Risk Factors Comparison 2024-02-29 to 2023-03-15 Form: 10-K

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Risks Related to Our Financial Position and Need for Additional Capital We have a limited operating history and have incurred significant losses since inception and anticipate that we may continue to incur losses for the foreseeable future, and may never achieve or maintain profitability. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are an oncology company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying product candidates, establishing our intellectual property portfolio and conducting research, preclinical studies and clinical trials. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. As an organization, we have not yet completed any clinical trials, obtained regulatory approvals, manufactured a commercial- scale product (or arranged for a third party to do so on our behalf), or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products. Since inception, we have not generated any product revenue and have incurred significant operating losses. Our net losses were $ ~~86~~ **104. 2 million and $ 75** . 8 million ~~and $ 104. 2 million~~ in ~~2021 and~~ 2022 **and 2023** , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~267~~ **342** . ~~0~~ **8** million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, as well as to building our management team and infrastructure. It could be at least several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we: • continue to advance our research and preclinical and clinical development of our product candidates; • expand and initiate further clinical trials for our product candidates; • seek to identify additional product candidates; • seek marketing approvals for our product candidates that successfully complete clinical trials, if any; • establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; • maintain, expand, protect and enforce our intellectual property portfolio and obtain licenses to third- party intellectual property; • attract, hire and retain additional administrative, clinical, regulatory and scientific personnel; • enter into third- party relationships for clinical trials, manufacturing and supply; and • incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company. In addition, because of the numerous risks and uncertainties associated with pharmaceutical products and development, we are unable to accurately predict the timing or amount of increased expenses and when, or if, we will be able to achieve profitability. Our expenses could increase and profitability could be further delayed if we decide to or are required by the FDA or other comparable foreign regulatory authorities such as the European Medicines Agency (" EMA "), or the U. K. Medicines & Healthcare Products Regulatory Agency (the " MHRA "), to perform studies or trials in addition to those currently expected, or if there are any delays in the development or completion of any current or future preclinical studies or clinical trials of our current and future product candidates. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our current and future product candidates. 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 decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in value also could cause you to lose all or part of your investment. We will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts. Identifying and developing potential product candidates and conducting preclinical studies and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and begin selling any approved products. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials, initiate additional clinical trials for our product candidates and seek regulatory approval for our current product candidates and any future product candidates we may develop. Our expenses could increase beyond our current expectations if the FDA, or comparable foreign regulatory authorities, require us to perform clinical trials and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce or terminate our research and development programs or future commercialization efforts. As of December 31, ~~2022~~ **2023** , we had $ ~~661~~ **611** . ~~0~~ **2** million in cash and investments, and an accumulated deficit of $ ~~267~~ **342** . ~~0~~ **8** million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital

requirements will depend on many factors, including: • the scope, rate of progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates; • the number and development requirements of product candidates that we may pursue, and other indications for our current product candidates that we may pursue; • the costs, timing and outcome of regulatory review of our product candidates; • the scope and costs of manufacturing development and commercial manufacturing activities; • the cost associated with commercializing any approved product candidates; • the cost and timing of developing our ability to establish sales and marketing capabilities, if any; • the costs of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights, defending intellectual property- related claims and obtaining licenses to third- party intellectual property; • our ability to establish and maintain collaborations on favorable terms, if at all; and • the extent to which we acquire or in- license other product candidates and technologies and associated intellectual property. We may require additional capital to complete our planned clinical development programs for our clinical stage product ~~candidate~~ **candidates as well as** ~~NUV- 868 and~~ our ~~other~~ **preclinical** product candidates to obtain regulatory approval. Any additional capital raising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. In addition, we cannot guarantee that future financing will be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and our issuance of additional securities, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common stock to decline. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to delay, reduce or terminate one or more of our research and development programs or the commercialization of any product candidates that may be approved. This could harm our business and could potentially cause us to cease operations. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our earnings. Any new taxes could adversely affect our business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us ~~.~~ **, which could require us to pay additional taxes on a prospective** ~~For~~ **or** ~~example~~ **retroactive basis** , **as well as penalties, interest and** ~~the~~ **other costs, including compliance costs. The** Tax Cuts and Jobs Act enacted in 2017 (the " Tax Act "), the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020 and the Inflation Reduction Act enacted in 2022 made many significant changes to the U. S. tax laws. **For example,** ~~Effective~~ **effective** January 1, 2022, the Tax Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to any such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. Our ability to use our net operating loss carryforwards and certain other tax attributes to offset taxable income or taxes may be limited. As of December 31, ~~2022~~ **2023** , we had federal and state net operating loss, (" NOL "), carryforwards of $ ~~67~~ **95** . ~~8~~ **2** million and $ ~~124~~ **140** . ~~9~~ **3** million, respectively. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but ~~the deductibility of~~ such federal ~~net operating is limited~~ **NOLs are permitted to be used in any taxable year to offset only up** to 80 % of taxable income **in such year** ~~. It is uncertain if and to what extent various states will conform to federal tax laws~~ . Separately, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which generally is defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post- change income or taxes may be limited. The completion of the Merger, together with private placements and other transactions that have occurred since our inception, may **have** ~~trigger~~ **triggered** such an ownership change pursuant to Section 382. We have not completed a Section 382 analysis, and therefore, there can be no assurances that our NOLs are not already limited. We also may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre- change NOL carryforwards to offset U. S. federal taxable income may be subject to

