthcare Privacy Laws." Compliance with these laws and regulations is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. If we, our agents, or our third party partners fail to comply or are alleged to have failed to comply with these or other applicable data protection and privacy laws and regulations, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices. Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity or those of any business partners. Despite the implementation of security measures, our internal computer systems and those of our contractors, vendors, customers and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber- intrusions over the Internet, loss of funds or information from phishing or other fraudulent schemes, attachments to emails, persons inside our organization, or persons with access to systems inside our organization or those with whom we do business. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations or loss of Company funds and have a negative financial consequence on our business. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or could result in a delay of the services provided by our vendor. ~~On February 21, 2024, Change Healthcare experienced a cyberattack forcing the shutdown of its insurance claims processing systems. Change Healthcare is the sole claims processor for the vendor that administers the XHANCE co- pay support program. Change Healthcare has not provided a timeline for resolution of this incident which is impairing the ability of XHANCE patients to access benefits available through our co- pay support program. In response we have implemented temporary programs in an effort to minimize the disruption to XHANCE patients and our business and our co- pay support program administrator is exploring alternative processors. To date, we have not experienced a material adverse impact to our business because of this incident. However, the full impact of this incident has yet to be determined and depending on the duration of the impact, it could have a material adverse impact to our results of operations and business.~~ Although we are targeted for cyber- attacks from time to time, we are only aware of one instance where an unauthorized third party accessed certain parts of our computer systems and we believe we have addressed the matter without any known financial implication, loss of data or exposure of confidential or personal information. To the extent that any disruption or security breach were to result in a loss of or damage to our data, misappropriation of funds to unintended recipients, or inappropriate disclosure of confidential, proprietary or personal information, we could incur material legal claims and liabilities and damage to our reputation and the development and commercialization of XHANCE and our other product candidates could be delayed. Additionally, breach remediation costs may be significant. Despite our efforts and the ever- changing threat landscape, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber- attacks or security breaches that could adversely affect our business. We also maintain insurance coverage to mitigate losses associated with certain cybersecurity incidents that impact our third party systems, networks and technologies. We may be exposed to liabilities under the U. S. Foreign Corrupt Practices Act and other U. S. and foreign anti- corruption anti-

money laundering, export control, sanctions, and other trade laws and regulations, and any determination that we violated these laws could have a material adverse effect on our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Control. We are also subject to the U. S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and possibly other anti- bribery and anti- money laundering laws in countries outside of the U. S. in which we conduct our activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees and third- party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector. As we commercialize XHANCE and any other product candidates that we may develop, we may engage with third- party manufacturers and collaborators who operate abroad and are required to obtain certain necessary permits, licenses and other regulatory approvals with respect to our business. Our activities abroad create the risk of unauthorized payments or offers of payments by employees, consultants, sales agents or distributors, even though they may not always be subject to our control. We have implemented policies to discourage these practices by our employees, consultants, sales agents and distributors. However, our employees, consultants, sales agents, or distributors of our company may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities. Noncompliance with anti- corruption, anti- money laundering, export control, sanctions, and other trade laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and / or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. Responding to any action will likely result in a materially significant diversion of management' s attention and resources and significant defense and compliance costs and other professional fees. In addition, the U. S. government may seek to hold us liable for successor liability FCPA violations committed by companies in which we invest or that we acquire. As a general matter, enforcement actions and sanctions could harm our business, results of operations, and financial condition.