Risk Factors Comparison 2024-03-27 to 2023-02-28 Form: 10-K

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In addition to the other information included in this Annual Report, the following risk factors should be carefully considered when evaluating an investment in us. These risk factors and other uncertainties may cause our actual future results or performance to differ materially from any future results or performance expressed or implied in the forward- looking statements contained in this report and in other public statements we make. In addition, because of these risks and uncertainties, as well as other variables affecting our operating results, our past financial performance is not necessarily indicative of future performance. See " Forward- Looking statements " in Item 1 of this Annual Report. Risks Related to Our Business, Financing Requirements, Product Development and Clinical Trials We have incurred significant losses since our founding and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability. We are a clinical- stage biotechnology company and have not yet generated revenues from product sales. To date, substantially all of our revenues have been derived from **past** grants and contracts with governmental agencies ~~, consisting primarily of our BARDA contract for our anthrax vaccine product candidate~~ . We have incurred net losses in most periods since our inception, including a net loss of $ **88. 4 million and $** 84. 7 ~~million and $ 97. 1~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As of December 31, ~~2022~~ **2023** , we have an accumulated deficit of $ ~~377~~ **466** . ~~9~~ **3** million. To date, we have not received regulatory approvals for any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable. We have devoted most of our financial resources to research and development, including preclinical and clinical development of our product candidates. We have not completed pivotal clinical trials for any product candidate. Our leading product candidates remain in early **-** stage clinical development, and it may be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, reimbursement from third- party payers and other factors. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. Our profitability depends on our ability to develop and commercialize our current and future product candidates. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, forming strategic partnerships and alliances with third parties and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability. If some or all of our product candidates do not prove to be safe, pure and efficacious, then we may have to abandon those product candidates altogether and we will be unable to generate revenues from sales of such products. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we: ● continue our clinical trials for our product candidates; ● initiate additional preclinical studies, clinical trials or other studies or trials for our other product candidates; ● manufacture material for clinical trials and, if any product candidate is approved for marketing, for commercial sale; ● seek regulatory approvals for our product candidates that successfully complete clinical trials; ● establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; ● seek to discover and develop additional product candidates; ● acquire or in- license other product candidates and technologies; ● make royalty, milestone or other payments under any in- license agreements; ● form strategic partnerships and / or make additional acquisitions; ● maintain, protect and expand our intellectual property portfolio; ● attract and retain skilled personnel; and ● create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, ~~or~~ if there are any delays in completing our clinical trials or the development of any of our product candidates, **or if we choose to perform additional studies for marketing purposes** our expenses could increase. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. Future conditions might require us to make substantial write- downs in our assets, which would adversely affect our balance sheet and results of operations. We review our long- lived tangible and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. We also test our indefinite- lived intangible assets for impairment at least annually in the fourth quarter, or when events or changes in the business environment indicate that the carrying value of the reporting unit may exceed its fair value. **The preliminary data from the HepTcell Phase 2 trial indicates that the results are not sufficient to warrant moving forward with this product candidate.** As **a result** ~~of December 31, 2021~~ , we recorded non- cash impairment charges of $ ~~11~~ **12** . 4 million for

~~construction~~ **an acquired In** ~~in- progress~~ **Process Research and Development** ~~assets~~ **asset** ~~that were previously capitalized~~ in connection with the discontinuation of ~~AdCOVID~~ **our product candidate HepTcell** . **This and other** ~~At December 31, 2022, we continued to carry $ 12. 4 million of indefinite lived intangible assets. Any such~~ significant write- downs of our long- lived assets in the future could adversely affect our balance sheet and results of operations. We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts. We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in an amount sufficient to fully fund our operations for the foreseeable future, if ever. Therefore, we will use our existing cash resources, and will require additional funds to maintain our operations, continue our research and development programs, commence future preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our products. As of December 31, ~~2022~~ **2023** , our cash, cash equivalents, restricted cash and short- term investments were $ ~~184~~ **197** . 9 million. Based on our current operating plan, we believe that our existing cash will be sufficient to fund our projected operating expenses and capital expenditure requirements for at least a twelve- month period from the issuance date of our December 31, ~~2022~~ **2023** financial statements. However, we do not expect that these funds will be sufficient to enable us to complete the clinical trials needed to seek marketing approval or commercialize any of our product candidates. ~~42Furthermore~~ **44Furthermore** , our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. We believe that we will continue to expend substantial resources for the foreseeable future developing our product candidates. These expenditures will include costs associated with research and development, maintaining our intellectual property estate, potentially acquiring new technologies, obtaining regulatory approvals and manufacturing products, forming partnerships and strategic alliances, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Our future capital requirements depend on many factors, including: ● the progress, results and costs of our clinical trials for our leading product candidates; ● the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates; ● the amount of funding that we receive from other non- dilutive funding sources; ● the number and development requirements of other product candidates that we pursue; ● the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful and the outcome of regulatory review of our product candidates; ● our ability to contract with third- party manufacturing facilities for adequate supply and to establish processes that meet regulatory requirements for commercialization; ● the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs; ● the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; ● our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements; and ● the costs involved in preparing, filing and prosecuting patent applications, and maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation. We may also seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. Our ability to raise capital may be limited by applicable laws and regulations. Using a shelf registration statement on Form S- 3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S- 1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, SEC rules and regulations. Under SEC rules and regulations, if our public float (the market value of our common stock held by non- affiliates) is less than $ 75. 0 million, then the aggregate market value of securities sold by us or on our behalf under our Form S- 3 in any 12- month period is limited to an aggregate of one- third of our public float. While our public float is currently more than $ 75. 0 million, we have been subject to this limitation in the past and we may be subject to it again in the future. If our ~~43ability~~ **45ability** to utilize a Form S- 3 registration statement for a primary offering of our securities is limited to one- third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S- 1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S- 3 registration statement ~~. In addition, under current SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to utilize a Form S- 3 registration statement (i) for a primary offering, if our public float is not at least $ 75. 0 million as of a date within 60 days prior to the date of filing the Form S- 3 or a re- evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i. e., a resale offering). While currently our common stock is listed on the NASDAQ Global Market, there can be no assurance that we will be able to maintain such listing~~ . Our ability to timely raise sufficient additional capital also may be limited by NASDAQ' s stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, NASDAQ requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20 % or more of our then outstanding common stock, unless the transaction is considered a " public offering " by NASDAQ. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering without stockholder approval. NASDAQ also requires that we obtain stockholder approval if the issuance

or potential issuance of additional shares will be considered by NASDAQ to result in a change of control of our company. Obtaining stockholder approval is a costly and time- consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital or alter the terms of the transaction, which may materially and adversely affect our ability to execute our business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction. Raising additional capital may cause dilution to stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates on unfavorable terms. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, and license and development agreements through strategic partnerships with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt or preferred stock financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, issuing additional equity, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates, or otherwise grant licenses on terms that are not favorable. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our leading product candidates or our preclinical product candidates, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue. Our preclinical and clinical results are not necessarily predictive of the final results of our ongoing or future clinical trials. ~~We have initiated a Phase 2 clinical trial of HepTcell and are currently in Phase 2 and Phase 1 clinical development with pemvidutide for multiple indications.~~ Success in preclinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials of a product candidate may not be replicated in later and larger clinical trials. ~~44Clinical~~ **Clinical** trials are expensive, time consuming and uncertain as to outcome, and we cannot guarantee that any of these activities will be successful. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet our clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates, or we may determine to suspend development of or abandon specific product candidates. For example, we suspended the development of a Densigen platform- based product candidate, Flunisyn, which was being developed as a T- cell vaccine for the treatment of influenza, in favor of NasoVAX. Clinical trials with this product candidate showed that it was generally well- tolerated and able to induce robust T- cell responses ~~against~~ **46against** the viral sequences represented, but a comparison of the entire study population in later- stage clinical trials showed no statistical differences between the vaccinated and placebo groups for several measures of protection. In addition, we can offer no assurances that we have correctly estimated the resources or personnel necessary to seek partners, co- developers or acquirers for our programs. If a larger workforce or one with a different skillset is ultimately required to maintain these operations, we may be unable to maximize our existing programs. Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to additional audit, validation and verification procedures that could result in material changes in the final data. From time to time, we ~~may~~ publish interim data, including interim top- line results or preliminary results from our clinical trials. Any interim data and other results from our clinical trials may materially change as more patient data become available. Preliminary or top- line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results, once we have received and fully evaluated additional data. Differences between preliminary or interim data and final data could adversely affect our business. The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to acquisition of materials, process development or scaling- up of our manufacturing capabilities. The manufacture of our product candidates is complex, highly ~~-~~regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with our clinical development plans and add additional costs. It is possible that we will make changes to our manufacturing process at various points during product development or commercialization for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes can be costly and carry the risk that they will not achieve their intended objectives, or these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of a commercialized product. In some circumstances, changes in the manufacturing process may require us to perform analytical or clinical comparability studies and to collect additional data prior to undertaking more advanced clinical trials, and such studies may introduce additional costs or delays to the program. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and / or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate. Compliance with cGMP requirements and other quality or regulatory issues may arise with our current or any future contract manufacturing organizations (“ CMOs ”).

