Risk Factors Comparison 2025-03-27 to 2024-03-07 Form: 10-K

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

Risks Related to Development and Commercialization of our Product Candidate We are substantially dependent upon the clinical, regulatory, and commercial success of our sole product candidate, **MOLBREEVI** ~~molgramostim nebulizer solution (molgramostim)~~ . If we are unable to successfully complete clinical development of, obtain regulatory approval for, and successfully commercialize ~~molgramostim~~ **MOLBREEVI** , our business may be harmed. The success of our business is dependent on our ability to advance the clinical development of our sole product candidate, ~~molgramostim~~ **MOLBREEVI, an investigational inhaled GM- CSF** for the treatment of ~~patients with~~ aPAP. To date, we have never obtained regulatory approvals for or commercialized a product candidate, and we may never be able to develop a marketable product. We are devoting, and expect to continue to devote, substantially all our efforts and financial resources to the development of ~~molgramostim~~ **MOLBREEVI** for aPAP, including clinical trials, regulatory approval, and, if approved, commercialization. Our business depends heavily on the successful completion of clinical development and subsequent regulatory approval of ~~molgramostim~~ **MOLBREEVI** for aPAP. We are conducting IMPALA- 2, a global Phase 3 pivotal trial designed to compare the efficacy and safety of ~~molgramostim~~ **MOLBREEVI** 300 µg administered once daily by inhalation with matching placebo in patients with aPAP. ~~There can be no assurance that the IMPALA- 2 pivotal trial will demonstrate with statistical significance that molgramostim is effective for the proposed indication compared to placebo or that it will establish adequate safety. Any failure to do so would adversely impact the potential for regulatory approval of molgramostim. Even if molgramostim demonstrates a statistically significant difference compared to placebo for the primary endpoint, we may not be able to demonstrate differences for our secondary endpoints. Additionally, clinical trial data frequently are susceptible to varying interpretations.~~ Although we may believe the trial demonstrates promising results, regulatory authorities may analyze or weigh trial data differently, resulting in delay or failure to obtain marketing approval or a requirement to conduct confirmatory studies. We are not permitted to commercialize ~~molgramostim~~ **MOLBREEVI** in the U. S. until we receive approval of a BLA, or in any other country until we receive the requisite approvals from the appropriate regulatory authorities. Failure to obtain such approvals could impair our ability to generate revenues from the product candidate, which would have a material adverse effect on our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock. Given the developmental nature of our product candidate, we are subject to risks associated with initiating, completing, and achieving positive outcomes from our current and future ~~clinical trials, including: • slow implementation, enrollment, and completion of the clinical trials; • inability to enroll enough patients in the clinical trials; • low patient compliance and adherence to dosing and reporting requirements, for example, incomplete reporting of patient reported outcomes in the clinical trials or missed doses; • lack of safety and efficacy in the clinical trials; • delays in manufacture of supplies for both drug and device components due to delays in formulation, process development, or manufacturing activities; • requirements for additional nonclinical or clinical trials based on changes to formulation and / or changes to regulatory requirements; and • poor quality or missing data from the~~ clinical trials. If we successfully complete the necessary clinical trials for our product candidate, our success will be subject to the risks associated with obtaining regulatory approvals, product launch, and commercialization, including: • rejection of our regulatory submissions for our product candidate by the FDA or other regulatory authorities; • delays during regulatory review and / or requirements of additional chemistry, manufacturing, and controls, nonclinical, or clinical studies, resulting in increased costs and / or delays in marketing approval and subsequent commercialization of the product candidate in the U. S. and other markets; • inability to consistently manufacture commercial supplies of drug and delivery devices resulting in slowed market development and lower revenue; • poor commercial sales due to: othe inability of our future sales organization or our potential commercialization partners to effectively sell the product candidate; oour lack of success in educating physicians and patients about the benefits, administration, and use of our product candidate; othe availability, perceived advantages, relative cost, relative safety, and relative efficacy of other products or treatments for the targeted indications of the product candidate; olow patient demand for the product candidate; and opoor prescription coverage and inadequate reimbursement for our product candidate; oour inability to enforce our intellectual property rights in our product candidate; and oreduction in the safety profile of our product candidate following approval. Many of these clinical, regulatory, and commercial matters are beyond our control and are subject to other risks described elsewhere in this Item 1A, Risk Factors section. Accordingly, we cannot assure that we will be able to advance our product candidate further through final clinical development, or obtain regulatory approval of, commercialize, or generate significant revenue. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed. Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our product candidate. If development of our product candidate is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and be unable to commercialize our product candidate on a timely basis, if at all. Pharmaceutical products are subject to stringent regulatory requirements covering quality, safety, and efficacy. Only after successfully completing extensive pharmaceutical development, nonclinical testing, and clinical trials may a product be considered for regulatory approval. Clinical trials are expensive, difficult to design and implement, the outcome is inherently uncertain, and failure or delay may occur at any time. We may experience a number of unforeseen events that cause our clinical trials not commence or not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including: • inability to raise sufficient funding to initiate or continue a clinical trial; • delays in obtaining regulatory approval to commence or extend a clinical trial; • delays in identifying and reaching agreement on acceptable terms with prospective CROs,

clinical trial sites, and investigators, which agreements can be subject to extensive negotiation and may vary significantly among trial sites; • delays in obtaining regulatory approval in a prospective country; • delays in obtaining ethics committee approval to conduct or extend a clinical trial at a prospective site; • delays in reaching agreements on acceptable terms with prospective CMOs or other vendors for the production and supply of clinical trial material and, if necessary, drug administration devices, which agreements can be subject to extensive negotiation; • delays in the production or delivery of sufficient quantities of clinical trial material or drug delivery devices from our CMOs and other vendors to initiate or continue a clinical trial; • delays in distributing clinical trial material due to import restrictions or licenses in target countries; • delays due to product candidate recalls as the result of stability failure, excessive product complaints, or other failures of the product candidate during its use or testing; • invalidation of clinical data caused by premature unblinding or integrity issues; • invalidation of clinical data caused by mixing up of the active drug and placebo through randomization or manufacturing errors; • delays on the part of our CROs, CMOs, and other third- party contractors in developing procedures and protocols or otherwise conducting activities in accordance with applicable policies and procedures and in accordance with agreed upon timelines; • delays in identifying and hiring or engaging, as applicable, additional employees or consultants to assist in managing clinical trial- related activities; • delays in recruiting and enrolling individuals to participate in a clinical trial, which historically can be challenging in orphan diseases; • delays caused by patients dropping out of a clinical trial due to side effects, concurrent disorders, difficulties in adhering to the trial protocol, unknown issues related to different patient profiles than in previous trials, or otherwise; • delays in having patients complete participation in a clinical trial; • delays resulting from clinical trial sites dropping out of a trial, providing inadequate staff support for the trial, problems with shipment of trial supplies to clinical sites, or focusing its staff' s efforts on enrolling trials that compete for the same patient population; • suspension of enrollment at a trial site or the imposition of a clinical hold by the FDA or other regulatory authority following an inspection of clinical trial operations at trial sites or finding of a drug- related serious adverse event; • delays in quality control / quality assurance procedures necessary for trial database lock and analysis of unblinded data; • delays, inconsistencies, or negative results in statistical analyses of clinical trial data; • delays in enrollment and the treatment of patients caused by global health risks; and • delays due to supply chain disruptions as a result of global health risks, international conflict, or other unexpected event. Clinical trials may not begin on time or be completed in the time frames we anticipate and may be costlier than we anticipate for a variety of reasons, including one or more of those described above. The length of time necessary to successfully complete clinical trials vary significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and / or availability of results from our clinical trials, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons, including patient enrollment rates, length of time needed to prepare raw trial data for analysis and then to review and analyze it, and other factors described above. If we experience delays in the completion of a clinical trial, if a clinical trial is terminated, or if failure to conduct a trial in accordance with regulatory requirements or the trial' s protocol leads to deficient safety and / or efficacy data, the regulatory approval and / or commercial prospects for our product candidate may be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials have in the past and may in the future ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize a product candidate, the standard of care may have changed or other therapies for the same indications may have been introduced to the market in the interim and may establish a competitive threat to us or diminish the need for our products. Failure at any stage of clinical testing is not uncommon and we may encounter problems that would require additional, unplanned trials or cause us to abandon a clinical development program. In addition, a clinical trial may be suspended or terminated by us, an IRB, a data safety monitoring board, the FDA, or other regulatory authorities due to a number of factors, including: • lack of adequate funding to continue the trial; • failure to conduct the trial in accordance with regulatory requirements or the trial' s protocol; • inspection of clinical trial operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; • unforeseen safety issues, including adverse side effects; or • changes in governmental regulations or administrative actions **, such as lay- offs and staffing at regulatory agencies such as the FDA** . Changes in governmental regulations and guidance relating to clinical trials may occur and we may need to amend clinical trial protocols to reflect these changes, or we may amend trial protocols for other reasons. Amendments may require us to resubmit protocols to IRBs for re- examination and approval or renegotiate terms with CROs, clinical trial sites, and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidate. There are significant risks that ongoing and future clinical trials of our product candidate will not be successful. The results of preclinical and early clinical trials may not be predictive of the results of later- stage clinical trials, and the possible lack of standardization across multiple investigative sites may induce variability in the results which can interfere with the evaluation of treatment effects. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. For example, the top line results from our IMPALA trial were released by us on June 12, 2019 and did not meet all of the statistical goals and protocol end points. On October 1, 2019, we received a written response from the FDA in connection with a Type C meeting regarding the ~~molgramostim~~ **MOLBREEVI** development program for aPAP and results from IMPALA in which the FDA indicated that the data provided did not provide sufficient evidence of efficacy and safety for the treatment of aPAP. Negative or inconclusive results could cause the FDA and other regulatory authorities to require us to repeat or conduct additional clinical trials, which could significantly increase the time and expense associated with development of that product candidate or cause us to elect to discontinue one or more clinical programs. There is significant uncertainty regarding the regulatory approval process for any investigational new drug. Substantial further testing and validation of our product candidate and related manufacturing processes