limitations, which potentially could result in increased future tax liability to us. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, this could harm our future operating results by effectively increasing our future tax obligations. In addition, due to changes in laws and regulations, including changes proposed or implemented by the current or a future U. S. presidential administration, such as alternative minimum taxes, or other unforeseen reasons, our existing net operating losses could become unavailable to reduce future income tax liabilities. Further, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Risks Related to the Development of our Product Candidates If we do not obtain regulatory approval for and successfully commercialize our product candidates in one or more indications or we experience significant delays in doing so, we may never generate any revenue or become profitable. We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We are very early in our development efforts. We have invested substantially all of our efforts in developing and identifying potential product candidates and conducting preclinical studies. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of NUV- 868. We cannot be certain that NUV- 868 or any other product candidate will receive regulatory approval or will be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of product candidates is, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our preclinical studies or clinical trials. For example, based on its preclinical or clinical experience since February 2022, Nuvation Bio has discontinued or deprioritized three of the five programs, including the lead program, that it was pursuing at that time. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success of our product candidates will depend on several additional factors, including: • successful completion of preclinical studies; • successful initiation of clinical trials; • successful patient enrollment in, and completion, of clinical trials that demonstrate their safety and efficacy; • receiving marketing approvals from applicable regulatory authorities; • obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates; • completing any post- marketing studies required by applicable regulatory authorities; • making and maintaining arrangements with third- party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates; • establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • the prevalence and severity of adverse events experienced with our product candidates; • acceptance of our product candidates by patients, the medical community and third- party payors; • a continued acceptable safety profile following approval; • obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates; • competing effectively with other cancer therapies, including with respect to the sales and marketing of our product candidates, if approved; and • obtaining licenses to any third- party intellectual property we deem necessary or desirable. Many of these factors are beyond our control, including the time needed to adequately complete preclinical studies, clinical testing and the regulatory submission process, our ability to obtain and protect intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects. In addition, the clinical trial requirements of the FDA, the European Commission, competent authorities of EU Member States, the MHRA and other comparable regulatory authorities and the criteria regulators may use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Our approach to the discovery and development of product candidates based on our DDC platform is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete. The success of our business depends in part upon our ability to identify, develop and commercialize products based on our proprietary Drug- Drug Conjugate (“ DDC ”) platform, which leverages a novel and unproven therapeutic approach within the drug- conjugate class of anti- cancer therapies. While we have had positive preclinical study results based on our technology, we have not yet succeeded and may not succeed in demonstrating safety and efficacy for any DDC product candidates in clinical trials or in obtaining marketing approval thereafter. Our product candidates arising from our DDC platform are in pre- clinical development and we have not yet completed any clinical trials for any such product candidate. Our research methodology and novel approach to oncology using our DDC platform may be unsuccessful in identifying additional product candidates, and any product candidates based on our technology may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In addition, adverse developments with respect to one of our DDC platform- based programs may have a significant adverse impact on the actual or perceived likelihood of success and value of similar programs. In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our DDC platform. If we fail to stay at the forefront of technological change in utilizing our DDC platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our DDC platform obsolete, or limit the commercial

value of our product candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our DDC platform and potential of our DDC platform- based product candidates. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would harm our business. Our DDC platform- based product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development. We have concentrated our product research and development efforts on our novel DDC platform, and our future success depends in part on the successful development of product candidates arising from our DDC platform. There can be no assurance that any development problems we may experience in the future related to our DDC platform will not cause significant delays or unanticipated costs, or that such development problems can be efficiently solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. We may in the future develop product candidates in combination with other therapies and that may expose us to additional risks. We may develop future product candidates for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially. We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates. Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove safe or effective in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Preclinical investigation and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical investigation or clinical trial process. For example, in August 2022, we announced the discontinuation of development of our former lead program, NUV- 422, following the emergence of a safety signal, uveitis, which is a form of inflammation of the eye. In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later- stage preclinical studies or clinical trials. The results generated to date in preclinical studies for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later- stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later- stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected. Interim, " topline, " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical

trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy 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 candidate for its intended indications. Preclinical studies and clinical trials are expensive, time- consuming and uncertain as to outcome. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of preclinical or clinical development include: • delays in conducting experiments or preclinical studies or unsatisfactory results from such experiments or studies; • delays in reaching a consensus with regulatory authorities on trial design **, dose optimization or dose selection** ; • delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites; • delays in opening sites and recruiting suitable patients to participate in our clinical trials; • delays in enrollment due to travel or quarantine policies, or other factors, related to **health epidemics** ~~COVID- 19~~ , other pandemics or other events outside our control; • imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations or trial sites; • delays in having patients complete participation in a trial or return for post- treatment follow- up; • occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols. For instance, **health epidemics** ~~the ongoing COVID- 19 pandemic~~ and the measures taken **in response** by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may: • be delayed in obtaining marketing approval, if at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; • be subject to additional post- marketing testing requirements; • be required to perform additional clinical trials to support approval or be subject to additional post- marketing testing requirements; • have regulatory authorities withdraw, vary or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS, or comparable foreign restrictions; • be subject to the addition of labeling statements, such as warnings or contraindications; • be sued; or • experience damage to our reputation. Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Further, we, the FDA or comparable foreign regulatory authorities, an ~~IRB~~ **Institutional Review Board** , or an Ethics Committee may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with applicable regulatory requirements, including the FDA' s current Good Clinical Practice, (" GCP ") and foreign equivalents, regulators find that we are exposing participants to unacceptable health risks or if the FDA or comparable foreign regulatory authorities find deficiencies in our INDs, clinical trial applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely. If we encounter continued or new difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We have experienced and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including challenges resulting from **health epidemics** ~~the ongoing COVID- 19 pandemic~~ , labor shortages, and global supply chain interruptions. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors,