Furthermore, ongoing stability studies subsequent to manufacture must be periodically conducted to demonstrate that each of our product candidates do not undergo unacceptable deterioration over its shelf life. If issues affecting the quality of our product candidates ~~,~~ or those of our CMOs are discovered, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the issue. To the extent any adversely affected material is being used in an ongoing clinical trial, the FDA could impose a clinical hold on our trial to investigate and remedy the quality issue. We cannot assure that any manufactured product or ~~45product~~ -- **product** candidate will not suffer a loss in stability or that other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our CMOs may experience manufacturing difficulties due to resource constraints, **including manufacturing capacity,** material constraints, or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized. ~~We~~ **47We** may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include: ● delays or failure in reaching a consensus with regulatory agencies on trial design; ● delays or failure in reaching agreement on acceptable terms with prospective contract research organizations (" CROs ") and clinical trial sites; ● delays or failure in obtaining required approvals from the IRB or other similar committees or bodies at each clinical trial site; ● imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability or after an inspection of clinical operations or trial sites; ● failure to perform clinical trials in accordance with the FDA' s GCP or applicable regulatory guidelines in other **relevant** countries ~~, including the United Kingdom, Canada, Germany, Italy, Spain, Thailand and Australia~~ ; ● delays or failure in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites, including as a result of supply chain delays in obtaining materials for the manufacture of our clinical trial materials; ● ~~delays in testing, analysis and other activities by our third- party contractors required in conducting and analyzing our clinical trials as a result of the ongoing COVID- 19 pandemic; ● any shelter- in- place orders from local, state or federal governments or clinical trial site policies resulting from the ongoing COVID- 19 pandemic that determine essential and non- essential functions and staff, which may impact the ability of site staff to conduct assessments, or result in delays to the conduct of the assessments, as part of our clinical trial protocols, or the ability to enter assessment results into clinical trial databases in a timely manner; ●~~ the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may ~~, including as a result of the ongoing COVID- 19 pandemic,~~ withdraw from our clinical trials, fail to complete dosing or fail to return for post- treatment follow- up at higher rates than we anticipate, any of which could result in significant delay; ● withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate; ● occurrence of serious adverse events in clinical trials that are associated with the product candidate that are viewed to outweigh its potential benefits; ~~46~~ ● our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators or funders may require us, to conduct additional preclinical testing or clinical trials or to abandon projects that we expected to be promising; ● our third- party contractors (such as CROs, product manufacturers, or investigators) may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner; ● fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review or one or more of our marketing applications by regulatory agencies; ● the cost of our clinical trials may be greater than we anticipate; ● additional trials may be necessary, including trials to analyze different dose strengths or dosing schemes; **48** ● the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge by jurisdiction; ● evolution in the standard of care that require amendments to ongoing clinical trials and / or the conduct of additional preclinical studies or clinical trials; or ● changes in regulatory requirements and guidance that require amending or submitting new clinical protocols. We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial. For example, we have had delays in previous clinical trials, including those conducted for NasoVAX, as a result of clinical holds imposed by the FDA or other regulatory authorities and requests for additional or new information on vaccine product testing in connection with an IND submitted to the FDA. We have previously experienced multiple failures during the manufacturing of clinical materials for use in a NasoVAX Phase 2 clinical trial. We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by manufacturing failures or other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates. Even if our clinical trials are successfully completed as planned, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre- clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would

significantly adversely affect our business prospects. We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates. Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit subjects to participate in testing our product candidates. If subjects are unwilling to participate in our trials **due to** ~~because of the ongoing COVID- 19 pandemic and~~ restrictions on travel or healthcare institution policies, negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of potential ~~47products~~ **products** may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of subjects, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Subject enrollment is affected by several factors, including: ● severity of the disease under investigation; ● design of the trial protocol; ● size of the patient population; ● eligibility criteria for the trial in question; **49** ● perceived risks and benefits of the product candidate being tested; ● willingness or availability of subjects to participate in our clinical trials ~~(including due to the COVID- 19 pandemic)~~; ● proximity and availability of clinical trial sites for prospective subjects; ● our ability to recruit clinical trial investigators with appropriate competencies and experience; ● availability of competing vaccines and / or therapies and related clinical trials; ● efforts to facilitate timely enrollment in clinical trials; ● our ability to obtain and maintain subject consents; ● patient referral practices of physicians; and ● ability to monitor subjects adequately during and after treatment. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible subjects to participate in the clinical trials required by regulatory agencies. Even if we enroll a sufficient number of eligible subjects to initiate our clinical trials, we may be unable to maintain participation of these subjects throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those subjects. For example, we may face difficulties in identifying patient populations with active disease to enroll in ~~our Phase 2~~ clinical ~~trial~~ **trials** of HepTcell in patients with chronic HBV. Other clinical trials involving patients with active HBV have sometimes faced difficulties in working with these patient populations, which may include significant numbers of individuals with difficulties with treatment compliance, such as active drug users. While we are developing strategies to address this issue, there is no guarantee that these strategies will prove successful. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of subjects to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business. It may be difficult to predict the time and cost of product development ~~.~~ **for our product candidates, and** ~~Unforeseen~~ **unforeseen** problems may prevent further development or approval of our product candidates. Because our product candidates involve novel therapeutic approaches, it may be difficult to predict the time and cost of product development. For example, the Densigen platform involves synthetic peptide T- cell vaccines and the EuPort platform involves a novel peptide-based dual GLP- 1 / glucagon receptor agonist. Unforeseen problems with our ~~48approaches~~ **approaches** to vaccines and therapies may prevent further development or approval of our product candidates. Because of the novelty of our approaches, there may be unknown safety risks associated with the vaccines and therapies that we develop or the clinical endpoints that we establish in trials may not be generally accepted by regulatory agencies, which may therefore require us to perform large field studies to demonstrate efficacy. There can be no assurance that any development problems we may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. In addition, novel vaccine adjuvants, which are included in HepTcell, our product candidate based on the Densigen technology, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Any vaccine, because of the presence of an adjuvant, may have side effects considered to pose too great a risk to patients to warrant approval of the vaccine. Traditionally, regulatory authorities have required extensive study of novel adjuvants because vaccines typically get administered to healthy populations, in particular infants, children and the elderly, rather than in people with disease. As a result, although it is anticipated that HepTcell is intended ~~for~~ **50for** the treatment of patients suffering from a disease, regulatory agencies such as the FDA may nevertheless require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe adverse events caused by our product candidates that include novel vaccine adjuvants. If approved, the novel mechanism of action of the vaccines may adversely affect physician and patient perception and acceptance of our products. Public perception of vaccine safety issues, including adoption of novel vaccine mechanisms of action, may adversely influence willingness of subjects to participate in clinical trials, or if approved, to prescribe and receive novel vaccines. For example, GSK pulled from the market an approved vaccine to prevent Lyme disease (Lymerix) in February 2002 after anecdotal evidence of joint pain resulted in subjects' unwillingness to receive the vaccine. The FDA found no evidence that the vaccine caused a safety risk; however, GSK pulled the vaccine due to low sales resulting from the negative public perception associated with the reports on joint pain. We rely, and expect to continue to rely, on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates. We rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to assist in managing, monitoring and otherwise carrying out our clinical trials. We compete with many other companies for the resources of these third parties. The third parties on whom we rely generally may terminate their engagements at any time and causing us to enter into alternative arrangements would delay development and commercialization of our product candidates. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our

responsibilities. For example, the FDA and foreign regulatory authorities require compliance with applicable law, regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials complies with GCP requirements. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with applicable law, regulations and standards, including our general investigational plan and protocol. Furthermore, if these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, then the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, then preclinical development activities or clinical trials may be extended, ~~49delayed~~ -- **delayed**, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all. Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our preclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they cannot perform their contractual duties or obligations due to the impacts of **public health crises** ~~the ongoing COVID- 19 pandemic~~ on their operations or at the sites they are overseeing, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, receive regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. ~~If~~ **51If** any of our relationships with these third parties terminates, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. Switching or adding additional third- party service providers involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third- party service provider begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. We face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing or commercializing products before, or more successfully, than we do. The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we intend to commercialize, if successfully commercialized, will compete with existing market-leading products. Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Large and established companies such as Eli Lilly, Roche, Novo Nordisk ~~and ,~~ Pfizer **, AstraZeneca, Amgen, Boehringer Ingelheim and Merck**, among others, compete in the same market as our product candidates. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co- development and licensing opportunities from large and established pharmaceutical companies. We face competition for pemvidutide, our dual GLP **-** 1 / glucagon dual agonist for the treatment of obesity and ~~NASH~~ **MASH**. For obesity, we face competition from companies such as Novo Nordisk, whose GLP- 1 agonist, brand named Wegovy, or compound name semaglutide, was approved **for weight loss** in June 2021. Other companies with potentially competitive **products or product** candidates ~~in development~~, include Eli Lilly with GLP- 1 / glucose- dependent insulinotropic polypeptide receptor (" GIP ") dual agonists, including ~~Mounjaro~~ **Zepbound**, or compound name tirzepatide, ~~currently~~ approved for ~~type 2 diabetes~~ **obesity in November 2023**; Boehringer Ingelheim ~~, Merck / Hanmi Pharmaceutical~~, AstraZeneca, Innovent Biologics / Eli Lilly, **and Roche through its acquisition of** Carmot and D & D Pharma, with ~~50GLP~~ -- **GLP** - 1 / glucagon receptor dual agonists; Hanmi Pharmaceutical and Eli Lilly with GLP- 1 / glucagon / GIP triple agonists; Amgen with its GLP- 1 agonist / GIP antagonist antibody; and Novo Nordisk with Amylin and Amylin- GLP- 1 combination candidates. **Other companies have been developing oral candidates for the treatment of obesity with GLP- 1 monoagonist or GLP- 1 / GIP dual receptor agonists including Pfizer, Lilly, Structure Therapeutics, AstraZeneca through its acquisition of Eccogene and Roche through its acquisition of Carmot. In addition, Novo Nordisk has an FDA- approved oral GLP- 1 therapy, Rybelsus or compound name semaglutide.** We face competition in ~~NASH~~ **MASH** from companies such as ~~Intercept Pharmaceuticals, which is developing a farnesoid X receptor (" FXR ") agonist;~~ Madrigal Pharmaceuticals,