may be required, and regulatory approval may be conditioned, delayed, or denied, any of which could delay or prevent us from successfully marketing our product candidate and substantially harm our business. Regulatory approval is required before a pharmaceutical product can be commercially marketed and sold, and various federal and foreign statutes and regulations also govern or materially influence the manufacturing, safety, labeling, storage, record keeping, and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U. S. and foreign statutes and regulations is time- consuming and requires the expenditure of substantial resources. Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including ~~molgramostim~~ **MOLBREEVI** . Regardless of any guidance the FDA or foreign regulatory agencies may provide a drug' s sponsor during its development, the FDA or foreign regulatory agencies retain complete discretion in deciding whether to accept a BLA, or the equivalent foreign regulatory approval submission for filing or, if accepted, whether to approve a BLA. There are many components to a BLA or marketing authorization application submission in addition to clinical trial data. For example, the FDA or foreign regulatory agencies will review the sponsor' s internal systems and processes, as well as those of its CROs, CMOs, and other vendors, related to development of its product candidates, including those pertaining to its clinical studies and manufacturing processes. Before accepting a regulatory approval submission for review or before approving such submission, the FDA or foreign regulatory agencies may request that we provide additional information that may require significant resources and time to generate, and there is no guarantee that our product candidate will be approved for any indication for which we may apply. The FDA or foreign regulatory agencies may choose not to approve a BLA or its equivalent for a variety of reasons, including a decision related to the safety or efficacy data, manufacturing controls or systems, or for any other issues that the agency may identify related to the development of its product candidates. Even if one or more Phase 3 clinical trials are successful in providing statistically significant evidence of the efficacy and safety of the investigational drug, the FDA or foreign regulatory agencies may not consider efficacy and safety data from the submitted trials adequate scientific support for a conclusion of effectiveness and / or safety and may require one or more additional Phase 3 or other trials prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and competitors may bring products to market before us, which could impair our ability to generate revenues from the product candidate, or even seek approval, if blocked by a competitor' s Orphan Drug exclusivity, which would have a material adverse effect on our business, financial condition, and results of operations. Further, development of our product candidate and / or regulatory approval may be delayed for reasons beyond our control. Regulations or policies may be changed prior to submission of a marketing application that result in delays or require higher hurdles than currently anticipated. These may occur as a result of drug scandals, recalls, or a political environment unrelated to our products. For example, the FDA has granted ~~molgramostim~~ **MOLBREEVI** for aPAP Fast Track and BTD, which are each designed to expedite the development and review of certain drugs. If there were a change in FDA policies and we were to lose those designations, it could cause delays in the regulatory review process. Additionally, **changes in FDA priorities due to a new administration, layoffs, or** U. S. federal government shut- downs or budget sequestrations, such as ones that occurred during January 2018 and December 2018 through January 2019, may result in significant reductions to the FDA' s budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidate or obtain regulatory approval for our product candidate. Even if the FDA or foreign regulatory agencies grant approvals for a product candidate, the conditions or scope of the approval (s) may limit successful commercialization of the product candidate and impair our ability to generate substantial sales revenue. For example, ~~molgramostim~~ **MOLBREEVI** could be approved with restrictions for use only by patients unresponsive to the current standard of care **,** or the FDA may approve label claims with age restrictions and / or treatment duration limitations. The FDA may limit the label of ~~molgramostim~~ **MOLBREEVI** to a subset of patients based on a review of which patient groups had the greatest efficacious response in clinical trials. Such label restriction may be undesirable and may limit successful commercialization. The FDA or foreign regulatory agencies may also only grant marketing approval contingent on the performance of costly post- approval nonclinical or clinical studies, or subject to warnings or contraindications that limit commercialization. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, and continued compliance with cGMP, ~~good clinical practice (" GCP ")~~, international conference on harmonization regulations, and good laboratories practice (" GLP"), which are regulations and guidelines that are enforced by the FDA or foreign regulatory agencies for all clinical development and for any clinical studies that we conduct post- approval. The FDA or foreign regulatory agencies may decide to withdraw approval, add warnings, or narrow the approved indications in the product label, or establish risk management programs that could restrict distribution of our products. These actions could result from, among other things, safety concerns, including unexpected side effects or drug interaction problems, or concerns over misuse of a product. If any of these actions were to occur following approval, we may have to discontinue commercialization of the product, limit our sales and marketing efforts, implement risk minimization procedures, and / or conduct post- approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues. Our ~~molgramostim~~ **MOLBREEVI** product candidate may cause undesirable side effects or adverse events or have other properties that could delay or prevent our clinical development, regulatory approval, or commercialization. Undesirable side effects or adverse events caused by our ~~molgramostim~~ **MOLBREEVI** product candidate could interrupt, delay, or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidate. A significant challenge in clinical development is that the patient population in early trials, where small numbers of patients are required, is different from the patient population observed in later stage trials, where larger groups of patients are required. As such, efficacy or safety results may differ significantly between trials. If we fail to demonstrate the efficacy of our drug candidate or undesirable side effects