including: • the patient eligibility criteria defined in the protocol; • the size and health of the patient population required for analysis of the trial' s primary endpoints; • the proximity of patients to study sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; • our ability to obtain and maintain patient consents; and • the risk that patients enrolled in clinical trials will drop out of the trials before completion. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our current or planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications, even those that we have begun investigating and that may have shown promise, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised. Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including: • withdrawal, variation, suspension or limitation by regulatory authorities of approvals of such product; • product candidate is approved under 21 CFR 314 (Subpart H, accelerated approval) or we receive a conditional marketing authorization but required confirmatory trials may fail to verify clinical benefit or we may fail to fulfill requirements of the conditional marketing authorization; • seizure of the product by regulatory authorities; • recall of the product; • restrictions on the marketing of the product or the manufacturing process for any component thereof; • requirement by regulatory authorities of additional warnings on the label, such as a " black box " warning or contraindication; • requirements that we implement a REMS, or comparable foreign strategies, or create a medication guide outlining the risks of such side effects for distribution to patients; • commitment to expensive additional safety studies prior to approval or post- marketing studies required by regulatory authorities of such product; • adverse impact on the product' s competitiveness; • initiation of regulatory investigations and government enforcement actions; • initiation of legal action against us to hold us liable for harm caused to patients; and • harm to our reputation and resulting harm to physician or patient acceptance of our products. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could harm our business, financial condition, results of operations and prospects. We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved. For more information regarding the risks associated with intellectual property- related litigation, see " Risk Factors — Risks Related to Our Intellectual Property. " Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen or rare side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a

successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Even if we receive Fast Track designation or granting of other FDA expedited programs, or other comparable foreign expedited programs, for any of our product candidates, there is no guarantee that such product candidates will experience a faster regulatory review or obtain regulatory approval. If a product is intended for the treatment of a serious or life- threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we receive Fast Track designation for any of our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve such product candidates. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason. Similarly, the FDA' s other expedited drug development programs (e. g., Breakthrough Therapy, Accelerated Approval, Priority Review) do not guarantee a product candidate' s faster regulatory review or regulatory approval. The EMA has a similar program called PRIME. Even if we receive Orphan Drug designation for any of our product candidates, we may be unable to maintain the benefits associated with such designation, including the potential for market exclusivity. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as Orphan Drugs. Under the Orphan Drug Act, the FDA may designate a drug as an Orphan Drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for certain clinical trial costs and user- fee waivers. Generally, if a drug with an Orphan Drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States. Even if we receive Orphan Drug designation for any of our product candidates, there is no guarantee that we will obtain approval or Orphan Drug exclusivity for such product candidates. Even if we obtain Orphan Drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product candidates from competition because different therapies can be approved for the same condition and the same therapy could be approved for different conditions. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Moreover, Orphan Drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Risks Related to Commercialization of Our Product Candidates We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators. We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies of our product candidates and enrolling patients in ~~a~~ clinical trials for our clinical stage product ~~candidate~~ **candidates** ~~, NUV- 868~~ . We currently have no sales force, marketing, manufacturing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and manufacturing capabilities or outsource these activities to a third party. Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time- consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the U. S., the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We are developing our initial product candidates for the treatment of cancer, and currently none of these therapies are approved. There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these

approved drugs are well established therapies and are widely accepted by physicians, patients and third- party payors. Insurers and other third- party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of replacing existing therapies with our product candidates. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop. In addition, most of these companies have substantially greater sales, marketing and other experience and reserves than we do. Competition may further increase as a result of advances in the commercial applicability of technologies for drug discovery and development and greater availability of capital for investment in cancer therapies. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make our product candidates less competitive. In addition, any new product that competes 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. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations. The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition, results of operations and prospects. Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If NUV- 868 and our other current and future product candidates receive marketing approval, whether as a single agent or in combination with other therapies, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may never become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the ability of NUV- 868 and our other product candidates to treat cancer, as compared with other available drugs, treatments or therapies; • the prevalence and severity of any adverse side effects associated with NUV- 868 and our other product candidates; • limitations or warnings contained in the labeling approved for NUV- 868 or our other product candidates by the FDA or comparable foreign regulatory authorities; • availability of alternative treatments; • the size of the target patient population, and 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 and timing of market introduction of competitive products; • publicity for our product candidates and competing products and treatments; • pricing and cost effectiveness; • the effectiveness of our sales and marketing strategies; and • our ability to obtain sufficient third- party coverage and adequate reimbursement. The successful commercialization of certain of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, comparable foreign healthcare programs, private health insurers and other third- party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates and, if desired, attract collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid, the 340B drug pricing program and TRICARE, or comparable foreign healthcare programs, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the U. S., the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U. S., third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and

reimbursement for our product candidates. Obtaining and maintaining reimbursement status is time- consuming and costly. No uniform policy for coverage and reimbursement for products exists among third- party payors in the U. S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. Moreover, increasing efforts by governmental and third- party payors in the U. S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect: • the demand for any products 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. In addition, in case a drug product needs companion diagnostics, then companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for ~~their~~ **the** ~~companion~~ pharmaceutical or biological ~~products~~ **product** . Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight. Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record- keeping. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with **current Good Manufacturing Practice ("** cGMP **")** , regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product' s approved labeling. If we receive marketing approval for any future product candidates we may develop, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off- label uses, we may become subject to significant liability. The FDA or comparable foreign regulatory authorities may also require a REMS, or comparable foreign regulatory strategies as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of 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 U. S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include: • issuing warning or untitled letters; • seeking an injunction or imposing civil or criminal penalties or monetary fines; • suspension or imposition of restrictions on operations, including product manufacturing; • seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall; • suspension, variation or withdrawal of our marketing authorizations; • suspension of any ongoing clinical trials; • refusal to approve pending applications or supplements to applications submitted by us; or • requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects. If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved. We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. 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 product candidates on our own include: • our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future product candidates; • 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 enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third- party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Risks Related to Our Dependence on Third Parties We rely on third parties to perform the chemistry work associated with our drug discovery and preclinical activities and to conduct our preclinical studies and future clinical trials, and our business could be substantially harmed if these third parties cease performing services or perform in an unsatisfactory manner. We do not have any laboratory facilities and have relied on CROs to perform most of the medicinal chemistry work associated with our drug discovery activities. We also do not currently have the ability to independently conduct preclinical studies or clinical trials without outside assistance. We have relied on CROs to conduct all of our preclinical studies to date and intends to conduct our future clinical trials by leveraging expertise and assistance from CROs as appropriate. We plan to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or assist us in conducting GCP- compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities. We and our CROs and other vendors are required to comply with cGMP, GCP, and good laboratory practice (“ GLP ”), which are regulations and guidelines enforced by the FDA, the competent authorities of EU Member States and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we will rely on CROs to conduct any current or planned GLP- compliant preclinical studies and GCP- compliant clinical trials and has limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with our investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, European Commission, MHRA or any comparable foreign regulatory authority may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, the competent authorities of EU Member States, the MHRA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third- party manufacturing vendors may be found on regulatory inspection by the FDA, the competent authorities of EU Member States, the MHRA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third- party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process. While we or our CROs have or will have agreements governing their activities, we will not be able to control whether or not they devote sufficient time and resources to our future chemistry work and preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other chemistry or drug discovery or development activities. We face the risk of potential unauthorized disclosure, infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors, and other third parties, to access and exploit our proprietary technology. CROs also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property- related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials or other drug discovery or development activities may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. If our relationships with our CROs were to terminate, we might not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional

CROs involves substantial cost and requires management time and focus, and could delay the discovery, development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition. We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of NUV- 868 and our other current and future product candidates. We have limited experience in drug formulation and manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage, distribution or testing. To date, we have obtained active pharmaceutical ingredients (“ APIs ”) and drug product for our investigational products mostly from single- source third- party CMOs. We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which CMOs will generally provide us with necessary quantities of API and drug product on a project- by- project basis based on our development needs. We seek to use a different CMO for each investigational product and will consider further diversification of drug product and supply organizations as circumstances warrant. Third- party CMOs may be unable or unwilling to supply us with sufficient clinical and commercial grade quantities of our clinical materials due to production shortages or other supply interruptions resulting from **health epidemics** ~~the ongoing COVID- 19 pandemic or otherwise~~ , because they are purchased by one of our competitors or another company that decides not to continue supplying us with these materials, or for other reasons. If one or more of these events occur and we are unable to timely establish an alternate supply from one or more third- party CMOs, we could experience delays in our development efforts as we locate and qualify new manufacturers. Under such circumstances, we may be required to receive drug substance for use on a purchase order basis, and as such, there can be no assurance that we actually receive sufficient quantities. See also the risk factor titled “ — Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics ~~, including the ongoing COVID- 19 pandemic~~ , on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others. ” Further, our reliance on third- party manufacturers exposes us to risks beyond our control, including the risk of: • inability to meet our product specifications and quality requirements consistently; • delay or inability to procure or expand sufficient manufacturing capacity; • manufacturing and quality issues, including related to scale- up of manufacturing; • costs and validation of new equipment and facilities required for additional scale- up; • failure of the manufacturer to comply with cGMP and similar foreign standards; • inability to negotiate manufacturing agreements with third parties on commercially reasonable terms; • termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; • reliance on a limited number of sources, and in some cases, single sources for components, such that if we are unable to secure a sufficient supply of these drug components, we will be unable to manufacture and sell NUV- 868 or other product candidates in a timely fashion, in sufficient quantities or under acceptable terms; • lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier; • operations of our third- party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of a FDA Form 483 notice, warning letter, or cease and desist order; • carrier disruptions or increased costs that are beyond our control; and • failure to deliver our products under specified storage conditions and in a timely manner. Some of these events could be the basis for FDA or comparable foreign regulatory authority action, including injunction, recall, seizure or total or partial suspension of production. In addition, our third- party manufacturers and suppliers are subject to FDA inspection and may be subject to inspections from comparable foreign regulatory authorities from time to time. Failure by our third- party manufacturers and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen, or comparable foreign regulatory authorities' approval regimen, with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our third- party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business. In addition, our CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier’ s or manufacturer’ s facility. If the FDA or a comparable foreign regulatory authority finds these facilities unsatisfactory in compliance with applicable regulations, does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved. As we prepare for later- stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third- party suppliers or manufacturers. In order to conduct larger or late- stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and our components, if that product candidate is approved for sale, our CMOs and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third- party contractors may not be able to successfully increase the manufacturing capacity for any such product candidates in a timely or cost- effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the

FDA and comparable foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale- up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If our third- party CMOs are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, results of operations and prospects. If we are not able to establish collaborations, we may have to alter some of our future development and commercialization plans. Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may enter into collaboration agreements with pharmaceutical and biotechnology companies for the future development and potential commercialization of our product candidates. If we enter into one or more such collaborations, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we may enter into. We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization experience and capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, European Commission, MHRA or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaboration agreements on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our collaboration partners, if any, may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further if we are unable to successfully obtain rights to required third- party intellectual property rights or maintain and protect the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of our product candidates, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. Doing so will likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. Risks Related to Regulatory Compliance Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may charge for such product candidates. The U. S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the " Affordable Care Act "), includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There have been judicial, executive and congressional challenges to certain aspects of the Affordable Care Act. On June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (" IRA ") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business. In addition, other legislative changes

have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation' s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2 % per fiscal year until ~~2031~~ **2032** unless Congress takes additional action ~~. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester~~. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Recently, there has been increasing legislative and enforcement interest in the U. S. with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the Department of Health and Human Services (" HHS ") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will~~ take effect progressively starting in fiscal year 2023 **. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations** , although ~~they~~ **the** ~~may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. ~~Further,~~ **In response to** the Biden administration ~~released an additional~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS ~~to~~ **released a** report ~~on how~~ **outlining three new models for testing by** the Center for Medicare and Medicaid Innovation ~~can~~ **which will** be ~~further leveraged~~ **evaluated on their ability** to ~~test new~~ **lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the** models ~~for lowering drug costs for Medicare and Medicaid beneficiaries~~ **will be utilized in any health reform measures in the future** . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. **Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework.** We are unable to predict the future course of federal or state healthcare legislation in the U. S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations **. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs** . We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations, including comparable foreign healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Although we do not currently have any products on the market, our current and future operations may be, directly or indirectly through our prescribers, customers and third- party payors, subject to various U. S. federal and state healthcare laws and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. The laws that may affect our ability to operate include: • the U. S. federal

Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U. S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and Civil Monetary Penalties Laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • the U. S. federal Health Insurance Portability and Accountability Act of 1996, (" HIPAA "), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, (" HITECH "), and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by " covered entities ", i. e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their " business associates " and covered subcontractors that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information; • the U. S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; • the U. S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children' s Health Insurance Program to report annually to the **Centers for Medicare & Medicaid Services ("** CMS **")** information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; • analogous state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and • European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U. S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time- consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. We and our collaborators and third- party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the U. S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, such as

Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators and third- party providers. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the U. S., these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self- regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. Furthermore, California recently enacted the California Consumer Privacy Act (the " CCPA "), which became effective in January 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. 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. At this time, we do not collect personal data on residents of California but should we begin to do so, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions. Foreign data protection laws, including EU General Data Protection Regulation (the " GDPR "), may also apply to health- related and other personal information obtained outside of the U. S. The GDPR, which came into effect in 2018, introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of € 20. 0 million or 4 % of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e. g., the right to access, correct and delete their data). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U. S., and the efficacy and longevity of current transfer mechanisms between the EU and the U. S. remains uncertain. For example, in 2016, the EU and U. S. agreed to a transfer framework for data transferred from the EU to the U. S., called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. At this time, we do not believe we are subject to the GDPR, but should this change, the GDPR will increase our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. Compliance with U. S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and third- party providers to comply with U. S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market. Our success depends in significant part on our ability and the ability of any licensors and collaborators to obtain, maintain, protect and enforce patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others. The patent prosecution process is uncertain, expensive and time- consuming. We 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. It is also possible that we or our future licensors will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a same or similar, independently- developed invention. Such competitor' s or other third party' s patent application or published information may pose obstacles to or prohibit our ability to obtain patent protection or limit the scope of the patent protection we may obtain. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection in certain jurisdictions. In addition, publications of discoveries in the scientific literature often lag behind actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until approximately 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our future licensors were the first to conceive the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions. The patent

position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain. Our and our licensors' pending and future patent applications may not mature into patents or result in issued patents that protect our technology or product candidates, in whole or in part, or effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or in- license may be challenged or, circumvented by third parties or narrowed, invalidated or held unenforceable in litigation or post- grant proceedings. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects. The patent protection we obtain for our product candidates and technology may be challenged or not sufficient to provide us with any competitive advantage. Even if our owned or licensed patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the U. S. and abroad, or circumvented. We may be subject to a third- party preissuance submission of prior art to the U. S. Patent and Trademark Office (the " USPTO "), a federal court or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re- examination, post- grant and inter partes review or interference proceedings, or other similar proceedings, challenging our patent rights or the patent rights of others. An adverse determination as a result of any such submission, proceeding or litigation could reduce the scope of, invalidate, or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, we, or one of our licensors, may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing could harm our business, financial condition, results of operations and prospects. Moreover, some of our owned or in- licensed patents and patent applications may in the future be co- owned with third parties. If we are unable to obtain an exclusive license to any such co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co- owners in order to enforce such patents against third parties, and such cooperation may not be provided to us. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to discover, develop and manufacture our product candidates, we must, at times, share certain of our trade secrets with them. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality provisions, including if applicable, confidentiality agreements, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure could impair our competitive position and may harm our business. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets could impair our competitive position and have an adverse impact on our business. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged. Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other

unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid and / or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid and / or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated and / or held unenforceable, interpreted narrowly or interpreted in a manner that would not prevent competitors from entering the market. Further, we may find it impractical or undesirable to enforce our intellectual property against some third parties. In patent litigation in the U. S., defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including, e. g., lack of novelty, obviousness, non- enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable product candidates or technology covered by the patent rendered invalid and / or unenforceable. Such a loss of patent protection could materially harm our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Such licenses may not be available on commercially reasonable terms, or at all, or may be non- exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in- licensed patents. The loss of exclusivity or the narrowing of scope of our owned and / or licensed patents could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. 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 or proceeding. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, more likely to be able to sustain the costs of complex patent litigation or proceedings than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in- license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business, financial condition, results of operations and prospects. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S.. As such, we may choose not to seek to protect our intellectual property in certain jurisdictions, which could leave us without recourse to prevent competitive products from being manufactured or commercialized in such jurisdictions. 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 U. S.. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries or from selling or importing products made using our inventions in all jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the U. S.. 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 foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other

violation of our intellectual property rights generally. Proceedings to enforce our intellectual property 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. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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, which could adversely affect our business, financial condition, results of operations and prospects. We may not identify relevant third- party patents or pending patent applications or may incorrectly interpret the relevance, scope or expiration of a third- party patent which might adversely affect our ability to develop and market our product candidates. We are developing certain product candidates in highly competitive areas and cannot guarantee that any patent searches or analyses that we may conduct, including the identification of relevant patents or pending patent applications, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending patent application in the U. S. and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U. S. patent applications filed before November 29, 2000 and certain U. S. patent applications filed after that date that will not be filed outside the U. S. remain confidential until patents issue. Patent applications in the U. S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patents or pending patent applications covering our product candidates could have been or may be filed in the future by third parties without our knowledge. Additionally, patents and pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the manufacturing or use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third- party patent or pending patent application or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U. S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents or pending patent applications may negatively impact our ability to develop and market our product candidates. If we fail to identify or correctly interpret relevant patents or pending patent applications or if we are unable to obtain licenses to relevant patents or pending patent applications, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, potentially including in the form of future royalties, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects. If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed. It may be necessary for us to use the patented or other proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license or ownership from these third parties. The licensing or acquisition of third- party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to license or acquire such intellectual property or technology, or if we are forced to in- license such intellectual property or technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, or the cost of development, manufacture or commercialization may be materially increased, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we fail to comply with our obligations under any future license agreements, such counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or commercialize, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. If we were to lose our rights to licensed

intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the U. S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, and a given patent may be subject to other term adjustments, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive products, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and one or more of our foreign patents may be eligible for patent term extension under similar legislation, for example, in the European Union. In the U. S., the Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process provided other requirements are met. However, there are no assurances that the FDA, USPTO or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part and the length of any available extension may vary based on a number of factors. For example, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be adversely affected. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents. For example, in recent years the U. S. Supreme Court has ruled on several patent cases that have been interpreted to have either narrowed the scope of patent protection or weakened the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the U. S., the first to invent the claimed invention was entitled to the patent, while outside the U. S., the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy- Smith America Invents Act enacted in September 2011 (the " Leahy- Smith Act "), the U. S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy- Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO- administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, particularly the first inventor- to- file provisions. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could harm our business, financial condition, results of operations and prospects. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and certain pending patent applications are required to be paid to the USPTO or foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we may rely on our licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Noncompliance events that could result in abandonment or

lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including re- examination, interference, post- grant review, inter partes review or derivation proceedings, or other similar proceedings, before the USPTO, a federal court or an equivalent foreign body. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are invalid and / or unenforceable, that our product candidates do not infringe such patents, or that we would be able to replace such technology with alternative, non- infringing technology. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third- party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third- party patents asserted against us are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third- party patents. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. If we are found to infringe, misappropriate or otherwise violate a third party' s intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business, financial condition, results of operations and prospects. We may be subject to claims by third parties asserting that we or our employees have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of **others, such as** any such individual' s former employer. Litigation may be necessary to defend against these claims. In addition, we or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in- licensed patents or other intellectual property as an inventor or co- inventor. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives, develops or reduces to practice intellectual property that we regard as our own. Our and their assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in litigating such

claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business, financial condition, results of operations and prospects. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising 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 collaborations that would help us commercialize our product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We rely on trade secrets and agreements containing confidentiality obligations to protect our unpatented know- how, technology and other proprietary information and to maintain our competitive position. With respect to our research and development programs, we consider trade secrets and know- how to be one of our important sources of intellectual property, including our extensive knowledge of certain drug delivery techniques and drug conjugation. Trade secrets and know- how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U. S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position. We intend to rely on both registered and common law rights for our trademarks. We have applied to register certain of our trademarks with the USPTO and trademark authorities in certain other countries and may in the future seek to register additional trademarks in the U. S. or other countries. Our current and future trademark applications may not mature to registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In the U. S. and some foreign jurisdictions, our ability to obtain and maintain trademark registrations and acquire enforceable trademark rights depends on making use of our marks in commerce, meaning we must make a certain amount of progress, depending on the jurisdiction, in our clinical studies or in the commercialization of our products. If we fail to satisfy these requirements or any other requirements of applicable regulatory authorities, we may not have enforceable trademark rights or registrations in such jurisdictions. We have yet to obtain trademark registrations for the NUVATION or NUVATION BIO trademarks in the U. S., and we have yet to apply to register any brand name for any product candidate in the U. S. or any other jurisdiction. In addition, the registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may be unable to develop any enforceable trademark rights in relevant countries, or to protect the rights that we do develop. We may be forced to stop using our trademarks or trade names, which we need for name recognition by potential partners and customers in our markets of interest, and spend time and money rebranding. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in enforcing our rights, we may not be able to use these trademarks to develop brand recognition of our company, technologies, products or services. In addition, there could be potential trade name or trademark infringement litigation brought against us by owners of other trademarks that incorporate variations of our registered or unregistered trademarks or trade names. During the trademark registration process, we may receive office actions from the USPTO or from comparable agencies in foreign jurisdictions refusing to register our trademarks. Although we would be given an opportunity to respond to those refusals, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may in the future be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, third parties may file first for our trademarks or similar variations thereof in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third- party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition

based on our trademarks and trade names, we may be unable to compete effectively, which could have an adverse effect on our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license now or in the future; • we, or our current or future licensors, might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license now or in the future; • we, or our current or future licensors, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights; • it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by other persons; • our competitors might conduct research and development activities in the U. S. under FDA- related safe harbor patent infringement exemptions and / or in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents or pending patent applications of others may harm our business; and • we may choose not to file for patent protection in order to maintain certain trade secrets or know- how, and a third party may subsequently file for and obtain a patent covering such intellectual property. Should any of these events occur, they could harm our business, financial condition, results of operations and prospects. Risks Related to Our Business Operations, Employee Matters and Managing Growth Our business ~~, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID- 19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others. Our business~~ could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of CMOs, CROs and other third parties upon whom we rely. For example, the **recent** COVID- 19 pandemic ~~has~~ presented a substantial public health and economic challenge around the world and **affected** ~~is affecting~~ employees, patients, communities and business operations, as well as the U. S. economy and financial markets. ~~Many geographic~~ **Geographic** regions ~~have imposed, or in the future~~ may impose ~~,~~ " shelter- in- place " orders, quarantines or similar orders or restrictions to control the spread of **epidemic disease** ~~COVID- 19~~. Our headquarters are located in the New York, New York and San Francisco, California areas and at present, we have implemented **injury and illness prevention** ~~work- from- home~~ policies for all employees. The effects of the ~~executive order~~ **orders** and our **injury and illness prevention** ~~work- from- home~~ 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. We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter- in- place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur **may** ~~, whether related to COVID- 19 or other infectious diseases, could~~ impact personnel at third- party manufacturing facilities in the U. S. and other countries, or the availability or cost of materials or supplies, which could disrupt our supply chain or our ability to enroll patients in or perform testing for our clinical trials. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines. If our relationships with our suppliers or other vendors are terminated or scaled back as a result of ~~the COVID- 19 pandemic or other~~ health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. See " Risk Factors — Risks Related to Our Dependence on Third Parties. " In addition, our clinical trials may be affected by **health epidemics** ~~the COVID- 19 pandemic~~. In the future, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward **such health epidemics** ~~the COVID- 19 pandemic~~ or concerns among patients about participating in clinical trials during a **health** ~~pandemic~~ **epidemic** and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to **epidemic disease** ~~COVID- 19~~ or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations. **Health epidemics may** ~~The spread of COVID- 19 has also led~~ **lead** to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. ~~The~~ **Health epidemics may also result in volatile** trading prices for the common stock of ~~other~~ biopharmaceutical companies ~~have, at times, been highly volatile as a result of COVID- 19~~. To the extent **health epidemics** ~~the COVID- 19 pandemic~~ adversely ~~affects~~ **affect** our business, financial results and value of our common stock, it may also affect our ability to access capital, which could in the future negatively affect our liquidity ~~. The global pandemic of COVID- 19 continues to evolve rapidly. The ultimate impact of the~~