Terns, Aligos and Viking Therapeutics, which are developing orally administered, thyroid hormone receptor (“ THR ”) β- selective agonist; Akero Therapeutics, 89Bio, Novo Nordisk ~~,~~ **and** Boston Pharmaceuticals ~~and Roche~~ , which are developing fibroblast growth factor 21 **(“ FGF- 21 ”)** analogs; Novo Nordisk, which is developing a GLP- 1 agonist; ~~and~~ **Merck / Hanmi Pharmaceutical, which is developing a GLP- 1 / glucagon dual agonist, Eli Lilly, which is developing a GLP- 1 / GIP dual agonist** , Inventiva, which is developing a pan- peroxisome proliferator- activated receptor (“ PPAR ”) agonist ~~and orally based~~ **; Sagimet which is developing a fatty acid synthetase inhibitor, HEC Pharma which is developing a** GLP- 1 ~~agents that either deliver~~ **/ FGF- 21dual agonist; and Pfizer and Eli Lilly, which are developing small molecule** GLP- 1 **agonists** ~~monoagonist activity either as a peptide (Novo Nordisk) or small molecule (Pfizer, Eli Lilly)~~ . In addition, many other small companies are developing other new technologies directed towards obesity or ~~NASH~~ **MASH** ~~. Finally, we face competition for HepTcell, our immunotherapeutic HBV product candidate, from companies such as GSK, Janssen, Vaccitech VBI Vaccines, all of which are developing a therapeutic vaccine against chronic HBV infection. In addition, many other companies are developing direct acting antivirals against HBV~~ . As a result of all of these factors, our competitors may succeed in obtaining patent protection and / or FDA approval or discovering, developing and commercializing products before we do. In addition, any new product that we develop that ~~competes~~ **52competes** with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow, and our financial condition and operations will suffer. We are heavily dependent on the success of our leading product candidate, pemvidutide. If we ultimately are unable to develop, obtain regulatory approval for or commercialize pemvidutide, or any other product candidate, our business will be substantially harmed. We currently have no products approved for commercial distribution. Our business strategy is to build a pipeline of product candidates using our proprietary platforms, including our leading product candidate, pemvidutide, and to progress the product candidate through clinical development for the treatment of different types of diseases. We may not be able to develop products that are safe and effective for all or any of the indications that we target. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidates, which introduces risks to our business model and potential limitations to any success we may achieve. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our leading product candidate, pemvidutide, would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates. **If we fail to establish and maintain strategic partnerships related to pemvidutide, we will bear all of the risk and costs related to its development which could negatively affect the development of pemvidutide and materially affect our business and financial condition.** Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payers and others in the medical community necessary for commercial success. If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payers, and others in the medical community. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including: ● efficacy and potential advantages compared to alternative treatments; ~~51~~ ● the ability to offer our products, if approved, for sale at competitive prices; ● convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the ~~strength of marketing and distribution support; ● the~~ ability to obtain sufficient third- party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy; ● the cost of treatment in relation to alternative treatments, including generic products; **53** ● the extent and strength of our third- party manufacturer and supplier support; ● the extent and strength of marketing and distribution support; ● ~~the~~ **any** limitations or warnings contained in a product’ s approved labeling; ● **any** distribution and use restrictions imposed by the FDA or other regulatory authorities outside the United States or that are part of a REMS or voluntary risk management plan; and ● the prevalence and severity of any side effects, including the tolerability and effect on comorbidities relative to alternative treatments. For example, even if our products have been approved by the FDA, physicians and patients may not immediately be receptive to them and may be slow to adopt them. If our products do not achieve an adequate level of acceptance among physicians, patients and third- party payers, we may not generate meaningful revenues and we may not become profitable. We may not be able to comply with the requirements of foreign jurisdictions in conducting trials within the United Kingdom, European Union **(“ EU ”)** or any other foreign country. We ~~are conducting our Phase 2~~ **have in the past conducted** clinical ~~trial~~ **trials** ~~of HepTcell~~ in the U. S. ~~, United Kingdom, Canada, Germany Italy, Spain~~ and ~~Thailand~~ **other countries** ; and future clinical trials may be conducted in other foreign jurisdictions. Our ability to successfully initiate, enroll and complete a clinical trial in any other foreign country is subject to numerous risks unique to conducting business in foreign countries, including: ● difficulty in establishing or managing relationships with CROs and physicians; ● different standards for the approval and conduct of clinical trials; ● our inability to locate qualified local consultants, physicians and partners; **and** ● the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements,

including the regulation of the conduct of clinical trials, pharmaceutical and biotechnology products and treatment ~~; and ● the acceptability of data obtained from studies conducted outside the United States to the FDA in support of U. S. marketing authorizations, such as an NDA or BLA~~. If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval for our product candidates in the United States or in countries outside of the United States. ~~52If~~ **If** we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates. We are highly dependent on members of our senior management, including Dr. Vipin Garg, our President and Chief Executive Officer, Richard Eisenstadt, our Chief Financial Officer, Dr. Scott Harris, our Chief Medical Officer, Dr. M. Scot Roberts, our Chief Scientific Officer and Raymond Jordt, our Chief Business Officer. Although we have entered into employment agreements with each of these members of senior management and key employees, the loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, commercialization and business development objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities ~~and~~ **54and** research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than the Company and may have commitments under consulting or advisory contracts with other entities that may limit their availability to the Company. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. A pandemic, epidemic or outbreak of an infectious disease in the United States such as the COVID- 19 pandemic may adversely affect our business. Our global operations expose us to risks associated with public health crises and epidemics / pandemics, such as COVID- 19. **Such risks include** ~~The global spread of COVID- 19 has created~~ significant volatility, uncertainty and worldwide economic disruption ~~, resulting~~ **which resulted** in an economic slowdown of potentially extended duration ~~and may~~ **. Similar events in the future could** impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. For example, ~~the ongoing~~ **future outbreaks of infectious disease, such as** COVID ~~-~~19 **,** ~~pandemic (including the Delta and Omicron variants~~ and any future variants **or subvariants** that may emerge ~~),~~ **,** may delay preclinical testing and enrollment in our clinical trials due to prioritization of laboratory and hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. ~~In addition, since the beginning of the COVID- 19 pandemic, several vaccines for COVID- 19 have received Emergency Use Authorization by the FDA and a number of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates.~~ The spread of an infectious disease, including COVID ~~-~~19, its subvariants and other SARS- CoV- 2 viruses, may **affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates or** also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Third parties and CROs on which we rely may also reduce staffing which could impact our ability to continue preclinical testing and clinical trials on expected timeframes. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations. ~~53In~~ **In** response to COVID ~~-~~19 ~~-~~related government and public health directives and orders, we ~~have~~ implemented **and continue to maintain** work- from- home and hybrid policies for certain employees. The effects of these ~~orders and our work- from- home and hybrid~~ policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines ~~, the magnitude of which will depend, in part, on the length~~ and ~~severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations~~ could negatively impact our business, operating results and financial condition. In addition, the trading prices for our common stock and other biopharmaceutical companies ~~have been~~ **may be** highly volatile as a result of **a** ~~the COVID- 19~~ pandemic **, epidemic or the spread of infectious disease** . As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. ~~The extent to which the COVID- 19 pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus, the geographic spread of the disease, the duration of the outbreak, new strains of the virus, and any future variants that may emerge, and the actions to contain the coronavirus or treat its impact, including vaccination campaigns, travel restrictions and other social distancing restrictions in the United States and other countries, among others.~~ A significant outbreak of ~~coronavirus and other~~ infectious ~~diseases~~ **disease** could result in a widespread health crisis

that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations. Labor shortages and constraints in the supply chain could adversely affect our results of operations ~~. In 2022, many companies experienced labor shortages and other labor- related issues, which were pronounced as a result of the ongoing COVID- 19 pandemic~~ . A number of factors may adversely affect the labor force available to us or increase labor costs, including high employment levels, federal unemployment subsidies, increased wages offered by other employers, vaccine mandates and other government regulations and our responses thereto. As more employers offer remote work, we may have more difficulty recruiting for jobs that require on- site attendance. ~~We have recently observed an overall tightening and increasingly competitive labor market.~~ If we are unable to hire and retain employees capable of performing at a high- level, our business could be adversely affected. A sustained labor shortage, lack of skilled labor, or increased turnover within our employee base, caused by ~~COVID- 19~~ **a pandemic, epidemic or the spread of infectious disease** or as a result of general macroeconomic factors, could have a material adverse impact on our business and operating results. In addition, recent developments in the national and worldwide supply chain slowdown, including as a result of **the conflict in Israel and the Gaza Strip, and** the conflict in Ukraine, have resulted in increased cost and reduced supply for supplies and materials. It is impossible to predict how long this supply chain slowdown will last or how much it will impact our business operations, but it is likely that our costs will increase for supplies. **55Our overall performance depends in part on worldwide economic conditions and uncertainties. Global inflation rates have increased to levels not seen in several decades, which may result in increases in our operating costs, including our labor costs, constrained credit and liquidity, reduced government spending and volatility in financial markets which may adversely affect the Company' s business and financial condition. Additionally, the upcoming 2024 U. S. Presidential election could cause additional** ~~Legal~~ **legal** , political and economic uncertainty ~~surrounding~~ **. The Federal Reserve and** ~~the~~ **other international government agencies have raised** ~~exit of the United Kingdom (" U. K. ")~~ , **and may again raise, interest rates in response to concerns over inflation risk. Increases in interest rates on credit and debt that would increase the cost of any borrowing that we may make** from **time to time and could impact our** ~~the European Union (" EU ") may be a source of instability~~ ---- **ability** ~~in international~~ **to access the capital** markets ~~, create significant currency fluctuations, adversely affect our operations in the U. K. and pose additional risks to our business, revenue, financial condition and results of operations. On June 23, 2016, the U. K. held a referendum in which a majority of the eligible members of the electorate voted to leave the EU. The U. K.' s withdrawal from the EU is commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on European Union, the U. K. ceased being a Member State of the EU on January 31, 2020. The U. K.' s withdrawal from the EU has created significant uncertainty concerning the future relationship between the U. K. and the EU. On December 24, 2020, the EU and U. K. reached an agreement in principle on the framework for their future relationship, the EU- UK Trade and Cooperation Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the U. K. in relation to goods, including medicinal products. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of the Agreement, the EU and the U. K. will recognize GMP inspections carried out by the other Party and the acceptance of official GMP documents issued by the other Party. The Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. 54Among the areas of absence of mutual recognition are batch testing and batch release. The U. K. has unilaterally agreed to accept EU batch testing and batch release for a period of at least two years until January 1, 2023. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the U. K. must be retested and re- released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. This lack of clarity on future U. K. laws and regulations and their interaction with EU laws and regulations may negatively impact foreign direct investment in the U. K., increase costs, depress economic activity, and restrict access to capital. The uncertainty concerning the U. K.' s legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and / or otherwise adversely affect trading agreements or similar cross- border co- operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit. These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U. K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility. We may also face new regulatory costs and challenges that could have an adverse effect on our operations~~ . Our acquisitions may expose us to unknown liabilities. Because we have **historically** acquired all the outstanding shares of most of our acquired companies, our investment in those companies are or will be subject to all of their liabilities other than their respective debts which we paid or will pay at the time of the acquisitions. If there are unknown liabilities or other obligations, our business could be materially affected. We may also experience issues relating to internal controls over financial reporting, issues that could affect our ability to comply with the Sarbanes- Oxley Act, tax examinations by the IRS or state tax authorities, or issues that could affect our ability to comply with other applicable laws. Tax laws could change. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws resulting from