occur, they could possibly prevent approval, which would have a material and adverse effect on our business **. Additionally, the patient population in our clinical trials is a defined subset of patients who have agreed to enter the trials. It is possible undesirable side effects could be seen in the larger addressable patient population that were not observed in the clinical trials** . If our product candidate receives marketing approval and we or others later identify undesirable side effects caused by the product: • regulatory authorities may withdraw their approval of the product; • regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication; • we may be required to change the way the product is administered, conduct additional clinical trials, or change the labeling of the product; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenue from its sale. Even if we receive regulatory approval for our product candidate, we may face regulatory difficulties that could materially and adversely affect our business, financial condition, and results of operations. Even if initial regulatory approval is obtained, as a condition to the initial approval, the FDA or a foreign regulatory agency may impose significant restrictions on a product' s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies or marketing surveillance programs, any of which would limit the commercial potential of the product. Our ~~molgramostim~~ **MOLBREEVI** product candidate also will be subject to ongoing FDA requirements related to the manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record- keeping, and submission of safety and other post- market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post- approval clinical studies, and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers, and manufacturers' facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a CMO of ours fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters or enforcement letters; • impose civil or criminal penalties; • suspend or withdraw regulatory approval; • suspend or terminate any ongoing clinical trials; • refuse to approve pending applications or supplements to approved applications; • exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare in the U. S.; • impose restrictions or affirmative obligations on our or our CMO' s operations, including costly new manufacturing requirements; • close the facilities of a CMO; or • seize or detain products that are deemed to be adulterated. If our product candidate receives regulatory approval but fails to achieve significant market acceptance among the medical community, patients, or third- party payers, the revenue we generate from its sales will be limited and our business may never achieve profitability. Our success will depend in substantial part on the extent to which our product candidate, if approved, is accepted by the medical community and patients and reimbursed by third- party payers, including government payers. The degree of market acceptance with respect to our approved product, if any, will depend upon a number of factors, including: • the safety and efficacy of our product as demonstrated in clinical trials; • acceptance in the medical and patient communities of our product as a safe and effective treatment; • the product' s taste, ease of use, or features associated with the delivery device; • the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment; • the indications for which our product is approved; • claims or other information (including limitations or warnings) in a product' s approved labeling; • reimbursement and coverage policies of government and other third- party payers; • pricing and cost- effectiveness of our product relative to alternative treatments; • availability of alternative treatments; • smaller- than- expected market size due to lack of disease awareness of a rare disease, or the patient population with a specific rare disease being smaller than anticipated; • inappropriate diagnostic efforts due to limited knowledge and / or resources among clinicians; • difficulties identifying patients; • the prevalence of off- label substitution of chemically equivalent products or alternative treatments; and • the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product. We cannot predict with reasonable accuracy whether physicians, patients, healthcare insurers, health maintenance organizations, or the medical community in general, will accept or utilize our product, if approved. If our product candidate is approved but does not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or remain profitable. In addition, our efforts to educate the medical community and third- party payers regarding benefits of our product may require significant resources and may never be successful. If we determine that a product candidate may not achieve adequate market acceptance or that the potential market size does not justify additional expenditures on the program, we may reduce our expenditures on the development and / or the process of seeking regulatory approval of the product candidate while we evaluate whether and on what timeline to move the program forward. Even if we receive regulatory approval to market our product candidate in the U. S., we may never receive approval or commercialize our product outside of the U. S., which would limit our ability to realize the full commercial potential of our product candidate. In order to market products outside of the U. S., we must establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries generally differs from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U. S., as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U. S. As described above, such effects include the risks that our product candidate may not be approved for all indications requested, which could limit the uses of our product candidate and have an adverse effect on product sales, and that such approval may be subject to limitations on the

indicated uses for which the product may be marketed or require costly, post- marketing follow- up trials. Risks Related to Our Capital Requirements and Financial Condition We have incurred significant losses since inception and expect that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability. We are a clinical development- stage biopharmaceutical company, and we have not been profitable since we commenced operations and may not ever achieve profitability. In addition, we have limited history as an organization and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. We have not obtained any regulatory approvals for a product candidate, commercialized a product candidate, or generated any product revenue. We have devoted significant resources to research and development and other expenses related to our ongoing clinical trials and operations, in addition to acquiring product candidates. For the year ended December 31, ~~2023~~ **2024**, we incurred a net loss of $ ~~54~~ **95**. ~~7~~ **9** million, and net cash used in operating activities was $ ~~51~~ **89**. 1 million. At December 31, ~~2023~~ **2024**, our cash, cash equivalents and short- term investment securities were approximately $ ~~162~~ **196**. 3 million, and working capital was approximately $ ~~155~~ **187**. 4 million. At December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~393~~ **489**. ~~4~~ **3** million. We expect to continue to incur substantial operating losses for the next several years as we seek to advance our ~~molgramostim~~ **MOLBREEVI** product candidate through clinical development ~~(IMPALA- 2 pivotal trial)~~, global regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, our current product candidate, ~~molgramostim~~ **MOLBREEVI**, is approved by the FDA or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering- related funding, outcomes which we may not achieve. We may require additional financing to obtain regulatory approval for ~~molgramostim~~ **MOLBREEVI** and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our product development efforts or other operations. Since our Aravas subsidiary was formed in 2007, most of our resources have been dedicated to the development and acquisition of our product candidates, primarily ~~molgramostim~~ **MOLBREEVI**. Our priority remains the continued development of ~~molgramostim~~ **MOLBREEVI** for the treatment of aPAP ~~and our IMPALA- 2 pivotal trial~~. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidate, and there is no certainty that we will be able to raise the necessary capital on reasonable terms or at all. If adequate funds are not available to us on a timely basis, we ~~will~~ **may** be required to delay, limit, reduce, or terminate our establishment of sales and marketing, manufacturing or distribution capabilities, development activities, other activities that may be necessary to commercialize our product candidate, or conduct preclinical or clinical trials. Our capital requirements for the foreseeable future will depend in large part on, and could increase significantly as a result of, our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties, and will depend on, and could increase significantly as a result of, many factors, including: • the number, size, complexity, results, and timing of our drug development programs; • the timing and terms of any collaborative or other strategic arrangement that we may establish; • the number of clinical and nonclinical studies necessary to demonstrate acceptable evidence of the safety and efficacy of our product candidate; • changes in standards of care which could increase the size and complexity of our clinical trials; • the number of patients who participate, the rate of enrollment, and the ratio of randomized to evaluable patients in each clinical trial; • the ability to locate patients to participate in a trial given the limited number of patients available for orphan or ultra- orphan indications; • the number and location of sites and the rate of site initiation in each trial; • the duration of patient treatment and follow- up; • the potential for additional safety monitoring or other post- marketing trials that may be requested by regulatory agencies; • the time and cost to manufacture clinical trial material and commercial product, including process development and scale- up activities, and to conduct stability studies, which can last several years; • the degree of difficulty and cost involved in securing alternate manufacturers or suppliers of drug product, components, or delivery devices, as necessary to meet FDA requirements and / or commercial demand; • the costs, requirements, timing of, and the ability to, secure regulatory approvals; • the extent to which we increase our workforce and the costs involved in recruiting, training, and incentivizing new employees; • the costs related to developing, acquiring, and / or contracting for sales, marketing, and distribution capabilities, supply chain management capabilities, and regulatory compliance capabilities, if we obtain regulatory approval for our product candidate and commercialize it without a partner; • the costs involved in evaluating competing technologies and market developments or the loss in sales in case of such competition; • the costs involved in establishing, enforcing, or defending patent claims and other proprietary rights; and • the continuing negative impacts of global health risks. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidate, technologies, future revenue streams, or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our stockholders will be diluted, and the terms of any new equity securities may have preferential rights over our common stock. In particular, due to the price per share of our common stock, any sale of our equity securities to raise significant capital would result in substantial ownership dilution to our stockholders. If we raise additional capital through debt financing, it may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures, or subject to specified financial ratios, any of which could restrict our ability to develop and commercialize our product candidate or operate as a business. Our loan agreement contains covenants which may adversely impact our business; the failure to comply with such covenants could cause our outstanding debt to become immediately payable or accelerate principal payments. We are a party to an Amended and Restated Loan and Security Agreement with Silicon Valley Bank, now a division of First Citizens Bank (the " Amended Loan Agreement "), pursuant to which we have pledged substantially all of our assets, other than our intellectual property (which is subject to a negative pledge). The Amended Loan Agreement includes a number of restrictive covenants, including restrictions on incurring additional debt, making investments, granting liens,