~~COVID- 19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID- 19 situation closely~~ . Our future success depends on our ability to retain Dr. Hung and our other key employees, consultants and advisors and to attract, retain and motivate qualified personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of Dr. Hung and our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is 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 and commercialization objectives and seriously harm our ability to successfully implement our business strategy. In particular, in light of Dr. Hung' s central role in the discovery of all of our current product candidates, our ongoing discovery activities and development programs, the recruitment of our other executives and key employees and all other aspects of our strategy and operations, we believe our loss of Dr. Hung' s services for any reason would severely impair our business and prospects. 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 for and commercialize our product candidates. Competition to hire qualified personnel in our industry 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. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and 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 us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, financial condition, results of operations and prospects. We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, ~~2022~~ **2023** , we had ~~53~~ **51** employees. As our preclinical and clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research, clinical operations, regulatory affairs, general and administrative and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws, regulations and guidance of the FDA, the European Commission, the EMA, the MHRA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U. S. and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, 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. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations. International operations may expose us to business,

regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U. S. Our business will be subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the U. S. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the U. S. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the U. S. Doing business internationally involves a number of risks, including but not limited to: • multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; • rejection or qualification of foreign clinical trial data by the competent authorities of other countries; • delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad ~~, including those that may result from the ongoing COVID- 19 pandemic~~ ; • additional potentially relevant third- party patent and other intellectual property rights; • complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property; • difficulties in staffing and managing foreign operations; • complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; • limits in our ability to penetrate international markets; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations; • natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, ~~including COVID- 19~~ and related shelter- in- place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; • certain expenses including, among others, expenses for travel, translation and insurance; and • regulatory and compliance risks that relate to anti- corruption compliance and record- keeping that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti- corruption or anti-bribery laws in other countries. Any of these factors could harm our future international expansion and operations and, consequently, our results of operations. Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or experience security breaches or other unauthorized or improper access. Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber attacks or cyber intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third- party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break- ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third- party providers will be successful in preventing cyber attacks or successfully mitigating their effects. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed. Risks Related to Ownership of Our Securities The market price of our securities may be volatile and fluctuate substantially, which could result in substantial losses for our investors and may subject us to securities litigation suits. The market price of our securities may be volatile. The

stock market in general and the market for pharmaceutical 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 securities or above the price they paid. The market price for our securities may be influenced by many factors, including: • adverse regulatory decisions; • any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; • the impact of **health epidemics** ~~the continued effects of and responses to the ongoing COVID- 19 pandemic~~ ; • the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates; • adverse results from, delays in or termination of clinical trials; • unanticipated serious safety concerns related to the use of our product candidates; • lower than expected market acceptance of our product candidates following approval for commercialization; • changes in financial estimates by us or by any securities analysts who might cover our securities; • conditions or trends in our industry; • changes in the market valuations of similar companies; • stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry; • publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; • announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; • announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; • investors' general perception of our company and our business; • recruitment or departure of key personnel; • overall performance of the equity markets; • trading volume of our securities; • disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies; • significant lawsuits, including patent or stockholder litigation; • proposed changes to healthcare laws in the U. S. or foreign jurisdictions, or speculation regarding such changes including changes in the structure of healthcare payment systems; • general political and economic conditions; and • other events or factors, many of which are beyond our control. In addition, 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. The dual- class structure of our common stock has the effect of concentrating voting power with our Chief Executive Officer, which limits other stockholders' ability to influence the outcome of important transactions, including a change in control. Dr. Hung holds all of the outstanding shares of our Class B common stock and approximately 27 % of our Class A and Class B common stock outstanding. In addition to voting together with the Class A common stock (with one vote per share) on all matters, the holders of Class B common stock have (i) the right to elect and remove without cause three of our directors plus at least 50 % of all directors in excess of seven and (ii) an approval right over any acquisition (whether by merger, sale of shares or sale of assets) or our liquidation. Accordingly, Dr. Hung has the ability to control or exert substantial influence over all matters submitted to our stockholders for approval, including the election of directors and amendments of our organizational documents, and an approval right over any acquisition or liquidation of our company. Dr. Hung may have interests that differ from those of the other stockholders and may vote in a way with which the other stockholders disagree and which may be adverse to their interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale of our company, and might ultimately affect the market price of shares of our Class A common stock. We cannot predict the impact our dual- class structure may have on the market price of our Class A common stock. We cannot predict whether our dual- class structure, combined with the concentrated voting power of Dr. Hung by virtue of his ownership of 100 % of the outstanding shares of our Class B common stock, will result in a lower or more volatile market price of our Class A common stock in the future, or in adverse publicity or other adverse consequences. Certain index providers have announced restrictions on including companies with multi- class share structures in certain of their indices. For example, in July 2017, FTSE Russell and Standard & Poor' s announced that they would cease to allow most newly public companies utilizing dual or multi- class capital structures to be included in their indices. Under the announced policies, our dual- class capital structure makes us ineligible for inclusion in any of these indices. Given the sustained flow of investment funds into passive strategies that seek to track certain indices, exclusion from stock indices would likely preclude investment by many of these funds and could make our securities less attractive to other investors. As a result, the market price of our Class A common stock could be adversely affected. There can be no assurance that we will be able to comply with the continued listing standards of the NYSE. Our Class A common stock and Public Warrants are listed on the NYSE under the symbols " NUVB " and " NUVBW, " respectively. Our continued eligibility for listing will depend on our compliance with the continued listing standards of the NYSE and may depend on the number of our shares that are redeemed. If the NYSE delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including: • 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, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our common stock; • a limited amount of analyst coverage; and • a decreased ability to issue additional securities or obtain additional financing in the future. Future sales, or the perception of future sales, by us or our stockholders in the public market following the Merger could cause the market price for our securities to decline. The sale of our securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of our securities. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of the consummation of the Merger, we had a total of approximately 217, 650, 055 shares of common stock outstanding, consisting of approximately 216, 650, 055 shares of Class A common stock and 1, 000, 000 shares of Class B common stock. All shares issued in the Merger are freely tradable without registration under the