legislative, administrative or judicial decisions may have adverse tax consequences on our business, cash flow, financial condition or results of operations or to a holder of our common stock. Shareholders should consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock. We may not be able to utilize a significant portion of our net operating loss carryforwards, which could harm our results of operations. We had U. S. federal and state net operating loss carryforwards of approximately $ ~~134~~ **152. 7 million and $ 143** . 3 million ~~and $ 103. 7 million~~ , respectively, as of December 31, ~~2022~~ **2023** , of which a portion of the federal and state amount of $ 7. 1 million and $ ~~103~~ **143** . ~~7~~ **3** million, respectively, has a 20- year carry forward period that will expire at various dates beginning in 2024. Under current law, the remaining federal amount of $ ~~127~~ **145** . ~~2~~ **6** million has an indefinite life and generally may not be carried back to prior taxable years. For net operating losses arising in taxable years beginning after December 31, 2017, we are permitted a net operating loss deduction that is limited to 80 % of our taxable income in such year. The net operating loss carryforwards are subject to a 382- limitation related to ownership changes. Under Section 382 of the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its net operating losses (" NOLs "), to offset U. S. federal and state taxable income. For these purposes, an ownership change generally occurs in the event of a ~~55cumulative~~ -- **cumulative** change in ownership of the Company of more than 50 % within any three- year period. We have ~~not determined if we have experienced~~ **reviewed our stock ownership for any ownership changes as defined under IRC** Section 382 **from January 1, 2021 through November 3, 2023 and determined that the** ownership ~~changes~~ **change was less than 50 % during that period** ~~in the past and if a portion of our NOL and tax credit carryforwards are subject to an annual limitation under Section 382~~ . Our existing NOLs are subject to limitations arising from previous ownership changes ~~that~~ **impacting the timing and amount, and the** impact **of such changes is reflected in** the **NOL** ~~timing and amount~~ **amounts disclosed above** . In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change. Accordingly, we may not be able to utilize a material portion of our NOLs and this could harm our future operating results by effectively increasing our future tax obligations. As of December 31, ~~2022~~ **2023** , we have recorded a valuation allowance of $ ~~57~~ **83** . ~~2~~ **0** million against our net deferred tax asset. ~~Risks~~ **56Risks** Related to the Regulatory Approval ProcessWe cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and foreign jurisdictions. Failure to obtain marketing approval for our product candidates will prevent us from commercializing them in those markets. We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our current product candidates nor any product candidates that we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. We expect to rely on third- party CROs and consultants to assist in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication of each of our product candidates to establish the product candidates' safety and efficacy for such indications. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, regulatory authorities. The pathway to regulatory approvals is time consuming and unpredictable, involves substantial costs and consumes management time and attention. It is not possible to predict the timing or success of obtaining regulatory approvals with any degree of certainty, and as a result, it is difficult to forecast our future financial results or prospects. Any unexpected development in the regulatory approval process, including delays or denials of regulatory approvals or significant modifications to our product candidates required by our regulators, could materially and adversely affect our business, results of operations and financial condition, and could substantially harm our stock price. To obtain marketing approval, United States laws require: ● controlled research and human clinical testing; ● establishment of the safety and efficacy of the product for each use sought; ● government review and approval of a submission containing, among other things, manufacturing, preclinical and clinical data; and ● compliance with cGMP regulations. The process of reviewing and approving a drug is time- consuming, unpredictable, and dependent on a variety of factors outside of our control. The FDA and corresponding regulatory authorities in other jurisdictions have a significant amount of discretion in deciding whether or not to approve a marketing application. Our product candidates could fail to ~~56receive~~ -- **receive** regulatory approval from the FDA or comparable regulatory authorities outside the United States for several reasons, including: ● disagreement with the design or implementation of our clinical trials; ● failure to demonstrate that our candidate is safe and effective for the proposed indication; ● failure of clinical trial results to meet the level of statistical significance required for approval; ● failure to demonstrate that the product candidate' s benefits outweigh its risks; **57** ● disagreement with our interpretation of preclinical or clinical data; and ● inadequacies in the manufacturing facilities or processes of third- party manufacturers. The FDA or a comparable regulatory authority outside the United States may require us to conduct additional preclinical and clinical testing, which may delay or prevent approval and our commercialization plans or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post- marketing clinical trials. Any of these scenarios could materially harm the commercial prospects of a product candidate, and our operations will be adversely affected. Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential. Significant adverse events caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause us, an IRB or ethics committee, and / or regulatory authorities to interrupt, delay or halt clinical trials and could

result in clinical trial challenges such as difficulties in patient recruitment, retention, and adherence, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. The most common adverse events observed in clinical trials for product candidates developed using the Densigen platform include injection site reactions, headache, malaise and fatigue. Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed. In addition, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post- marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population- specific or long- term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or revocation of product marketing authorization. If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including: ● our clinical trials may be put on hold; ● we may be unable to obtain regulatory approval for our product candidates; ● regulatory authorities may withdraw approvals of our products; ● regulatory authorities may require additional warnings on the label; ● a medication guide outlining the risks of such side effects for distribution to patients may be required; ~~57~~ ● we could be sued and held liable for harm caused to patients; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining marketing approvals for and market acceptance of our product candidates and could have a material adverse effect on our business and financial results **. 58Fast track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not assure FDA approval of any product candidates that we may develop. FDA' s fast track program is intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life threatening condition and preclinical or clinical data demonstrate the product' s potential to address an unmet medical need for this condition, the sponsor may apply for FDA fast track designation. In October 2023, we announced that the FDA granted fast track designation to our clinical program investigating pemvidutide for the treatment of MASH. Even with fast track designation, we may not experience a faster development process, review or approval for pemvidutide compared to conventional FDA procedures, and fast track designation does not ensure that a product candidate will receive marketing approval at all. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program** . If we fail to obtain regulatory approval in non- U. S. jurisdictions, we will not be able to market our products in those jurisdictions. Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in receiving or maintaining regulatory approval of our product candidates in other jurisdictions. We intend to market certain of our product candidates, if approved, in the United Kingdom and other international markets, in addition to the United States. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, such as certain countries of the European Union, a vaccine or therapeutic must be approved for reimbursement, including the price that can be charged, before it can be approved for sale in that country. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product, and additional clinical research may be required to enable comparison of the cost effectiveness of our product candidate to other available alternatives. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval. We may also be required to conduct post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product potentially over many years. If the FDA or other regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP, and compliance with cGMP and GCP for any clinical trials that we conduct post- approval. Manufacturers and manufacturers' facilities are also required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. ~~Additionally, under the Food and Drug Omnibus Reform Act of 2022 (" FDORA "), sponsors of approved drugs and biologies must provide six- months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed.~~ Any such restrictions may result in significant additional expense or could limit sales of the approved product. If we, or any of the third parties on which we rely, fail to meet those requirements, the FDA or comparable regulatory authorities outside the United States could initiate enforcement action. Other

consequences include the issuance of fines, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, and permanent injunctions and consent decrees, including the imposition of civil or criminal penalties, among other consequences, that could significantly impair our ability to successfully commercialize a given product. ~~58Later~~ **59Later** discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, may result in, among other things: ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls; ● fines or warning letters, or clinical holds on clinical trials involving related product candidates; ● refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of product license approvals; ● product seizure or detention or refusal to permit the import or export of products; and ● injunctions or the imposition of civil, criminal and / or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in governmental reimbursement programs, such as Medicare, Medicaid and other federal health care programs and curtailment or restructuring of our operations. In addition, applicable regulatory policies of governmental authorities, such as the FDA, may change and additional government regulations may be enacted that could affect any regulatory approval that we may receive for our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time- consuming and uncertain and may prevent us or any of our existing or future collaboration partners from obtaining approvals for the commercialization of our current product candidates and any other product candidate we develop. Any current or future product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, import, export and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third- party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate' s safety and effectiveness. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately ~~59obtain~~ **60obtain** may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired. If the FDA or comparable foreign regulatory authorities approve generic or biosimilar versions of any of our products that receive marketing approval, or if we do not obtain the exclusivity periods for our approved products that we hope to achieve, the sales of our products could be adversely affected. If and when approved, our product candidates may face competition from ANDA or 505 (b) (2) product candidates referencing our drug product and from biosimilars product candidates referencing our biological product. Certain ANDAs, and certain biosimilar products that are deemed under applicable laws to be " interchangeable with " our biological product, once approved, may be substituted for our product candidates, subject to applicable state laws. We may also be subject to competition from biosimilar products in ~~Europe~~ **the EU** . To date, many biosimilar products have been authorized by the European Commission, after application at EMA for a centralized marketing authorization. As in the United States the regulatory approval pathway for biosimilar products in ~~Europe~~ **the EU** is abbreviated. A biosimilar sponsor must however still provide all of the preclinical and clinical data required to demonstrate the similarity of their product with the reference product. The level of data required is assessed on a case **-** by **-** case basis, but it will be less than that required for an original biological product. The pathway is more complex than the abridged procedure that may be followed to obtain authorization of a generic version of a non- biological product, but it would still allow the biosimilar product to be brought to market more quickly and less expensively than our original product. That said, in the EU, applications for marketing authorizations in relation to biosimilar products are subject to the same data and market exclusivity rules that apply to generic non- biologic products so no biosimilar product can be approved or placed on the market during the period such exclusivity applies to our product. Marketing authorization of a biosimilar

product in the EU does not guarantee that the biosimilar product may be substituted for the reference product. Interchangeability of a biosimilar product with the reference product is not assessed by the EMA but this determination is left to each of the member states. We cannot know at this stage the extent to which any biosimilar product would be interchangeable with our reference product, and this may vary between member states. We may pursue pediatric exclusivity for one or more of our product candidates but may not succeed in obtaining it. There is also a risk that a competitor may achieve pediatric exclusivity that would delay any potential approvals of our product candidates. In the United States, the FDA has the authority to award additional exclusivity for approved products where the sponsor conducts specified testing on pediatric or adolescent populations upon the written request of the FDA. If granted, pediatric exclusivity may add six months to certain patents or regulatory exclusivity periods for an approved drug, and to regulatory exclusivity periods for an approved biological product. In the EU, ~~as well,~~ pediatric studies are **also** incentivized by the reward of additional exclusivity. Pediatric Investigation Plans (" PIPs ") ~~, are determined by~~ **must be agreed with** the Pediatric Committee of the EMA **, unless a waiver or deferral applies with respect to the product** . Where an application for a marketing authorization is submitted in respect of a medicinal product designated as an orphan medicinal product and that application contains the results of ~~the~~ **studies conducted in compliance with an approved** PIP ~~studies~~ , market exclusivity for that orphan medicinal product ~~is~~ **may be** extended by two years. Where an application for a marketing authorization is submitted in respect of a medicinal product that is not designated as an orphan medicinal product and that application contains the results of ~~the~~ **studies conducted in compliance with an approved** PIP ~~studies~~ , it may be possible to obtain a **six** ~~6-~~ month extension of a supplementary protection certificate extending patent protection for a medicinal product. Orphan drug designation presents yet another regulatory incentive that may be available to us and our competitors. The FDA may grant orphan drug designation to products intended to treat a " rare disease or condition " that affects fewer than 200, 000 individuals in the United States, or affects more than 200, 000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation can provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user fee exemptions. In addition, if a product that has an orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the ~~product~~ **61product** may be entitled to orphan drug exclusivity, which means the FDA would not approve any other application to ~~60market~~ -- **market** the same drug for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. In the European Union, orphan drug status offers similar but not identical benefits as those in the United States. We may pursue orphan drug designation for one or more of our product candidates but obtaining such designation cannot be assured. Even if we obtain orphan drug exclusivity, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off- label in the orphan indication. Additionally, should a competitor receive orphan drug designation for a product to treat the same disease and same indication as one of our product candidates, there is a risk that the FDA or a comparable European regulatory body could delay approving our product candidate. Risks Related to Our Intellectual PropertyIt is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position and other intellectual property rights do not adequately protect our product candidates, others could compete against us (including directly), which could materially harm our business, results of operations and financial condition. We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, platform technology and know- how. The patent position of biotechnology companies is generally uncertain, because it involves complex legal and factual considerations. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. In addition, some countries do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. The patent applications that we own or in- license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. The patent prosecution process is expensive and time consuming, and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties, making us reliant on our licensors, licensees or collaborators. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of the Company' s business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be lost or impaired. If our licensors, licensees or collaborators are not fully cooperative or disagree with the Company as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If patent applications we hold or have in- licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We and our licensors have filed several patent applications covering aspects of our product candidates. We cannot offer any assurance about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be successfully challenged by third parties. Patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued. We cannot be certain that our licensors were the first to satisfy the requirements necessary to secure patent rights relating to any particular invention. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our patent applications. Even