disposing of assets, paying dividends, and redeeming or repurchasing capital stock, subject to certain exceptions. Collectively, these restrictive covenants could constrain our ability to grow our business through acquisitions or engage in other transactions. The Amended Loan Agreement includes customary events of default, such as our failure to pay amounts due, our failure to comply with covenants, or the occurrence of an event that would reasonably be expected to have a material adverse event on our business. Upon the occurrence and during the continuation of an event of default, Silicon Valley Bank could declare all outstanding loans under the Amended Loan Agreement immediately due and payable and exercise remedies against us and the collateral. Such an event would have a material adverse effect on our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline. Refer to Note 7. Debt Facility of the consolidated financial statements in this annual report on Form 10- K for additional discussion. Any future acquisitions that we make could disrupt our business and harm our financial condition. We may, from time to time, evaluate potential strategic acquisitions of complementary businesses, products, or technologies. In addition, we may evaluate joint ventures, licensing opportunities, and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance, or integrate acquisitions of any businesses, products, or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert our management' s time and resources from our core business and disrupt our operations. Any cash acquisition we pursue would diminish the funds otherwise available to us for other uses. Any acquisition using our stock would dilute our stockholders' ownership interests. If we engage in acquisitions of companies, products, or technologies in order to execute our business strategy, we may need to raise additional capital. We may raise additional capital in the future through one or more financing vehicles that may be available to us including (i) new collaborative agreements; (ii) expansions or revisions to existing collaborative relationships; (iii) private financings; (iv) other equity or debt financings; (v) monetizing assets; and / or (vi) the public offering of securities. If we are required to raise additional capital in the future, it may not be available on favorable financing terms within the time required, or at all. If additional capital is not available on favorable terms when needed, we will be required to raise capital on adverse terms or significantly reduce operating expenses through the restructuring of our operations or deferral of strategic business initiatives. If we raise additional capital through a public offering of securities, a substantial number of additional shares may be issued, which may negatively affect our stock price and these additional shares will dilute the ownership interest of our current investors. We have IPR & D and future impairment of IPR & D may have an adverse impact on our future financial condition and results of operations. As of December 31, ~~2023~~ **2024** , we had IPR & D of approximately $ ~~11~~ **10** . ~~0~~ **3** million. Our intangible assets have been previously impaired and remain subject to additional impairment analyses whenever an event or change in circumstances indicates the carrying amount of such an asset may not be recoverable and is tested annually on September ~~30~~ **30th** . Events giving rise to impairment are difficult to predict and are an inherent risk in the pharmaceutical industry. Some of the potential risks that could result in impairment of our IPR & D include negative clinical trial results, adverse regulatory developments, delay or failure to obtain regulatory approval, additional development costs, changes in the manner of our use or development of our product candidate, competition, earlier than expected loss of exclusivity, pricing pressures, higher operating costs, geopolitical conflicts, changes in tax laws, prices that third parties are willing to pay for our IPR & D or similar assets in an arm' s- length transaction being less than the carrying value of our IPR & D, and other adverse market and economic environment changes or trends. Events or changes in circumstances may lead to significant impairment charges on our IPR & D in the future, which could materially adversely affect our financial condition and results of operations. Adverse developments affecting financial institutions, companies in the financial services industry, or the financial services industry generally, such as actual events or concerns involving liquidity, defaults, or non- performance, could adversely affect our operations and liquidity. Actual events involving limited liquidity, defaults, non- performance, or other adverse developments that affect financial institutions or other companies in the financial services industry, or the financial services industry generally, or concerns or rumors about any such events, have in the past and may in the future lead to market- wide liquidity problems. For ~~example~~ **instance** , **in** ~~on March 10,~~ 2023 ~~,~~ the Federal Deposit Insurance Corporation (" FDIC") took control of Silicon Valley Bank, where the Company maintains depository accounts and has a debt facility ~~, and created the National Bank of Santa Clara to hold the deposits of Silicon Valley Bank after Silicon Valley Bank was unable to continue its operations. On March 27, 2023, First Citizens BancShares, Inc. (Nasdaq: FCNCA) announced that it had entered into an agreement with the FDIC to purchase all of the assets and liabilities of Silicon Valley Bank and all bank deposits~~ . Although the failure of Silicon Valley Bank did not cause us to experience any material impacts on our financial condition or results of operations, our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements face liquidity constraints or failures. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations, or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity. Risks Related to Our Dependence on Third Parties We do not have, and do not have plans to, establish commercial manufacturing facilities. We completely rely on third parties for the manufacture and supply of our clinical trial drug and delivery device supplies and, if approved, commercial product materials. The loss of any of these vendors or a vendor' s failure to provide us with an adequate supply of clinical trial or commercial product material in a timely manner and on commercially acceptable terms, or at all, could harm our business. We outsource the manufacture of our ~~molgramostim~~ **MOLBREEVI** product candidate and do not plan to establish our own manufacturing facilities. To manufacture our product candidate, we have made numerous custom modifications at CMOs, making us highly dependent on these CMOs. For clinical and commercial supplies, if approved, we have supply agreements

with third party CMOs for drug substance, finished drug product, drug delivery devices and other necessary components of our ~~molgramostim~~ **MOLBREEVI** product candidate. While we have secured long- term commercial supply agreements with many of the third party CMOs, we would need to negotiate agreements for commercial supply with several important CMOs, and we may not be able to reach agreement on acceptable terms. In addition, we rely on these third parties to conduct or assist us in key manufacturing development activities, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials, demonstrating comparability of DS and DP, and conducting stability testing, among other things. If these third parties are unable to perform their tasks successfully in a timely manner, whether for technical, financial, or other reasons, we may be unable to secure clinical trial material, or commercial supply material if approved, which likely would delay the initiation, conduct, or completion of our clinical trials or prevent us from having enough commercial supply material for sale, which would have a material and adverse effect on our business. There have been and could be additional delays in the manufacturing supply chain for our product candidate, including delays in procurement of materials for certain of our clinical trials, potentially resulting in delays in clinical trials and recruitment. Further, we have experienced an increase in costs associated with the supply chain disruption. The extent to which circumstances such as global health threats, global conflicts, and social unrest impact our ability to procure sufficient supplies for the development and commercialization of our product candidate going forward will depend on the severity and duration of such circumstances. For example, our primary CMO for drug substance operates in Argentina, which is experiencing high inflation, a weakening currency, labor strikes and social and political unrest. Those conditions could result in supply chain disruptions or increased costs. All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with cGMP requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include manufacturing, quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our clinical trial material may be unable to comply with these cGMP requirements and with other FDA, state, and foreign regulatory requirements. While we and our representatives generally monitor and audit our manufacturers' systems, we do not have full control over their ongoing compliance with these regulations. Although the responsibility to maintain cGMP compliance is a requirement of third- party manufacturers, we bear ultimate responsibility for our supply chain and compliance with regulatory standards. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval. Identification of and discussions with alternative vendors, if necessary, may be protracted and / or unsuccessful, or these new vendors may be unsuccessful in producing the same results as the current primary vendors producing the material. Therefore, if our primary and back- up vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which would materially and adversely affect our development programs, commercial activities, operating results, and financial condition. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling- up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, and shortages of qualified personnel. Our product candidate has not been manufactured at the scale we believe will be necessary to maximize its commercial value and, accordingly, after initial licensure and commercialization, we may encounter difficulties in attempting to scale- up production and may not succeed in that effort on a timely basis or at all. In addition, the FDA or other regulatory authorities may impose additional requirements as we scale up initial production capabilities, which may delay our scale- up activities and / or add expense. If our manufacturers encounter any of the aforementioned difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements due to capital constraints, we may have insufficient quantities of material to support ongoing and / or planned clinical trials or to meet commercial demand, if approved. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidate could delay the completion of our clinical trials, increase the costs associated with our development programs, and depending upon the period of delay, require us to commence new clinical trials at significant additional expense or terminate the trials completely. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. We cannot provide assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our clinical trial material or commercial product, if approved, or that third- party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such clinical trial material or commercial product, as applicable. In addition, ~~molgramostim~~ **MOLBREEVI** is currently manufactured entirely outside the U. S. and, as a result, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, changes in currency fluctuations, shipping costs, or import tariffs could adversely affect cost of goods sold. Any of the above factors could cause us to delay or suspend anticipated or ongoing trials, regulatory submissions, or commercialization of our product candidate, entail higher costs, or result in being unable to effectively commercialize our product. Our dependence upon third parties for the manufacture of our clinical trial material may adversely affect our future costs and our ability to develop and commercialize our product candidate on a timely and competitive basis. We rely significantly on third parties to conduct our nonclinical testing and clinical trials and other aspects of our ~~molgramostim~~ **MOLBREEVI** development program, and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our ~~molgramostim~~ **MOLBREEVI** product candidate could be adversely affected. We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, CROs, and others to assist in the design and conduct of nonclinical and clinical trials of our product candidate, with interpretation of the results of those trials, and with regulatory activities, and we expect to continue to outsource all or a significant amount of such activities. For example, we have engaged a