Securities Act, and without restriction by persons other than our " affiliates " (as defined under Rule 144 of the Securities Act, " Rule 144 "), including our directors, executive officers and other affiliates. In connection with the Merger, Legacy Nuvation Bio entered into certain agreements restricting the transfer of our securities held by such contracting parties, including agreements with the Sponsor, Dr. Hung, purchasers under the forward purchase agreement and certain of Legacy Nuvation stockholders. All of these lock- up agreements have now expired. In addition, the shares of Class A common stock reserved for future issuance under our equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock- up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. Our compensation committee of our board of directors may determine the exact number of shares to be reserved for future issuance under our equity incentive plans at its discretion. We have filed and expect to file registration statements on Form S- 8 under the Securities Act to register shares of Class A common stock or securities convertible into or exchangeable for shares of Class A common stock issued pursuant to our equity incentive plans. Any such Form S- 8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market. In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of Class A common stock issued in connection with an investment or acquisition could constitute a material portion of our then- outstanding shares of Class A common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders. Because we do not anticipate paying any cash dividends on our Class A common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment. We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our securities unless you sell your securities for a price greater than that which you paid for it. There is no guarantee that our warrants will be in the money at the time they become exercisable, and they may expire worthless. The exercise price for our warrants, including our Public Warrants, is $ 11. 50 per share of Class A common stock. There is no guarantee that any of our warrants will be in the money following the time they become exercisable and prior to their expiration, and as such, the warrants may expire worthless. We may issue additional securities without your approval, which would dilute your ownership interests and may depress the market price of our securities. As of December 31, ~~2022~~ **2023** , we have options outstanding to purchase approximately ~~22~~ **30** , ~~865~~ **649** , ~~714~~ **239** shares of Class A common stock. Pursuant to the 2021 Equity Incentive Plan (the " 2021 Plan ") and the Employee Stock Purchase Plan (the " 2021 ESPP "), we may issue an aggregate of up to ~~49~~ **53** , ~~859~~ **183** , ~~041~~ **065** shares of Class A common stock and Class B common stock, which amount will be subject to increase from time to time. We may also issue additional shares of Class A common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances. The issuance of additional shares or other equity securities of equal or senior rank would have the following effects: • existing stockholders' proportionate ownership interest in our company will decrease; • the amount of cash available per share, including for payment of dividends in the future, may decrease; • the relative voting strength of each previously outstanding common stock may be diminished; and • the market price of our securities may decline. Anti- takeover provisions in our amended and restated certificate of incorporation and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult, and may prevent attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation contains provisions that may delay or prevent an acquisition of the company or change in our management in addition to the significant rights of Dr. Hung as the holder of 100 % of the outstanding shares of our Class B common stock. These provisions may make it more difficult for stockholders to replace or remove members of our board of directors. Because the board of directors is responsible for appointing the members of the management team, these provisions could in turn frustrate or prevent any attempt by our stockholders to replace or remove our current management. In addition, these provisions could limit the price that investors might be willing to pay in the future for shares of our Class A common stock. Among other things, these provisions include: • the limitation of the liability of, and the indemnification of, our directors and officers; • a prohibition on actions by our stockholders except at an annual or special meeting of stockholders; • a prohibition on actions by our stockholders by written consent; and • the ability of the board of directors to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the board of directors. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the " DGCL "), which prohibits a person who owns 15 % or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15 % or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent a third party from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our Class A common stock, including transactions that may be in our stockholders' best interests. Finally, these provisions establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us

and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on our behalf; • any action asserting a breach of fiduciary duty; • any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and • any action asserting a claim against us that is governed by the internal- affairs doctrine or otherwise related to our internal affairs. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive- forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business. We are eligible to report as a " smaller reporting company, " and as a result of the reduced reporting requirements applicable to " smaller reporting companies, " our securities may be less attractive to investors. We are eligible to report as a smaller reporting company. For as long as we continue to be eligible to report as a " smaller reporting company, " ~~including with respect to any portions of our 2023 proxy statement that are incorporated by reference into this report,~~ we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not " smaller reporting companies, " including exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. If some investors find our securities less attractive because we rely on any of these exemptions, there may be a less active trading market for our securities and the price of our securities may be more volatile. General Risk Factors If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of the NYSE. Section 302 of the Sarbanes- Oxley Act requires, among other things, that public companies report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and, beginning with this report, Section 404 of the Sarbanes- Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10- K for that year. This has required us to incur substantial additional professional fees and internal costs to expand our accounting and finance functions and to expend significant management efforts. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the NYSE, the SEC or other regulatory authorities. In addition, our securities may not be able to remain listed on the NYSE or any other securities exchange. We will incur costs and demands upon our management as a result of complying with the laws and regulations affecting public companies in the U. S., which may harm our business. As a public company listed in the U. S., we will incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the NYSE may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from regular business activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management. If securities or industry analysts cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline. Equity research analysts may cease providing research coverage of our securities at any time, and such lack of research coverage may adversely affect the market price of our securities. In any event, we do not have any control over the analysts or the content and opinions included in their reports and the price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research

analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our securities' prices or trading volume to decline.