if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any successful challenge to our patents or patent applications, or to any other patents or patent applications owned by or ~~licensed~~ **62licensed** to us, could deprive us of the rights necessary to prevent competition from third parties, which may impair the ~~61commercial~~ -- **commercial** success of any product candidate that we may develop. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found, and prior art that we have not identified could be used by a third party to invalidate a patent or prevent a patent from issuing from a pending patent application. Furthermore, even if they are unchallenged, our patents and patent applications, or those of our licensors, may not adequately protect our technology, provide exclusivity for our product candidates, prevent others from designing around our patents with similar products, or prevent others from operating in jurisdictions in which we did not pursue patent protection. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. Any loss of, or failure to obtain, patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in some foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time. Patents have a limited lifespan. In most countries, including the United States, the natural expiration of a patent is 20 years from the date that the application for the patent is filed. In some cases, the term of a U. S. patent is shortened by a terminal disclaimer that reduces its term to that of an earlier- expiring patent. Various extensions of patent term may be available in particular countries; however, in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA- approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. ~~If any of our biologic products qualify as being a " first licensure " under the Biologics Price Competition and Innovation Act (" BPCIA ") provisions of the Affordable Care Act (" ACA "), we also expect to seek regulatory exclusivity for those products from the FDA, which can grant twelve (12) years of exclusivity under the BPCIA provisions of the ACA.~~ However, the applicable authorities, including the USPTO and FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available ~~or whether any of our products qualify as a first licensure,~~ and may refuse to grant extensions to our patents, or may grant more limited extensions than we request, or may not grant regulatory exclusivity. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, and then may be able to launch their product earlier than might otherwise be the case. ~~62We~~ **63We** may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets and / or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time consuming, which could divert management resources and harm our business and financial results. Many of our current and potential competitors have the ability to dedicate substantially greater resources to litigate intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Patent assertion, including initiating litigation, increases the likelihood that the accused third party will seek to narrow or invalidate our asserted patent. The scope and validity of our asserted patent may be challenged in a variety of post- grant proceedings before the USPTO and foreign patent offices. In addition, in an infringement proceeding, a court may decide that our asserted patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding or other legal proceeding could therefore put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery

required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Third- party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, and to use our or our licensors' proprietary technologies without infringing the patents and proprietary rights of third parties. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. We may not have identified all U. S. and foreign patents or published patent applications that affect our business either by blocking our ability to commercialize our product candidates or by covering similar technologies that affect our market. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims, for example, to materials, formulations, methods of manufacture, methods of analysis and / or methods for treatment related to the use or manufacture of our product candidates ~~. For instance, we and certain of our executive officers have been named in a lawsuit brought by a former employee, Dr- Chu Christopher Tang. The lawsuit asserts a number of claims, including claims that Dr. Tang owns certain portions of our intellectual property and that we wrongfully retained Dr. Tang' s lab notebooks after the conclusion of his employment in 2012. We believe the claims are without merit~~ . In some cases, we may have failed to identify such relevant third- party patents or patent applications. For example, patent applications filed before November 29, 2000 and certain patent applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our platform technology or our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or product candidates and / or the use, analysis and / or manufacture of our product candidates. If any third- party patents are held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, methods of analysis and / or methods for treatment, the holders of any such patents may be awarded monetary damages, obtain injunctive or other equitable relief, or both. An award of monetary damages may be substantial and may include treble damages and attorneys' fees for willful infringement. An award of injunctive relief could block our ability to develop and commercialize the applicable product candidate until such patent expired or ~~63unless~~ -- **unless** we obtain a license. Such licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be non- exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to redesign an infringing product, prevented from commercializing a product, or ~~forced~~ **64forced** to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party' s trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages. During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, platform technology or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. In addition, the uncertainties associated with litigation could have an adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market. We may be subject to claims that our employees, independent contractors or consultants have wrongfully used or disclosed alleged trade secrets of their former employers, or our employees may challenge the inventorship of our patents. As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these individuals, including members of our senior management, executed proprietary rights, non- disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we use reasonable efforts to ensure that our employees, independent contractors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. We may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. In addition, we may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We have in- licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such

intellectual property. We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Certain of our in- licensed intellectual property covers, or may cover, ~~RespirVec technology,~~ EuPort technology, and certain of our product candidates including pemvidutide. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other of our obligations. If there is any conflict, dispute, disagreement or issue of non- performance between ~~64the~~ **the** Company and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in ~~our~~ **65our** product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected. We may need to license certain intellectual property from third parties, and such licenses may not be available on commercially reasonable terms or at all. A third party may hold intellectual property, including patent rights, that is important or necessary to the development or commercialization of our product candidates. If the patented or proprietary technology of third parties is necessary for us to commercialize our product candidates, we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms or at all, which could materially harm our business. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of proprietary information. In addition to the protection afforded by patents, we rely on confidentiality agreements to protect trade secrets and proprietary know- how that may not be patentable or that we may elect not to patent, processes for which patents are difficult to enforce and any other elements of our technology and development processes that involve proprietary know- how, information or technology that is not covered by patents. In particular, we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. These agreements require that all confidential information developed by the individual or made known to the individual by the Company during the course of the individual' s relationship with us be kept confidential and not disclosed to third parties. We also enter into agreements with our employees that provide that any inventions conceived by the individual in the course of rendering services to the Company shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Although we use reasonable efforts to protect our know- how, our employees, consultants, contractors or outside scientific advisors might intentionally or inadvertently disclose our know- how or other proprietary information to competitors. In addition, competitors may otherwise gain access to our know- how or independently develop substantially equivalent information and techniques. Enforcing a claim that a third party illegally obtained and is using any of our know- how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U. S. courts to protect know- how. Misappropriation or unauthorized disclosure of our know- how could impair our competitive position and may have a material adverse effect on our business. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to those of the Company' s, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. For example, we have experienced threatened or actual opposition for two trademarks that we were pursuing. We decided to discontinue our use of one of those trademarks, and the other matter was resolved on favorable terms. Although these matters have been resolved on terms that did not materially harm the Company, we may become subject to other trademark challenges in the future. If we are unable to establish long- term name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. ~~65Risks~~ **66Risks** Related to Commercialization of the Company' s Product CandidatesOur future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third- party payers and others in the medical community. Even if we obtain marketing approval for our product candidates, or any other product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, third- party payers, patients and others in the medical community. Market acceptance of any approved products depends on a number of other factors, including: ● the efficacy and safety of the product, as demonstrated in clinical trials; ● the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label; ● acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new vaccines and / or therapies and of physicians to prescribe new vaccines and / or therapies; ● the cost, safety and efficacy of treatment in relation to alternative treatments; ● the availability of adequate course and reimbursement by third- party payers and government authorities; ● relative convenience and ease of administration; ● the prevalence and severity of adverse side effects; ● the effectiveness of our sales and marketing efforts; and ● the restrictions on the use of our products together with other medications, if any. Market acceptance is critical to our ability to generate significant revenue. Any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer. We rely on, and expect to continue to rely on, third parties to manufacture our product candidates and related materials for our **products, if approved, as well as for our** clinical trials and preclinical studies, and these third parties may not perform satisfactorily. We do not have any manufacturing facilities or personnel, and we rely on, and expect to continue to rely on, third- party manufacturers and suppliers to manufacture and supply

vaccines, drug substance and drug product for our preclinical studies and clinical trials, and on related materials, such as HBV products and pemvidutide. We rely on a small number of third- party manufacturers and suppliers to manufacture and supply bulk drug substance and drug product and fill finished vaccines for our initial clinical trials. This reliance on a small number of third parties increases the risk that we will not have sufficient quantities of our product candidates or other products needed for our preclinical studies and clinical trials, or that such quantities will be manufactured for us at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Any of these third parties that we rely upon may terminate their engagement with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. In addition, our reliance on these third parties for manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations regarding manufacturing. ~~Reliance~~ **67Reliance** on third- party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ~~itself~~ **ourself**, including: ● the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms; ~~66~~ ● reduced control as a result of using third- party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance. We do not have control over third party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures; ● delays as a result of manufacturing problems or re- prioritization of projects at a third- party manufacturer; ● our third- party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any; ● termination or non- renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; ● the possible misappropriation of our proprietary information, including our trade secrets and know- how or infringement of third- party intellectual property rights by our contract manufacturers; and ● disruptions to the operations of our third- party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy **or change in ownership** of the manufacturer or supplier. Any of these events could lead to preclinical study and clinical trial delays or failure to obtain regulatory approval or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA or other regulatory authority action, including clinical holds, fines, injunctions, civil penalties, license revocations, recall, seizure, total or partial suspension of production, or criminal penalties. In addition, our product candidates involve technically complex manufacturing processes, and even slight deviations at any point in the production process may lead to production failures and may cause the production of our product candidates to be disrupted, potentially for extended periods of time. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. Furthermore, a contract manufacturer may possess technology related to the manufacture of our product candidate that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product candidates. Third- party manufacturers may not be able to comply with applicable cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed, including clinical holds, fines, injunctions, civil penalties, delays, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. ~~Our~~ **68Our** third- party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man- made disaster, power loss, telecommunications failure, unauthorized entry, computer viruses, denial- of- service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events ~~. 67Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold due to the ongoing COVID- 19 pandemic, the FDA has been working to resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. \ Should FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Throughout the duration of the public health emergency, several companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic and may experience delays in their regulatory activities. The extent to which the ongoing COVID- 19 pandemic may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID- 19, the emergence of new variants, and the actions to contain COVID- 19 or treat its impact, among others~~. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure

on the part of our existing or future manufacturers could delay clinical development or marketing approval. We have limited arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and it may prove very difficult and time consuming to identify potential alternative manufacturers who could manufacture our product candidates. Accordingly, we may incur added costs and delays in identifying and qualifying any such replacement. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. If we are unable to manufacture our products in sufficient quantities, or at sufficient yields, or are unable to obtain regulatory approvals for a manufacturing facility for our products, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution. Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale, and this manufacturing involves a complicated process with which we have limited experience. Even if clinical trials are successful, we still may be unable to commercialize a product due to difficulties in obtaining regulatory approval for our engineering processes or problems in scaling that process to commercial production. We have no experience manufacturing, or managing third parties in manufacturing, any of our product candidates in the volumes that will be necessary to support large- scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale- up, reproducibility, yield, purity, cost, potency or quality. We expect to rely on third parties for the manufacture of clinical and, if approved for marketing, commercial quantities of our product candidates. These third- party manufacturers must also receive FDA or other applicable governmental authority approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. We may not be able to enter into any necessary third- party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we may have to enter into technical transfer agreements and share our know- how with the third- party manufacturers, which can be time consuming and may result in delays. Our contract manufacturing organizations may encounter technical or scientific issues related to development or manufacturing that we may be unable to resolve in a timely manner or with available funds. If we or our manufacturing partners are unable to scale the manufacturing process to produce commercial quantities of our product candidates, or our manufacturing partners do not pass required regulatory pre- approval inspections, our commercialization efforts may be adversely affected. ~~68Our~~ -- **Our** reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third- party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, replacement of a manufacturer may be expensive and time consuming and may cause interruptions in the production of our product candidates. A third- party manufacturer may also encounter difficulties in production. These problems may include: ● difficulties with production costs, scale- up and yields; ● unavailability of raw materials and supplies; ● insufficient quality control and assurance; **69** ● shortages of qualified personnel; ● failure to comply with strictly enforced federal, state and foreign regulations that vary in each country where product might be sold; and ● lack of capital funding. Any delay or interruption in the manufacture of our products could have a material adverse effect on our business, financial condition, results of operations and cash flows. If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if they are approved. We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, and for which we decide to independently commercialize, we will need to establish a sales and marketing organization. In the future, we may build a focused sales and marketing infrastructure to market or co- promote some of our product candidates in the United States and in Europe, if and when they are approved. There are risks involved with our establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians; ● the lack of adequate numbers of physicians to prescribe any future products; ● the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we do not establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, could be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing ~~69and~~ -- **and** distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. We may encounter difficulties in managing our growth and expanding our operations successfully. As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for the Company. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future

growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate ~~additional~~ **70additional** management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our business. We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products. A key part of our strategy is to seek strategic partnerships in the future, including potentially with major biotechnology or pharmaceutical companies for late- stage development and commercialization of our product candidates. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time consuming and complex. In order for the Company to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other products available for licensing from other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to the Company, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. In addition, any future partnerships we may enter into pose a number of risks, including that our partners may breach their agreements with the Company, and we may not be able to adequately protect our rights under these agreements. Furthermore, prospective partners will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we would. If we fail to establish and maintain strategic partnerships related to our product candidates, **including pemvidutide,** we will bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise which we do not have and for which we have not budgeted. This could negatively affect the development of any unpartnered product candidate **and materially affect our business and financial condition** . We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense. As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations. In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write- offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would ~~70otherwise~~ -- **otherwise** focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost- effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to the Company, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions. ~~If~~ **71If** product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for any product candidates or products that we may develop; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● significant costs to defend the related litigations; ● a diversion of management' s time and the Company' s resources; ● substantial monetary awards to trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● loss of revenue; ● the inability to commercialize any product candidates that we may develop; and ● a decline in our stock price. Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry worldwide product liability insurance covering our clinical trials in the amount of $ 10. 0 million in the aggregate. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any

amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. ~~71A~~ **A** breakdown in our information technology systems could result in a significant disruption to our business. Our operations and those of our business partners, such as CROs **, vendors** and others that manage sensitive data, are highly dependent on information technology systems, including Internet- based systems, which may be vulnerable to **damage or interruption from, among other things, computer viruses, computer hackers, phishing attacks, ransomware, malware, social engineering, malicious code, employee theft, fraud, misconduct or misuse, denial- of- service attacks, sophisticated nation- state and nation- state- supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures,** breakdown, wrongful intrusions, data breaches and malicious attack. Information security risks have generally increased in recent years. Our systems, and those of our third- party providers, are potentially vulnerable to data security breaches or cyberattack, whether by employees or others, which may expose sensitive data to unauthorized persons. A data security breach **or compromise** could lead to the loss of trade secrets or other intellectual property, the value of which may be contingent upon maintaining our confidentiality, or could lead to ~~the~~ **72the** public exposure of personal information (including sensitive personal medical information) of clinical trial participants, our employees and others, or adversely impact the conduct of scientific research and clinical trials, including the submission of research results to support marketing authorizations. This could require us to expend significant efforts and resources or incur significant expense to eliminate these problems and address related security concerns. In addition, procedures and safeguards must continually evolve to meet new data security challenges, and enhancing protections, and conducting investigations and remediation, may impose additional costs on the Company. If we **or our third- party providers** were to **experience a cybersecurity compromise or breach or other security incident,** suffer a breakdown in our systems, storage, distribution or tracing, we could experience significant disruptions affecting our business, **supply chain interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary, personal or confidential information, and** reputational harm **which could negatively impact** ~~or~~ **our relationship with our customers, partners, vendors and other third parties, and fines and penalties resulting from** claims against us by private parties and / or governmental agencies ~~. In addition, the European Parliament and the Council of the European Union have adopted a new pan- European General Data Protection Regulation (" GDPR "), effective May 25, 2018, which increases privacy rights for individuals in Europe, extends the scope of responsibilities for data controllers and data processors and imposes increased requirements and potential penalties on companies, offering goods or services to individuals who are located in Europe or monitoring the behavior of such individuals (including by companies based outside of Europe). Noncompliance can result in penalties of up to the greater of EUR 20 million, or 4 % of global company revenues. While we expect to have substantially compliant programs and controls in place to comply with the GDPR requirements, our compliance with the new regulation is likely to impose additional costs on us and we cannot predict whether the interpretations of the requirements, or changes in our practices in response to new requirements or interpretations of the requirements could have a material adverse effect on our business~~ . Risks Related to Reimbursement and Government RegulationCoverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if they are approved, which could make it difficult for us to sell our products profitably. Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third- party payers and may be affected by existing and future health care reform measures. Third- party payers, such as government health care programs, and private health insurers and health plans, decide which drugs they will provide coverage for and establish reimbursement levels. Coverage and reimbursement decisions by a third- party payer may depend upon a number of factors, including the third- party payer' s determination that use of a product is: ● a covered benefit under its health plan; ● safe, effective and medically necessary; ● appropriate for the specific patient; ● cost- effective; and ● neither experimental nor investigational. Third- party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. Coverage and reimbursement can vary significantly from payer to payer. As a result, obtaining coverage and reimbursement approval for any approved product from each government and other third- party payer may require us to provide supporting scientific, clinical and cost- effectiveness data for the use of such products to each payer separately, with no assurance that we will be able to provide data sufficient to gain acceptance ~~72with~~ -- **with** respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates, and we cannot be sure that coverage determinations or reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products, even if they are approved by the FDA or other regulatory authorities. In addition, in the United States third- party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third- party payers will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. Price controls may be imposed, which may adversely affect our future profitability. In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a ~~product~~ **73product** . In addition, there can be considerable pressure by governments and other stakeholders on coverage, prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce revenues. In some countries, additional clinical research may be required to enable comparison of the cost- effectiveness

of our product candidates, if they are approved, to other available products in order to obtain or maintain coverage, reimbursement or pricing approval. Publication of discounts by third- party payers or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. In the United States, concerns about drug pricing have been expressed by members of Congress and presidential administrations. There can be no assurance that our product candidates, if approved, will be considered cost- effective by third- party payers, that an adequate level of reimbursement will be available or that the third- party payers' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. We are subject to multiple and substantial federal and state health care and other laws, and the complexity of our regulatory compliance obligations is likely to increase in the event our product candidates are commercialized. Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute and the federal FCA, and their implementing regulations ~~, such as recent rules finalized by OIG which added safe harbor protections under the Anti- Kickback Statute for certain coordinated care and value- based arrangements among clinicians, providers, and others and that (with exceptions) became effective January 19, 2021~~. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. In addition to the Anti- Kickback Statute, FCA and Physician Payments Sunshine Act and their implementing regulations, the laws that may affect our ability to operate include, but are not limited to: ● HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti- Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it. ~~73~~ ● federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; ● federal government price reporting laws that require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and / or discounts, on any of our product candidates that may be approved for marketing (participation in these programs and compliance with the applicable requirements may also subject us to potentially significant discounts on our products and increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); ● the FCPA, which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals), and anti- bribery laws and related laws, and laws pertaining to the accuracy of our internal books and records, which have been the focus of increasing enforcement activity in recent years; and ● state law equivalents of each of the above federal laws, such as anti- kickback, false claims, consumer protection and unfair competition laws, which may apply to our business practices, including but not limited ~~to~~ **74to** , research, distribution, sales- and- marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third- party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and / or increase enforcement scrutiny of the Company' s activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects. In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws, as well as compliance with the codes of practice of certain associations within such countries (for example, the Association of the British Pharmaceutical Industry (ABPI) in the United Kingdom). Efforts to help ensure that our business arrangements will comply with applicable health care laws and codes of practice may involve substantial costs. We have adopted policies and practices that are designed to help ensure that the Company, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but it is not always possible to assure compliance with applicable requirements, and the precautions we take to achieve compliance 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. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to the Company, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal and state health care programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations as well as additional reporting obligations and

oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. ~~74The~~ -- **The** impact of recent health care reform legislation and other changes in the health care industry and in health care spending on the Company is currently unknown and may adversely affect our business model. Our financial prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to, among other things, health care availability, or the method of delivery of or payment for health care products and services could negatively impact our business, operations and financial condition. For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the **Affordable Care Act of 2010 (the "** Health Care Reform Law **")**. The Health Care Reform Law substantially changed the way health care is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. The Health Care Reform Law contains provisions that may reduce the profitability of drug products, including, for example, by increasing the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care plans, addressing a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and imposing certain annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Health Care Reform Law established and provided significant funding for a new Patient- Centered Outcomes Research Institute to coordinate and fund comparative effectiveness research. While the stated intent of comparative ~~effectiveness~~ **75effectiveness** research is to develop information to guide providers to the most efficacious therapies, outcomes of comparative effectiveness research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results. Certain provisions of the Health Care Reform Law have been subject to judicial challenges, as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act **of** ~~enacted on December 22,~~ 2017, eliminated the tax- based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the " individual mandate, " effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare prescription drug plans, commonly known as the " donut hole, " by raising the manufacturer discount under the Medicare Part D coverage gap discount program **from 50 %** to 70 %. Additional legislative changes, regulatory changes and judicial challenges related to the Health Care Reform Law remain possible. It is unclear how the Health Care Reform Law and its implementation, as well as efforts to repeal, replace or otherwise modify, or invalidate, the Health Care Reform Law, or portions thereof, will affect our business. We cannot predict what affect further changes to the Health Care Reform Law would have on our business, especially including under the Biden administration. ~~Another provision of the Health Care Reform Law, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations have been extended to include transfers of value made (starting in 2021) to certain non- physician providers such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives. CMS publishes information from these reports on a publicly available website. Our compliance with these rules may also impose additional costs and may impact our relationships with physicians, teaching hospitals, and other non- physician health care providers.~~ In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, among ~~75other~~ -- **other** things ~~led to~~ **, created measures for spending reductions by Congress that include** aggregate reductions ~~in~~ **of** Medicare payments ~~for all items and services, including prescription drugs and biologics,~~ to ~~service~~ providers of ~~,~~ on average ~~,~~ 2 % per fiscal year ~~beginning April 1~~ , **which remain in effect through** ~~2013~~ - **2032 . Due** ~~,~~ ~~and, due~~ to **the Statutory Pay- As- You- Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and** subsequent legislation, **Medicare payments to providers** will ~~continue until 2030 (~~ **be further reduced starting in 2025 absent further legislation. The U. S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our drug candidates for which we may obtain regulatory approval or the frequency** with **which any such drug candidate is prescribed or used** ~~the exception of a temporary suspension from May 1, 2020, through March 31, 2021) unless Congress takes additional action~~ . Additional legislative changes, regulatory changes or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede biosimilar competition **. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products,**

which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (IRA), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out- of- pocket spending cap for Medicare Part D beneficiaries from $ 7, 050 to $ 2, 000 starting in 2025, thereby eliminating the so- called coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U. S. government to negotiate Medicare Part B and Part D price caps for certain high- cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of 76the IRA' s Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known . Further, there has been increasing legislative, regulatory and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. ~~For example, on November 20, 2020, CMS issued an interim final rule to implement a " Most Favored Nation " demonstration project to test Medicare Part B reimbursement of certain separately payable drugs and biologicals based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. If the rule survives judicial scrutiny, the Most Favored Nation model will subject certain drugs or biologicals identified by CMS as having the highest annual Medicare Part B spending to an alternative payment methodology based on international reference prices, with the list of products to be updated annually to add more products and products not to be removed absent limited circumstances. There has also been legislation that would establish an international reference price- based Medicare Part B drug and biological payment methodology.~~ It is possible that the Health Care Reform Law, as currently enacted or may be amended or otherwise modified in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare payment and other health care financing, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from commercial payers. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. These continuing health care reform initiatives may adversely affect: ● the demand for any product candidates for which we may obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● our ability to obtain coverage and reimbursement approval for a product; ● our ability to generate revenues and achieve or maintain profitability; and ● the level of taxes that we are required to pay. Certain business practices associated with the commercialization of pharmaceutical products are subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to the Company. The laws that would govern our conduct in the United States upon the commercialization of our product candidates are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Anti- Kickback Statute and FCA, the FD & C Act, or any regulations promulgated under their authority, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid, the Department of Defense, other regulatory authorities and the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and ~~76regulations~~ -- **regulations** or prompt lawsuits by private citizen " relators " under federal or state false claims laws. In the United States, among the laws that may affect our ability to operate and market our products include, but are not limited to: ● The federal Anti- Kickback Statute prohibits, among other activities, any person from knowingly and willfully, directly or indirectly soliciting, receiving, offering or paying any remuneration with the intent of (or in return for) generating referrals of individuals or purchases, orders or recommendations for services or items reimbursable by federal health care programs like Medicare and Medicaid. Courts have interpreted this law very broadly, including by holding that a violation has occurred if even one purpose of the remuneration is to generate referrals, even if there are other lawful purposes. Moreover, liability under the Anti- Kickback Statute may be established without proving actual knowledge of the law or specific intent to violate. There are statutory exceptions and regulatory safe harbors that protect certain arrangements from prosecution or administrative sanctions, but the exceptions and safe harbors are drawn narrowly. The fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti- Kickback Statute, but the arrangement may be subject to scrutiny based on the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are ~~no~~ **77no** safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Violations of the Anti- Kickback Statute may be punished by civil and criminal penalties, damages, fines, or exclusion from participation in federal health care programs like Medicare and Medicaid. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. ● The FCA prohibits any

person from, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or making, or causing to be made, a false statement material to a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, or decreasing, an obligation to pay or transmit money or property to the government. The FCA is commonly used to sue those who submit allegedly false Medicare or Medicaid claims, as well as those who induce or assist others to submit a false claim. " False claims " can result not only from non- compliance with the express requirements of applicable governmental reimbursement programs, such as Medicare or Medicaid, but also from non-compliance with other laws, such as the Anti- Kickback Law, FDA laws on off- label promotion, or laws that require quality care in service delivery. Actions under the FCA may be brought by the government or by whistleblowers referred to as relators, who may initiate an action in the name of the government and may share in any monetary recovery. Violations of the FCA can result in treble damages, mandatory per claim penalties, and exclusion from participation in federal health care programs. ● HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti- Kickback Law, a person or entity can be found guilty of violating the HIPAA fraud statute without actual knowledge of the statute or specific intent to violate it. ● The Physician Payments Sunshine Act, implemented as the Open Payments program, imposes reporting requirements for pharmaceutical, biologic, and device manufacturers regarding payments or other transfers of value made to physicians, teaching hospitals, and other healthcare providers, including investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Annual reporting of such transfers of value by manufacturers has increased scrutiny of the financial relationships between industry and the physicians, teaching hospitals and other healthcare providers. Failure to submit required annual information may result in civil monetary penalties, which may increase significantly for " knowing failures. " ~~77~~ ● Analogous state laws and regulations, including anti- kickback and false claims laws, which apply to items and services reimbursed under Medicaid or, in several states, regardless of the payer, including private payers. Some state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. Some states restrict the ability of manufacturers to offer co- pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Other states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes of conduct. ● The FD & C Act and comparable foreign laws, in addition to prohibiting the promotion of the safety or effectiveness of product candidates not yet approved for commercialization, an act known as pre- approval promotion, also generally restrict companies from promoting approved products for indications other than those indications for which a product is approved, which is also referred to as off- label use. This means, for example, that we may not make claims about the use of our products, should they be approved for sale, ~~outside~~ **78outside** of their approved indications, and we may not proactively discuss or provide information regarding any of their off- label uses subject to very specific and limited exceptions. If we or our business partners fail to comply with applicable laws and regulations governing off- label uses of our product candidates, if approved, then we could be subject to administrative or judicially imposed sanctions, including, but not limited to: (i) enforcement proceedings by regulatory agencies; (ii) reduced demand for our products; and (iii) civil or criminal sanctions. Furthermore, actions under the FCA have recently been brought against companies for allegedly promoting off- label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off- label promotion have been initiated by several states for Medicaid fraud. The bringing of any FCA or other enforcement investigation or action, even if unsuccessful, could require us to devote resources to investigate and defend the action, as well as result in reputational harm. Failure to comply with the fraud and abuse laws could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. In addition, many of these laws are vague, subject to modification, and subject to evolving interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance. We cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws could have a material adverse effect on our business. If our product candidates are commercialized, then we would also be required to report detailed and complex pricing information, net of included discounts, rebates and other concessions, to CMS for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations, and we would need to develop the expertise, as well as the systems for collecting and reporting this data accurately to CMS and have instituted a compliance program to assure that the information collected is complete in all respects. Companies that fail to accurately report this kind of pricing information to the U. S. government could be subject to fines and other sanctions (including potential FCA liability) that could adversely affect their business. We must comply with data privacy and security laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities. We must operate in compliance with various data privacy and security regulations in the United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, such as the ~~United Kingdom~~ **U. K.** , the ~~EU~~ **European Economic Area (" EEA ")** and Asia, where we conduct clinical trials **. Our operations entail the collection, use, disclosure, transfer, and processing of sensitive and personal information. Further, our operations extend to commercial partnerships and third- party processors, each of which may be governed by their distinct privacy regulations and**