CRO, Parexel, to support our IMPALA- 2 pivotal clinical trial development activities, and we are substantially dependent upon Parexel for the conduct of the IMPALA- 2 pivotal trial. Many important aspects of our development programs are and will continue to be outside our direct control, and our third- party service providers may not perform their activities as required or expected, including the maintenance of GCP, GLP, and cGMP compliance, which are ultimately our responsibility to ensure. Further, such third parties may not be as committed to the success of our programs as our own employees and, therefore, may not devote the same time, thoughtfulness, or creativity to completing projects or problem- solving as our own employees would. To the extent we are unable to successfully manage the performance of third- party service providers, our business may be adversely affected. The CROs that we engage to execute our clinical trials play a significant role in the conduct of the trials, including patient enrollment and the collection and analysis of trial data. We likely will depend on CROs and clinical investigators to conduct future clinical trials and to assist in analyzing data from completed trials and developing regulatory strategies for our product candidate. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our trials are conducted, are not our employees, and we have limited control over the amount or timing of resources that they devote to their programs. In addition, our CROs may be affected by business or workforce interruptions for many reasons over which they and we have limited control. If our CROs, trial investigators, and / or third- party sponsors fail to devote sufficient time and resources to trials of our product candidate, if we and / or our CROs do not comply with all GLP and GCP regulatory and contractual requirements, or if their performance is substandard, we may delay commencement and / or completion of these trials, submission of applications for regulatory approval, regulatory approval, and commercialization of our product candidate. Failure of CROs to meet their obligations to us could adversely affect development of our product candidate. In addition, CROs we engage may have relationships with other commercial entities, some of which may compete with us. Through intentional or unintentional means, our competitors may benefit from lessons learned on our projects that could ultimately harm our competitive position. Moreover, if a CRO fails to properly, or at all, perform our activities during a clinical trial, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs may increase costs and divert management time and attention. In addition, there likely would be a transition period before a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical trials, which could materially impact our ability to meet our desired and / or announced development timelines and have a material adverse impact on our business and financial condition. Our employees, independent contractors and consultants, principal investigators, CROs, CMOs, other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk that our employees, independent contractors and consultants, principal investigators, CROs, CMOs, other vendors, and any future commercial partners may engage in fraudulent conduct or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards required by cGMP or our standards, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to them. The misconduct of our employees and other service providers could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter such 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 or our service providers, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. For example, if one of our manufacturing partners were placed under a consent decree, we may be hampered in our ability to manufacture clinical or commercial supplies. The company intends to establish a redundant supply chain with second sources of drug substance and drug product manufacture. If the product manufactured at the second sources of manufacture is not demonstrated to be comparable with materials used in the clinical program, we may not be able to commercialize from these second sources. We have engaged third- parties for our drug product and drug substance manufacturing to serve as second source manufacturers and suppliers of ~~molgramostim~~ **MOLBREEVI** to attain uninterrupted supply and mitigate approvability risk. If the second sources do not demonstrate the ability to provide comparable product to our primary sources, the supply chain and scalability to commercialize ~~molgramostim~~ **MOLBREEVI** could be adversely impacted. Any new manufacturer or supplier would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing of such product or ingredients required by us. The FDA or foreign regulatory agency may require us to conduct additional clinical trials, collect stability data, and provide additional information concerning any new supplier, or change in a validated manufacturing process, including scaling- up production, before we could distribute products from that manufacturer or supplier or revised process. For example, if we were to engage a third party other than our current CMOs to supply the drug substance or drug product for future clinical trials or commercial sale, the FDA or regulatory authorities outside of the U. S. may require us to conduct additional clinical and nonclinical studies to ensure comparability of the drug substance or drug product manufactured by our current CMOs to that manufactured by the new supplier. Changing of suppliers is particularly challenging for companies like us, with inhalation products, because any change could alter the performance of the drug product. Risks Related to Competition, Retaining Key Employees and Managing Growth ~~Molgramostim~~ **MOLBREEVI** has received Orphan Drug Designation from the FDA and the EMA. If a competitor obtains Orphan Drug exclusivity for a product with the same active ingredient and route of delivery as molgramostim for aPAP, we may be unable to market our product candidate until the exclusivity of the competing product

expires. ~~Molgramostim~~ **MOLBREEVI** has received Orphan Drug Designation in the U. S. by the FDA and in Europe by the EMA for the treatment of aPAP. If approval is received to market ~~molgramostim~~ **MOLBREEVI** , the FDA will not approve a similar product, with the same active ingredient, to ~~molgramostim~~ **MOLBREEVI** for seven years and the EMA will not approve a similar product to ~~molgramostim~~ **MOLBREEVI** for ten years, unless we are unable to produce enough supply to meet demand in the marketplace or another similar product, with the same active ingredient, is deemed clinically superior. Similar product candidates, with the same active ingredient and route of delivery, may be granted Orphan Drug Designation during the development, but the Orphan Drug exclusivity is granted only to the first of such products approved, which means there is risk that a competitor product candidate may receive approval and Orphan Drug exclusivity before us, thus preventing us from marketing our product candidate until the exclusivity of the competing product expires. Also, the Orphan Drug status will not prevent a competitor with a different active ingredient from competing with our product candidate. If we are prevented from marketing ~~molgramostim~~ **MOLBREEVI** for aPAP due to a competitor' s Orphan Drug exclusivity, it would have a material adverse effect on our business. We expect competition in the marketplace for our ~~molgramostim~~ **MOLBREEVI** product candidate should it receive regulatory approval. The development and commercialization of new drug products is highly competitive and subject to rapid and significant change. Developments by others may render potential application of our ~~molgramostim~~ **MOLBREEVI** product candidate in aPAP obsolete or noncompetitive, even prior to completion of its development and approval. If successfully developed and approved, we expect our product candidate will face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical, and human resources than us, and may be better equipped to develop, manufacture, market, and distribute products. Many of these companies operate large, well- funded research, development, and commercialization programs, have extensive experience in nonclinical and clinical trials, obtaining FDA and other regulatory approvals **,** and manufacturing and marketing products, and have multiple products that have been approved or are in late- stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us and prevent us from competing due to their orphan drug protections. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, heightened awareness on the part of academic institutions, government agencies, and other public and private research organizations of the potential commercial value of their inventions have led them to actively seek to commercialize the technologies they develop, which increases competition for investment in our programs. Competitive products may be more effective, easier to dose, or more effectively marketed and sold than ours, which would have a material adverse effect on our ability to generate revenue. Although we are not aware of any companies developing an inhaled form of GM- CSF for the treatment of aPAP, **sargramostim (** Leukine ~~® (sargramostim~~), a yeast- derived recombinant human granulocyte- macrophage colony stimulating factor, rhu- GM- CSF, which is a product of Partner Therapeutics, Inc., is being pharmacy- compounded and utilized by some patients **in the U. S.** for the off- label treatment of aPAP. ~~Additionally, Partner Therapeutics, Inc. is working with the Pharmaceuticals and Medical Devices Agency and the MHLW in Japan for regulatory approval of Leukine ® for the treatment of aPAP.~~ We cannot assess ~~the likelihood of formal regulatory approval of Leukine ®,~~ the effectiveness of its off- label administration to patients with aPAP ~~,~~ or the number of aPAP patients **in the U. S.** using Leukine **as a** ~~® for the~~ pharmacy- compounded off- label treatment. ~~If Leukine ® were to~~ **Additionally, in April 2024, Partner Therapeutics' partner, Nobelpharma Co. Ltd., ~~receive~~ received** ~~formal~~ regulatory approval **from the PMDA to market sargramostim for the treatment of aPAP** in Japan **. Sargramostim** ~~, we believe it~~ has the potential to present a material competitive threat to the commercial success of ~~molgramostim~~ **MOLBREEVI** in Japan ~~,~~ which could have a material adverse effect on our business. If we fail to attract and retain senior management and key scientific personnel and develop and maintain relationships with service providers, consultants and advisers, we may be unable to successfully develop and commercialize our product candidate. We have historically operated with a limited number of employees that manage third parties for most development activities. Institutional knowledge is concentrated within a small number of employees. Our success depends on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel. Our future success is highly dependent upon the contributions of our senior management, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals, who all have at- will employment arrangements with us, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, or the commercialization of our product candidate. Replacing key employees may be a difficult, costly, and protracted process, and we may not have other personnel with the capacity to assume all the responsibilities of a key employee upon his / her departure. Transition periods can be difficult to manage and may cause disruption to our business. In addition, there may be intense competition from other companies and organizations for qualified personnel. Other companies and organizations with which we compete for personnel may have greater financial and other resources and different risk profiles than us, and a history of successful development and commercialization. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals. The success of our business will depend on our ability to develop and maintain relationships with respected service providers and industry- leading consultants and advisers. If we cannot develop and maintain such relationships as needed, the rate and success at which we can develop and commercialize our product candidate may be limited. In addition, our outsourcing strategy, which has included engaging consultants that spend considerable time to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition. We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidate, if approved, or generate product revenue. To commercialize our ~~molgramostim~~ **MOLBREEVI** product candidate, if approved, in the U. S. and other jurisdictions we seek to enter, we must build our marketing, sales, managerial, and other non- technical capabilities, or make

arrangements with third parties to perform these services, and we may not be successful in doing so. If our product receives regulatory approval, we expect to market such product in the U. S. through a focused, specialized sales force, which will be costly and time consuming. Institutionally, we have no prior experience in the marketing and sale of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Outside of the U. S., we may consider collaboration arrangements. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product in certain markets. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our product. If we are not successful in commercializing our ~~molgramostim~~ **MOLBREEVI** product, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we would incur significant additional losses. To establish a sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization, and we may experience difficulties in managing this growth. As ~~of March 7, 2024, we had 37 employees including 25 employees engaged in research and development. As~~ we advance our ~~molgramostim~~ **MOLBREEVI** product candidate through the development process and to commercialization, we will need to continue to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance, and other resources to manage our operations and clinical trials, continue our development activities, and commercialize our product candidate, if approved. As our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers, and other organizations. Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively maintain or manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the physical expansion of our operations may lead to significant costs and may divert our management attention and resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue, and operating results. Risks Related to Our Business Operations Our operations might be interrupted and financial results could be adversely impacted by the occurrence of a natural disaster, acts of war or terrorism **, tariffs** , IT system malfunction, telecommunication and electrical failures or other catastrophic event, or public health crises, such as a pandemic. Our corporate headquarters is located in a commercial facility in Langhorne, Pennsylvania. Important documents and records, including copies of our regulatory documents and other records for our product candidate, are located both at a secure offsite document storage facility as well as at our own facilities, and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, public health crises, severe weather conditions, social unrest ~~, such as that in Argentina,~~ or acts of war or terrorism ~~, such as the conflicts both in the Middle East and between Russia and Ukraine,~~ could significantly disrupt our operations and result in additional, unplanned expense. Any natural disaster or catastrophic event could disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that are not covered by or exceed the coverage available under these insurance policies. In addition, our operations may be adversely impacted by international conflict, such as the ongoing conflicts in ~~both the Middle East and~~ Ukraine **, and Russia** or social unrest, such as that currently in Argentina. The political and physical conditions in those regions, as well as neighboring countries, may disrupt our supply chain and increase our costs, which may adversely affect our ability to conduct ongoing clinical trials and impact patients' ability to partake in our clinical trials. While we do not believe these conflicts will have a material impact on our current operations, given the rapidly evolving situation, the full impact ~~of the conflict~~ remains uncertain **. Tariffs (including tariffs that have been or may in the future be imposed by the U. S. or other countries), trade protection measures, import or export licensing requirements, trade embargoes, sanctions (including those administered by the Office of Foreign Assets Control of the U. S. Department of the Treasury), other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries could have a negative impact on our operations and supply chain** . Our business and operations would suffer in the event of third- party computer system failures, cyber- attacks on third- party systems, or deficiency in our cybersecurity. We rely on IT systems, including third- party " cloud based " service providers, to keep financial records, maintain laboratory data, clinical data and corporate records, communicate with staff and external parties, and operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories, and archives. If any of these third- party IT providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber- attacks, or cyber- intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised, and we are unable to connect with third- party IT providers. The risk of a security breach or disruption, particularly through cyber- attacks or cyber- intrusion by computer hackers, foreign governments, or cyber- terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third- party IT provider' s operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in loss or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidate could be delayed or could fail. We have experienced and may continue to experience attempts to breach our security and attempts to introduce malicious software into