cybersecurity laws. These laws are continually evolving and subject to varying interpretations, which requires us to periodically update policies and procedures to maintain compliance . In the U. S., we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business, including, for example, state data breach notification laws, state health information and / or genetic privacy laws and federal and state consumer protection laws (e. g., Section 5 of the FTC Act and the **California Consumer Privacy Act (“** CCPA **”**) **), which** , govern the collection, use, disclosure, and protection of health- related and other personal information. Many of these laws **and regulations** differ from each other in significant ways and ~~may not have~~ the ~~same effect~~ **impact of such laws may vary** , thus **potentially** complicating ~~78compliance~~ -- **compliance** efforts. Compliance with these laws is difficult, constantly evolving, and time consuming **, thus we may be required to incur substantial costs and expenses in order to comply with them** . Federal regulators, state attorneys general, and plaintiffs’ attorneys, including class action attorneys, have been and will likely continue to be active in this space. HIPAA, for example, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Failure to comply with these laws and regulations can result in substantial penalties and other liabilities. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. ~~The~~ **79The** CCPA ~~became effective on January 1~~ , ~~2020 and~~ **for example,** establishes **data privacy rights for individuals located in California and imposes** certain requirements for **how businesses can collect and use personal** data **about them. The** ~~use and sharing transparency, and provides~~ California ~~residents certain~~ **Privacy Rights Act, or CPRA, significantly modified the CCPA and imposes additional obligations on covered businesses, including by expanding consumers’** rights **with respect to** ~~concerning the use, disclosure, and retention of~~ their personal data **and establishes a state agency vested with the authority to enforce the CCPA** . The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. ~~The CCPA~~ **Other states, such as Virginia, Colorado, Utah Connecticut, Texas, Oregon, Tennessee, Delaware** and **Iowa** ~~its implementing regulations~~ have **recently passed or** ~~already been amended multiple times since their enactment~~ - **enacted similar, comprehensive privacy and data protection legislation** . **Many** ~~The CCPA could mark the beginning of a trend toward more stringent~~ state privacy ~~legislation in~~ **and data protection laws differ from each** ~~the~~ **other in significant ways** ~~U. S.~~ , ~~which could increase our potential liability~~ and ~~adversely affect our business~~ **it is not yet fully clear how such laws will be enforced and interpreted** . The obligations to comply with the CCPA and other evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners. In ~~addition, the European~~ -- **Europe,** ~~Parliament and~~ the ~~Council~~ **collection and use** of **personal information, including health data, is governed by** the **EU’ s** ~~European Union have adopted a new pan- European~~ General Data Protection Regulation **and the United Kingdom’ s implementation of the same** (**collectively, the** “ GDPR ”) ~~, effective May 25, 2018, which increases privacy rights for individuals in Europe, extends the scope of responsibilities for data controllers and data processors and imposes increased requirements and potential penalties on companies, offering goods or services to individuals who are located in the EU or monitoring the behavior of such individuals (including by companies based outside of the EU)~~ . The GDPR ~~governs the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data. It~~ is wide- ranging in scope and imposes numerous requirements on **covered** companies ~~that process personal data~~ , including requirements ~~relating~~ **related** to ~~processing health and other sensitive data, providing information to individuals~~ - **individual notice** regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR. Noncompliance can result in penalties of up to the greater of EUR 20 million, or 4 % of annual global company revenues. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. ~~In addition, the GDPR includes restrictions on cross- border data transfers.~~ While we expect to have substantially compliant programs and controls in place to comply with the GDPR requirements, our compliance with the ~~new~~ regulation is likely to impose additional costs on us and we cannot predict whether the interpretations of the requirements, or changes in our practices in response to new requirements or interpretations of the requirements could have a material adverse effect on our business. There is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. ~~Further, the United Kingdom’ s decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. On June 28, 2021, the EU Commission adopted decisions on the U. K.’ s adequacy under the EU’ s GDPR. This means that most personal data can continue to flow from the EU and the EEA to the U. K. without the need for additional safeguards. However, restricted transfers from the U. K. to other countries, including to the EEA, are subject to transfer rules under the U. K. regime. On February 2, 2022, the U. K. announced the implementation of a new series of U. K. Standard Contractual Clauses, which must be adopted by U. K. companies no later than March 21, 2024. These U. K. transfer rules broadly mirror the EU GDPR rules, but the U. K. has the independence to keep the framework under review, lending uncertainty to future data transfers in to and out of the U. K. We must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties.~~ Any ~~such~~ investigation or charges by European data protection authorities could have a negative effect

on our existing business and ~~79on~~ **on** our ability to attract and retain new clients or pharmaceutical collaboration partners. We may also experience hesitancy, reluctance, or refusal by European or multi- national clients or pharmaceutical partners to ~~continue to~~ **do business with** ~~use~~ **us** ~~our products~~ due to the potential risk **of** exposure as a result of the current ~~(~~and ~~, in particular,~~ future ~~)~~ data protection obligations imposed on them by certain data protection authorities in interpretation of ~~current~~ **European privacy and data protection** ~~law~~ **laws** , including the GDPR. Such clients or ~~pharmaceutical collaboration~~ partners may ~~also~~ view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to ~~do business~~ **continue their relationship** with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations **and prospects, and we may be required to incur substantial costs and expenses in an effort to comply with our legal and regulatory obligations** . ~~We~~ **While data generally flows freely between the U. K. and the EEA and vice versa as a result of adequacy decisions and regulations, to enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with the GDPR. On June 4, 2021, the European Commission issued new forms of standard contractual clauses (" SCCs ") for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EEA (and not subject to the GDPR). As of December 27, 2022 the new SCCs replace the SCCs that were adopted previously under the EU Data Protection Directive. The UK is not subject to the European Commission' s new SCCs, and instead it has published the UK International Data Transfer Agreement (" IDTA ") and the International Data Transfer Addendum to the new SCCs (" Addendum "), which enable transfers from the UK. For new transfers, the IDTA (or SCCs and Addendum) must be in place, and such measures must be in place for all existing transfers from the UK from March 21, 2024. Companies relying on SCCs or the IDTA to govern transfers of personal data to third countries will also need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR, including an analysis of the laws in the recipient' s country. When conducting restricted data transfers, including to the U. S., under the EU GDPR and UK GDPR (i. e., the UK' s post-Brexit transposition of the GDPR), we must ensure these safeguards are in place. 80We** are subject to extensive government regulatory compliance and ethics oversight, and we will need to develop more extensive compliance and ethics policies in the future. Our business is subject to extensive government regulation and ethics oversight, which will become more complex and extensive if we succeed in commercializing products. We have enacted various compliance policies and procedures that govern our business practices as appropriate for a company in our stage of development. These policies and procedures are implemented through education, training and monitoring of our employees, distributors and suppliers. However, our adoption and enforcement of these various policies and procedures does not ensure that we will avoid investigation or the imposition of penalties by applicable government agencies. In addition, to enhance compliance with applicable health care laws and mitigate potential liability in the event of non- compliance, regulatory authorities, such as OIG, of the HHS have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2. 1 of the U. S. Sentencing Commission Guidelines Manual. Increasing numbers of U. S.- based pharmaceutical companies have such programs. Although we believe our existing compliance policies and procedures are adequate for our current operations, these policies and procedures would not be considered a comprehensive health care compliance program consistent with the HHS OIG' s recommendations. Depending upon the nature of our future operations, we anticipate developing a more extensive compliance program in the future. Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of fraudulent or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to comply with the laws of the FDA and similar foreign regulatory bodies; fails to comply with manufacturing standards we have established, or with federal, state and foreign health care fraud and abuse laws and regulations; fails to report financial information or data accurately, including to our regulators, such as the FDA and similar foreign regulatory bodies; or fails to disclose unauthorized activities to the Company. In particular, the promotion, sale and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent misconduct, including fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and, structuring and commissions, certain customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. We have adopted a Code of Business Conduct and Ethics Policy and other policies and practices that are designed to help ensure that the Company, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but 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 the Company, and in some cases regardless of the merits of those actions, those actions could have a significant impact on our business, including the costs of investigation, settlement arrangements, imposition of civil, criminal and administrative penalties (such as additional reporting requirements and oversight if we become subject to Corporate Integrity Agreements and other arrangements, damages, monetary fines, disgorgement, imprisonment, and possible exclusion from participation in Medicare, Medicaid and other federal health care programs), contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. ~~80We~~ **We** must comply with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities. We use hazardous chemicals and biological materials in certain aspects of our business and are subject to a

variety of federal, state and local laws and regulations governing the use, generation, manufacture, distribution, storage, handling, treatment and disposal of these materials. We cannot eliminate the risk of accidental injury or contamination from the use, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials. In the event of contamination ~~or~~ **81or** injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. In addition, we may be required to pay damages or civil judgments related to third- party claims, for which we are uninsured, including those relating to personal injury (including exposure to hazardous chemicals and biological materials), product quality issues, property damage or contribution to remedial obligations. Risks Related to our SecuritiesThe trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders. Our stock price has been and, in the future, may be subject to substantial volatility. For example, on September 13, 2018 we amended our Amended and Restated Certificate of Incorporation to effect a reverse stock split at a ratio 1- for- 30 (the " Reverse Stock Split "). The Reverse Stock Split was effective on September 13, 2018, and our shares of common stock commenced trading on NASDAQ on a post- Reverse Stock Split basis on September 14, 2018. The volatility of our stock price has increased since we effected the Reverse Stock Split. Since our common stock began trading on a post- Reverse Stock Split basis on September 14, 2018 and through December 31, ~~2022~~ **2023** , our stock has traded in a range with a low of $ 1. 51 and a high of $ 36. 25. Furthermore, the stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including: ● announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors; ● results of clinical trials of our product candidates or those of our competitors; ● announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements; ● actual or anticipated variations in our operating results and whether we have achieved key business targets; ● sales of our common stock, including sales by our directors and officers or specific stockholders; ● changes in, or our failure to meet, financial estimates by us or by any securities analysts who might cover our stock; ● changes in securities analysts' buy and / or sell recommendations; ● general economic, political, or stock market conditions; ● conditions or trends in our industry; ● changes in laws or other regulatory actions affecting us or our industry; ● stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; ~~81~~ ● announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; ● capital commitments; ● investors' general perception of our company, our business, and our prospects; **82** ● disputes concerning our intellectual property or other proprietary rights; and ● recruitment or departure of key personnel. In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources from our business. Future sales and issuances of our common stock or rights to purchase common stock could result in substantial dilution to the percentage ownership of our stockholders. We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock or other securities convertible into or exchanged for our common stock in one or more transactions, and in a manner we determine from time to time and at prices that may not be the same as the price per share paid by other investors, and dilution to our stockholders could result. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors. New investors could also receive rights, preferences and privileges senior to those of existing holders of our common stock. In addition, in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock, we may be required to proportionally adjust the conversion price, exercise price or number of shares issuable upon exercise of our outstanding warrants. If we do not meet the continued listing standards of ~~The~~ NASDAQ ~~Global Market~~ our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions. Our common stock is listed on **NASDAQ** ~~Nasdaq Global Market~~ , a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to satisfy the continued listing standards, including with respect to the maintenance of a minimum share price, or if NASDAQ in its discretion, determines that a condition exists that makes further dealings of our Company on the exchange unwarranted, NASDAQ may issue a non- compliance letter or initiate delisting proceedings. If our securities are delisted from trading on the NASDAQ exchange, our securities could be quoted on the OTCQB or on the Pink Open Market. As a result, we could face significant adverse consequences including: ● a limited availability of market quotations for our securities; ● a determination that our common stock is a " penny stock " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; ● a limited amount of news and analyst coverage for us; and ● a decreased ability to issue additional securities (including pursuant to short- form registration statements on Form S- 3) or obtain additional financing in the future. ~~82~~ **Shares that we may issue in the future in connection with certain capital- raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock. The issuance or even the expected issuance of a large number of shares of our common stock upon purchase, conversion or exercise of the securities described above could depress the market price of our stock and the issuance of such shares will dilute the stock ownership of our existing stockholders. Shares that we may issue in the future in connection with certain capital- raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock and result in the adjustment of the conversion terms of our existing securities. 83**