our IT systems; however, to date and to our knowledge, such attacks have not resulted in any material damage to us. Because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for the Company to be adversely impacted. Moreover, because the techniques used to gain access to or sabotage systems often are not recognized until launched against a target, we may be unable to anticipate the methods necessary to defend against these types of attacks, and we cannot predict the extent, frequency or impact these attacks may have on us. To the extent our business is interrupted, this impact could result in reputational, competitive, operational, or other business harm as well as financial costs and regulatory action, and the theft or unauthorized use or publication of our trade secrets and other confidential business information as a result of such an incident could adversely affect our competitive position. We are continually working to maintain reliable systems to improve our operations. Our efforts include, but are not limited to, the following: firewalls, antivirus protection, patches, log monitors, routine backups with offsite retention of storage media, system audits, data partitioning, and routine password modifications. Our internal IT systems environment continues to evolve, and our business policies and internal security controls may not keep pace as new threats emerge. No assurance can be given that our efforts to continue to enhance our systems will be successful. The Company' s remote working arrangements could significantly increase the Company' s digital and cybersecurity risks. A majority of our employees work remotely from their homes. With the shift to remote working and the use of virtual board and executive management meetings, cybersecurity risks are exponentially greater. Additionally, the Company' s adoption of remote work arrangements may introduce additional threats to our information technology networks and infrastructure. Technology in employees' homes may not be as robust and could cause the networks, information systems, applications, and other tools available to employees to be more limited or less reliable than in our offices. These cyber risks include greater phishing, malware, and other cybersecurity attacks, vulnerability to disruptions of our information technology infrastructure and telecommunication systems for remote operations, increased risk of unauthorized dissemination of confidential information, limited ability to restore the systems in the event of a systems failure or interruption, greater risk of a security breach resulting in destruction or misuse of valuable information, and potential impairment of our ability to perform critical functions, including wiring funds, all of which could expose us to risks of data or financial loss, litigation and liability and could seriously disrupt our operations. If we or our vendors fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity, which could negatively affect our operating results and business. We are subject to a number of state, national, and foreign laws and regulations related to the collection, use, retention, protection, disclosure, transfer, and other processing of personal data, including the EU' s General Data Protection Regulation (" GDPR "). The scope of these laws can be broad, and the statutory penalties can be high. For example, the GDPR imposes stringent requirements for the processing of personal data of individuals within the EU and provides for substantial penalties for non- compliance that can be up to the greater of € 20 million or 4 % of global annual revenues. The legal landscape in this area is rapidly evolving as different jurisdictions adopt new laws governing data privacy, which can differ in scope and applicability, subject to different interpretations, and be inconsistent among jurisdictions. In 2018, California enacted the California Consumer Privacy Act of 2018, which requires covered companies to provide new disclosures to California consumers and affords those consumers new rights related to their personal data, including the right to opt- out of certain sales of personal information and a private right of action for certain breaches. Since then, a number of other states have adopted comprehensive data privacy laws, which are either currently effective or scheduled to become effective. In Canada, both the federal government and certain provinces have also proposed new legislation imposing significant and unprecedented obligations, fines, and liabilities regarding data handling. As the applicable laws change, we may be required to implement additional mechanisms to comply, which may be difficult to implement and may require us to incur additional costs. If we or our vendors fail to comply with applicable data privacy laws, we could be subject to government enforcement actions and significant penalties, and our business could be adversely impacted. A data security breach or change in applicable privacy or security laws or regulations could require us to devote significant management resources to address the problems created by the breach or such change in laws or regulations, and, further, to expend significant additional resources to upgrade the security measures that we employ to guard against such breaches or comply with such change in laws or regulations, each of which could disrupt our business, operations, and financial condition. Because many of these laws are new, there is little clarity as to their interpretation, as well as a lack of precedent for the scope of enforcement. Although we plan to continue to work to prevent breaches and ensure compliance with applicable laws regarding the protection and unauthorized disclosure of personal information, our efforts may be unsuccessful and result in significant costs. We must comply with the U. S. Foreign Corrupt Practices Act and similar foreign anti- corruption laws. We are subject to anti- corruption laws, including the FCPA, the **UK** ~~U. K.~~ Bribery Act 2010, and other anti- corruption laws that apply in countries where we conduct business. Under those laws, it is generally illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We face the risk that an employee or agent could be accused of violating one or more of these laws, particularly in geographies where significant overlap exists between local government and healthcare industries. In many countries, hospitals are operated by the government and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Such an accusation, even if unwarranted, could prove disruptive to our developmental and commercialization efforts. The FCPA also obligates companies whose securities are listed in the U. S. to comply with certain accounting provisions, and the SEC may suspend or bar issuers from trading securities on U. S. exchanges for violations of those provisions. Our operations also subject us to similar laws in other countries. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the **EU** ~~E. U.~~, and the provision of benefits or advantages to physicians is also governed by the national anti- bribery laws.

Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain **EU** ~~E. U.~~ member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual country. These requirements are provided in the national laws, industry codes, or professional codes of conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment. Risks Related to Our Intellectual Property If we are unable to adequately protect our intellectual property rights related to our product candidate, it could have a material adverse effect on our business. We have no issued patents for ~~molgramostim~~ **MOLBREEVI** for the treatment of aPAP and primarily rely on the Orphan Drug exclusivity as our primary barrier to competition. Additionally, we have an exclusive supply agreement for the proprietary delivery device used for ~~molgramostim~~ **MOLBREEVI** and a proprietary cell bank used in the production of the drug substance. Our success will depend on our ability to: • obtain and maintain exclusivity rights with respect to our products and their uses; • prevent third parties from infringing upon our proprietary rights; • maintain proprietary know- how and trade secrets; • operate without infringing upon the patents and proprietary rights of others; and • obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, or if necessary, to secure exclusive rights to them, both in the U. S. and in foreign countries. We intend to rely on regulatory exclusivity for protection of our ~~molgramostim~~ **MOLBREEVI** product candidate, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or maintain the extent or duration of such protections that we expect for our product candidate, if approved, could affect our decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on our revenue or results of operations. For ~~molgramostim~~ **MOLBREEVI** , which is administered via nebulization, we may rely on regulatory exclusivity for the combination of ~~molgramostim~~ **MOLBREEVI** and its delivery system. However, there is no assurance that our ~~molgramostim~~ **MOLBREEVI** product and its delivery system, if approved, will benefit from this type of market protection. We have filed patent applications related to our ~~molgramostim~~ **MOLBREEVI** product candidate; however, there is no guarantee that patents will issue from any pending or future applications or that claims allowed will be sufficient to protect the technology we develop or that is used by us, our CMOs, or our other service providers. The patent prosecution process is expensive and time- consuming; we may not be able to file or prosecute patents on certain aspects of our product candidate at a reasonable cost, in a timely fashion, or at all, and we may fail to identify patentable aspects of inventions made during development activities before it is too late to obtain patent protection. Further, defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, which may cause them to be invalid or unenforceable. Any patents that are issued to us may be limited in scope or challenged, invalidated, infringed, or circumvented, including by our competitors. Even if a patent issues and is held valid and enforceable, rights we have under the patent may not provide a competitive advantage to us. Competitors may be able to design around our patents, such as by using pre- existing or newly developed technology. Additionally, given the amount of time required for the development, testing, and regulatory review of new drug candidates, patents protecting such candidates might expire shortly after such candidates are commercialized. If competitors can develop and commercialize technology and products similar to ours, our ability to successfully commercialize our technology and products may be impaired. We also rely on unpatented know- how and trade secrets and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with employees, consultants, collaborators, and others. We also have invention or patent assignment agreements with our employees and certain consultants. The steps we have taken to protect our proprietary rights, however, may not be adequate to preclude misappropriation of or otherwise protect our proprietary information or prevent infringement of our intellectual property rights, and we may not have adequate remedies for any such misappropriation or infringement. In addition, it is possible that inventions relevant to our business could be developed by a person not bound by an invention assignment agreement with us or independently discovered by a competitor. We may rely on trademarks, trade names, and brand names to distinguish our ~~molgramostim~~ **MOLBREEVI** product, if approved for commercial sale, from the products of our competitors ~~. We intend to seek approval for a new name for molgramostim that meets the FDA' s and foreign regulatory requirements~~ . However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks, in which case we may expend substantial resources to defend our proposed or approved trademarks and may enter into agreements with third parties that may limit our use of our trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. For example, we filed a trademark for the name " Savara " and were challenged. We decided to terminate the application, but we may revisit such filings at a future date. Further, our competitors may infringe on our trademarks, or we may not have adequate resources to enforce our trademarks. We may not be able to enforce our intellectual property rights outside of the U. S. Enforcement of intellectual property rights in certain countries outside the U. S. has been limited or non- existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions, which could permit others to use our discoveries or to develop and commercialize our technology and products without any compensation to us. Third parties may claim that our product, if approved, infringes on their proprietary rights and may challenge the approved use or uses of a product or its patent rights through litigation or administrative proceedings, and defending such actions may be costly and time consuming, divert management attention away from our business, and result in an unfavorable outcome that could have an adverse effect on our business. Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market, and sell our product candidate and use our proprietary technology without infringing

the proprietary rights of third parties. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. Because patent applications can take years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our product candidate or technology infringe, or that the process of manufacturing our product or any of our respective component materials, or the component materials themselves, infringe, or that the use of our product candidate or technology infringe. We or our CMOs or component material suppliers may be exposed to, or threatened with, litigation by a third party alleging that our product candidate and / or technology infringe its patents or other intellectual property rights, or that one or more of the processes for manufacturing our product or any of our respective component materials, or the component materials themselves, or the use of our product candidate or technology, infringe its patents or other intellectual property rights. If a third- party patent or other intellectual property right is found to cover our product candidate, technology, or our uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our product or use our technology or method unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, or at all. In addition, during litigation, the third- party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using, selling, or importing our product, technology, or method. There generally is a substantial amount of litigation involving patent and other intellectual property rights in the industries in which we operate, and the cost of such litigation may be considerable. We can provide no assurance that our product candidate or technology will not infringe patents or rights owned by others, licenses to which might not be available to us in a timely manner or on acceptable terms, or at all. If a third- party claims that we or our CMOs or component material suppliers infringe its intellectual property rights, we may face a number of issues, including, but not limited to: • infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert management' s time and attention from our business; • substantial damages for infringement, including the potential for treble damages and attorneys' fees, which we may have to pay if it is determined that the product and / or its use at issue infringes or violates the third party' s rights; • a court prohibiting us from selling or licensing the product unless the third party licenses its intellectual property rights to us, which it may not be required to do; • if a license is available from the third party, we may have to pay substantial royalties, fees and / or grant cross- licenses to the third party; and • redesigning our product or process so they do not infringe, which may not be possible or may require substantial expense and time. There may be issued or filed claims covering our product, product candidate, or technology or those of our CMOs or component material suppliers or the use of our product, product candidate, or technology. Additionally, such patents may be issued or filed in the future. Because of the large number of patents issued and patent applications filed in the industries in which we operate, there is a risk that third parties may allege they have patent rights encompassing our product, product candidate, or technology, or those of our CMOs or component material suppliers, or uses of our product, product candidate, or technology. In the future, it may be necessary for us to enforce our proprietary rights, or to determine the scope, validity, and unenforceability of other parties' proprietary rights, through litigation or other dispute proceedings, which may be costly, and to the extent we are unsuccessful, adversely affect our rights. In these proceedings, a court or administrative body could determine that our claims, including those related to enforcing patent rights, are not valid or that an alleged infringer has not infringed our rights. The uncertainty resulting from the mere institution and continuation of any patent or other proprietary rights- related litigation or interference proceeding could have a material and adverse effect on our business prospects, operating results, and financial condition. Risks Related to Our Industry We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our product, could hinder or prevent our product' s commercial success, if our product candidate is approved. The unavailability or inadequacy of third- party payer coverage and reimbursement could negatively affect the market acceptance of our product candidate and the future revenues we may expect to receive. The commercial success of our product candidate, if approved, will depend on the extent to which the costs of such product will be covered by third- party payers, such as government health programs, commercial insurance, and other organizations. Third- party payers are increasingly challenging the prices and examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy. These challenges to prices may be problematic to us since our products are targeted for a small number of patients (those suffering from an orphan disease), thus requiring us to charge very high prices to recover development costs and achieve a profit on our revenue. If these third- party payers do not consider our product to be cost- effective compared to other therapies, we may not obtain coverage for our product after approval as a benefit under the third- party payers' plans or, even if we do, the level of coverage or payment may not be sufficient to allow us to sell our product on a profitable basis. Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage, and payment. There is no uniform policy requirement for coverage and reimbursement for drug products among third- party payers in the U. S., therefore coverage and reimbursement for drug products can differ significantly from payer to payer. The coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product to each payer separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payer will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our product may be adversely affected if the amount of payment for our product proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our product less desirable to use. Third- party payer reimbursement to providers of our product, if approved, may be subject to a bundled payment that also includes the procedure of administering our product or third- party payers may require providers to perform additional patient testing to justify the use of our product. To the extent there is no separate payment for our product, there may be further uncertainty as to the adequacy of reimbursement amounts. The continuing efforts of governments, private insurance companies, and other organizations to contain or reduce costs

of healthcare may adversely affect: • our ability to set an appropriate price for our product; • the rate and scope of adoption of our products by healthcare providers; • our ability to generate revenue or achieve or maintain profitability; • the future revenue and profitability of our potential customers, suppliers, and collaborators; and • our access to additional capital. Our ability to successfully commercialize our product will depend on the extent to which governmental authorities, private health insurers, and other organizations establish what we believe are appropriate coverage and reimbursement for our product. The containment of healthcare costs has become a priority of federal and state governments worldwide and the prices of drug products have been a focus in this effort. For example, there have been several recent U. S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs, and ~~former~~ **then** President Trump signed four executive orders on July 24, 2020 aimed at bringing down pharmaceutical prices. We expect that federal, state, and local governments in the U. S., as well as in other countries, will continue to consider legislation directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidate or what actions federal, state, or private payers for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Furthermore, we expect that healthcare reform measures that may be adopted in the future are unpredictable, and the potential impact on our operations and financial position is uncertain, but may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price we may receive for approved products. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products, if approved. We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain whether such increased or additional insurance coverage can be obtained on commercially reasonable terms, if at all. Our business (in particular, the use of our product candidate in clinical trials and the sale of any products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies, or others selling or involved in the use of our products. If we cannot successfully defend ourselves against any such claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for our products and loss of revenue; • impairment of our business reputation; • delays in enrolling patients to participate in our clinical trials; • withdrawal of clinical trial participants; • a " clinical hold, " suspension or termination of a clinical trial or amendments to a trial design; • significant costs of related litigation; • substantial monetary awards to patients or other claimants; and • the inability to commercialize our product candidate. We maintain limited product liability insurance for our clinical studies, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. We expect that we will expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidate, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could consume a significant portion of our cash and adversely affect our business. Risks Related to our Common Stock Our stock price is expected to continue to be volatile. The market price of our common stock ~~has experienced substantial volatility since we announced the top- line results of our IMPALA Phase 2 / 3 trial of molgramostim for aPAP on June 12, 2019,~~ and our stock price will continue to be subject to significant volatility and fluctuations. Market prices for securities of early- stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: • failed or inconclusive data results from our clinical trials; • our ability to obtain regulatory approvals for our product candidate, and delays or failures to obtain such approvals; • failure to meet or exceed any financial and development projections that we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • failure of our product candidate, if approved, to achieve commercial success; • failure to maintain our existing third- party license and supply agreements; • failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights; • changes in laws or regulations applicable to our product candidate; • any inability to obtain adequate supply of our product candidate or the inability to do so at acceptable prices; • adverse regulatory authority decisions; • introduction of new products, services, or technologies by our competitors; • if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock; • failure to obtain sufficient capital to fund our business objectives; • sales of our common stock by us or our stockholders in the future; • trading volume of our common stock; • the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community; • announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • additions or departures of key personnel; • significant lawsuits, including patent or stockholder litigation; • changes in the market valuations of similar companies; • general market or macroeconomic conditions; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments; • adverse publicity relating

to the aPAP market generally, including with respect to other products and potential products in such market; • the introduction of technological innovations or new therapies that compete with or influence the demand for our product; • changes in the structure of health care payment systems; and • period- to- period fluctuations in our financial results. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. Additionally, financial markets and the global economy may be adversely affected by the current or anticipated impact of the ongoing military conflicts in the Middle East and Ukraine or other related geopolitical events. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company' s securities, such as the decline in our stock price, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. If we fail to satisfy all applicable Nasdaq continued listing requirements, including the $ 1. 00 minimum closing bid price requirement, our common stock may be delisted from Nasdaq, which could have an adverse impact on the liquidity and market price of our common stock. Our common stock is currently listed on the Nasdaq Global Select Market, which has qualitative and quantitative continued listing requirements, including corporate governance requirements, public float requirements, and a $ 1. 00 minimum closing bid price requirement. If we are unable to satisfy any of the continued listing requirements, Nasdaq may take steps to delist our common stock. Such a delisting would likely have an adverse effect on the market liquidity of our common stock, decrease the market price of our common stock, result in the potential loss of confidence by investors, suppliers, customers, and employees, fewer business development opportunities, and adversely affect our ability to obtain financing for the continuation of our operations. We do not expect to pay any cash dividends in the foreseeable future. We expect to retain any future earnings to fund the development and growth of our business and do not expect to pay any cash dividends. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain, if any, for the foreseeable future. We may be unable to use certain of our net operating losses and other tax assets. We have substantial tax loss carry forwards for U. S. federal income tax and state income tax purposes. In general, our net operating losses and tax credits have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. In particular, our ability to fully use certain U. S. tax loss carry forwards and general business tax credit carry forwards generated up to and including December 2023 to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock offerings or upon exercise of outstanding options, may limit or eliminate our ability to use certain net operating losses and tax credit carry forwards in the future.